

# Safety Data Sheets & Supplemental Safety Information

PREPARED ON: January 23, 2019

**378750-500**

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# Safety Data Sheets & Supplemental Safety Information

**378750-500**

January 23, 2019



spine 2-inch

# Safety Data Sheets & Supplemental Safety Information

**378750-500**

January 23, 2019



spine 1-inch

CUT ALONG DOTTED LINE AND  
INSERT IN SPINE OF BINDER

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# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Contact information

#### General



Par Sterile Products  
870 Parkdale Road, Rochester, M.I. 48307  
T: +1 (800) 828-9393  
F: +1 (201) 829-9222  
E-mail: [drugsafety@parpharm.com](mailto:drugsafety@parpharm.com)

#### Emergency telephone number

Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

<b>Product identifier</b>	Buprenorphine Hydrochloride (HCl) for Injection
<b>Synonyms</b>	<u>For buprenorphine HCl:</u> 21-Cyclopropyl-7alpha-((S)-1-hydroxy-1,2,2-trimethylpropyl)-6,14-endo-ethano-6,7,8,14-tetrahydrooripavine hydrochloride
<b>Trade names</b>	Generic brand
<b>Chemical family</b>	Mixture - contains an oripavine derivative
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical product/ Formulated pharmaceutical product packaged in final form for patient use; indicated for the treatment of pain.
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated drug product.

## SECTION 2 - HAZARDS IDENTIFICATION

<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.</b> Please consult the prescribing/packaging information. <b>The classification and labeling listed below is for bulk drug product, packaged in vials.</b>
<b>Globally Harmonized System [GHS]</b>	Not classified



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## SECTION 2 - HAZARDS IDENTIFICATION ...continued

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### Label elements

GHS hazard pictogram                None required

GHS signal word                    None required

GHS hazard statements            None required

GHS precautionary statements    None required

### Other hazards

Buprenorphine hydrochloride ("Buprenorphine") is an opioid analgesic compound. Common adverse effects reported with clinical use include gastrointestinal (GI) (nausea, vomiting, constipation, dry mouth) and CNS (*e.g.* drowsiness, lightheadedness, headaches, confusion, euphoria, hallucinations, blurred vision) effects. Skin rash and irritation were reported following transdermal patch use. Severe effects on the cardiovascular (heart attack) and respiratory (respiratory depression) systems have also occurred, usually with overdose. Hypersensitivity (allergic) reactions were also reported.

Buprenorphine is a narcotic. Although it has a lower potential for dependence than morphine, its use can lead to some psychological dependence and abuse, and minor withdrawal symptoms may occur upon abrupt cessation of a prolonged exposure. Neonatal withdrawal symptoms were reported in infants born to mothers treated with buprenorphine during pregnancy.

### Note

This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it is pharmacologically active.

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## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Buprenorphine hydrochloride	53152-21-9	258-396-8	0.03- 0.05 %	STOT-S3:H336; RT2:H361d

### Note

The ingredient(s) listed above are considered hazardous. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

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## SECTION 4 - FIRST AID MEASURES

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### Description of first aid measures

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**SECTION 4 - FIRST AID MEASURES ...continued**

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<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: none identified. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

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**SECTION 5 - FIREFIGHTING MEASURES**

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Personal precautions, protective equipment and emergency procedures</b>	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated. Do not breathe mist/spray.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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<b>Precautions for safe handling</b>	If vials are opened, crushed or broken, follow recommendations for handling bulk pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing mist/spray. Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store at controlled room temperature (20-25°C or 68-77 °F) (See USP Controlled Room Temperature) away from incompatible materials. Keep container upright. Protect from light. Discard unused portion.
<b>Specific end use(s)</b>	Pain reliever

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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<b>Note</b>	Wash hands, face and other potentially exposed areas immediately in the event of physical contact. Dispose of broken vials/syringes in a sharps container.
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### Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Buprenorphine hydrochloride	--	--	--

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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<b>Exposure/Engineering controls</b>	None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.
<b>Respiratory protection</b>	None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly worn powered air-purifying respirator equipped with appropriate HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
<b>Hand protection</b>	None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Liquid in vials
<b>Color</b>	Clear, colorless

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information identified.
<b>pH</b>	4.0-7.0
<b>Melting point/ freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Soluble
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	Aqueous solution; not anticipated to be explosive.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	Not applicable (Mixture)
<b>Molecular formula</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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**Note** No data for the mixture were identified. Data below are for the active ingredient and/or other ingredients, where applicable.

**Information on toxicological effects**

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Buprenorphine hydrochloride	LD <sub>50</sub>	Oral	Rat	>600 mg/kg
	LD <sub>50</sub>	Oral	Mouse	260 mg/kg
	LD <sub>50</sub>	Intravenous (IV)	Rat	31 mg/kg
	LD <sub>50</sub>	Intravenous (IV)	Mouse	24 mg/kg
	LD <sub>50</sub>	Dermal	Rat	>100 mg/kg
	LC <sub>50</sub>	Inhalation	Rat	>0.93 mg/L

**Irritation/Corrosion** Buprenorphine was mildly irritating to rabbit skin, but was not phototoxic.

**Sensitization** Buprenorphine was not a sensitizer in guinea pigs.

**STOT-single exposure** Signs associated with single buprenorphine exposure usually consist of convulsions and changes in motor activity (*e.g.*, ataxia), similar to other opioid agonists.

**STOT-repeated exposure/Repeat-dose toxicity** No mortality or target organ effects were reported in 90-day toxicity studies in rats and dogs treated with buprenorphine doses up to 5 and 25 mg/kg/day, respectively (route not specified).

**Reproductive toxicity** No fertility impairment was observed in rats treated with buprenorphine at oral or parenteral doses of 80 and 5 mg/kg/day, respectively. Labor difficulties were noted at doses as low as 0.8 and 0.1 mg/kg/day, respectively, in a perinatal rat study.

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**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**

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<b>Developmental toxicity</b>	An increase in neonatal mortality was observed at the doses mentioned above in the perinatal rat study. Increases in pre- and post-implantation loss were noted in rabbits treated orally and intravenously with doses as low as 1 and 0.2 mg/kg/day buprenorphine. Skeletal abnormalities were also reported in rats and rabbits at buprenorphine doses as low as 1 mg/kg/day by several routes.
<b>Genotoxicity</b>	Results from several <i>in vitro</i> studies with buprenorphine using bacteria, yeasts, and mammalian cells were equivocal.
<b>Carcinogenicity</b>	In a 27-month study with rats, an oral dose of 56 mg/kg/day buprenorphine produced a dose-related increase in benign Leydig cell (testicular) tumors. No evidence of tumorigenicity was noted in mice treated orally with up to 100 mg/kg/day. Overall, buprenorphine has a low carcinogenic potential. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Aspiration hazard</b>	No data available.
<b>Human health data</b>	See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**

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<b>Toxicity</b>	
<u>Compound</u>	<u>Type</u>
Buprenorphine hydrochloride	--
<u>Species</u>	<u>Concentration</u>
--	---
<b>Persistence and Degradability</b>	No data available.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Results of PBT and vPvB assessment</b>	Not performed.
<b>Other adverse effects</b>	No data available.
<b>Note</b>	The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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<b>Waste treatment methods</b>	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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## SECTION 14 - TRANSPORT INFORMATION

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<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Due to lack of data, avoid release to the environment.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

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## SECTION 15 - REGULATORY INFORMATION

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<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>WHMIS classification</b>	Not classified.
<b>TSCA status</b>	Drugs are exempt from TSCA.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional information</b>	No other information identified.

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## SECTION 16 - OTHER INFORMATION

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<b>Full text of H phrases and GHS classifications</b>	STOT-S3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H336 - May cause drowsiness or dizziness. RT2 - Reproductive toxicity Category 2. H361d - Suspected of damaging the unborn child.
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**SECTION 16 - OTHER INFORMATION ...continued**

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<b>Sources of data</b>	Information from published literature and internal company data.
<b>Abbreviations</b>	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
<b>Issue Date</b>	10 July 2015
<b>Revisions</b>	This is the first version of this SDS.
<b>Disclaimer</b>	<p>The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.</p> <p>No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.</p>



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>CLOMICALM 20 TABLETS FOR DOGS</b>
<b>Other means of identification</b>	
Item Code	CA4935
Synonyms	A-9571 A1 * CGA310816 TAB (20)
Recommended use	Veterinary Product
Recommended restrictions	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Email:	<a href="mailto:lilly_msds@lilly.com">lilly_msds@lilly.com</a>
Emergency Telephone Numbers:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Transportation Emergency Telephone:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity (fertility)	Category 2
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning	
<b>Hazard statement</b>		
H361	Suspected of damaging fertility.	
<b>Precautionary statement</b>		
<b>Prevention</b>		
P201	Obtain special instructions before use.	
P202	Do not handle until all safety precautions have been read and understood.	
P280	Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>		
P308 + P313	IF exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Not available.	
<b>Disposal</b>		
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Clomipramine Hydrochloride	CGA 310816 A 5H-dibenzo[b, f] azepine-5-propanamina, 3-cloro-10 ,11-dihidro-N, N-dimetil-, clorhidrato (1:1)	17321-77-6	11

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention or advice.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	May cause reproductive effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	If you feel unwell, seek medical advice (show the label where possible).

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect dust using a vacuum cleaner equipped with HEPA filter.  Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.  Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Storage temperature: between 2 °C and 30 °C. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	Novartis Internal Exposure Limit (NPIEL): 0.111 mg/m <sup>3</sup> 8 hour TWA (Clomipramine hydrochloride)
<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	In case of inadequate ventilation use suitable respirator.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Tablet.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Brown to grey.
<b>Odor</b>	Meaty.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Miscible.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
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<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	630 - 920 mg/kg (as salt)
	Rat	750 - 1450 mg/kg (as salt)
<b>Other</b>		
LD50	Rat	17 mg/kg -Intravenous

**Skin corrosion/irritation** Rabbit: No skin irritation. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Due to partial or complete lack of data the classification is not possible.

#### Respiratory or skin sensitization

**Respiratory sensitization** Due to partial or complete lack of data the classification is not possible.

**Skin sensitization** Due to partial or complete lack of data the classification is not possible.

**Germ cell mutagenicity** In vitro and in vivo tests did not show mutagenic effects. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No effects identified in animal studies. (Active ingredient)  
Based on available data, the classification criteria are not met.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Suspected of damaging fertility. (Active ingredient)

**Specific target organ toxicity - single exposure** May cause drowsiness and dizziness. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** No significant target organ toxicity reported. (Active ingredient)  
Based on available data, the classification criteria are not met.

**Aspiration hazard** Not applicable.

## 12. Ecological information

**Ecotoxicity** Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)			
Aquatic			
Acute			
Fish	LC0	Zebra danio (Danio rerio)	0.32 mg/l
	LC50	Zebra danio (Danio rerio)	0.43 mg/l
	LD100	Zebra danio (Danio rerio)	0.58 mg/l

**Persistence and degradability** The product is not readily biodegradable.

**Bioaccumulative potential****Partition coefficient n-octanol / water (log K<sub>ow</sub>)**

Clomipramine Hydrochloride

2.1 (at 23 °C)

**Mobility in soil**

No data available.

**Other adverse effects**

Not available.

**13. Disposal considerations****Disposal methods/information** Dispose of contents/container in accordance with local/regional/national/international regulations.**14. Transport information****General information**

Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

**DOT**

Not regulated as dangerous goods.

**IATA****UN number**

UN3077

**UN proper shipping name**

Environmentally hazardous substance, solid, n.o.s. (Clomipramine Hydrochloride)

**Transport hazard class(es)****Class**

9

**Subsidiary risk**

-

**Packing group**

III

**Environmental hazards**

Yes

**ERG Code**

9L

**Special precautions for user**

Read safety instructions, SDS and emergency procedures before handling.

**Other information****Passenger and cargo aircraft**

Allowed with restrictions.

**Cargo aircraft only**

Allowed with restrictions.

**IMDG****UN number**

UN3077

**UN proper shipping name**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Clomipramine Hydrochloride)

**Transport hazard class(es)****Class**

9

**Subsidiary risk**

-

**Packing group**

III

**Environmental hazards****Marine pollutant**

Yes

**EmS**

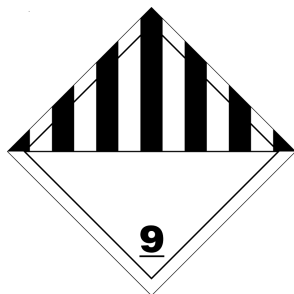
F-A, S-F

**Special precautions for user**

Read safety instructions, SDS and emergency procedures before handling.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

**IATA; IMDG**



## 15. Regulatory information

### US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
One or more components are not listed on TSCA.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

### US state regulations

#### US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Clomipramine Hydrochloride (CAS 17321-77-6)

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date 11-14-2016

Revision date 11-14-2016

Version # 02

**Lilly Lab Code**

Health: 1  
Fire: 1  
Reactivity: 0  
Special 1: R

**Disclaimer**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health  
0011+1-877-352-6261  
0011+1-800-428-4441

**Revision information**

Physical & Chemical Properties: Multiple Properties



**SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION**

**PRODUCT NAME:** FATAL-PLUS® SOLUTION

**PRODUCT DESCRIPTION:** Fatal-Plus is a euthanasia solution suitable for all animals, regardless of species. It is administered by intravenous injection.

**MANUFACTURER:** Vortech Pharmaceuticals, Ltd.

**ADDRESS:** 6851 Chase Road  
Dearborn MI 48126

**PHONE NUMBER:** (800) 521-4686  
(313) 584-4088

**OTHER NUMBER:** Poison Control Center : 1-800-222-1222

**SECTION 2. HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW**

This product is a controlled substance. The main health hazard associated with overexposure during normal occupational use and handling is irritation of contaminated tissues. This product may be toxic if swallowed or inhaled. This product is not flammable. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including e.g. carbon oxides, nitrogen oxides, and sodium oxides). This product is not reactive. Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

**Routes of Entry**

By eye contact, skin contact, ingestion or inhalation

**Carcinogenic Status**

Ethyl Alcohol: IARC (International Agency for Research on Cancer) has classified Alcoholic beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

**Target Organs**

This product effects the, eyes, skin, respiratory tract, gastrointestinal tract, liver and cardiovascular, central nervous and reproductive systems.

**Health Effects – Eyes**

This product may cause eye irritation, if contact occurs.

**Health Effects – Skin**

This product may cause skin irritation after prolonged and repeated contact occurs.

**Health Effects – Ingestion**

Ingestion of this product may cause adverse gastrointestinal, cardiovascular, liver, central nervous system and reproductive effects. Symptoms include: drowsiness, headache, mental depression, dizziness, confusion, lack of muscular control, impaired judgement and sedation. In cases of severe overdoses, this product may cause respiratory and cardiovascular suppression, coma and death due to respiratory and circulatory failure.

**Health Effects – Inhalation**

This product may cause irritation to the respiratory tract if inhaled.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Product Use:** Veterinary product

**Chemical Formula:** Mixture

CHEMICAL NAME	CAS NUMBER	CONCENTRATION
Pentobarbital Sodium	57-33-0	390 mg/ml
Propylene Glycol	57-55-6	0.01 ml/ml
Ethyl Alcohol	64-17-5	0.29 ml/ml
Benzyl Alcohol	100-51-6	0.02 ml/ml

This MSDS is written to provide health and safety information to individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient.

**SECTION 4. FIRST AID MEASURES****Eyes**

If this product comes into contact with the eyes, immediately wash the affected eye with water for at least fifteen minutes or until the irritation ceases. If irritation continues, seek medical attention.

**Skin**

If this product comes into contact with the skin, wash the affected area thoroughly with soap and water. If redness or soreness continues, seek medical attention.

**Ingestion**

If this product is ingested, **DO NOT** induce vomiting, unless directed to do so by a physician and **DO NOT** attempt to give anything by mouth to a seizing, drowsy or unconscious person. Seek medical attention **IMMEDIATELY**.

**Inhalation**

If this product is inhaled, move to an area of fresh air. If irritation occurs or persists, consult a physician. If person has any trouble breathing, get medical attention **IMMEDIATELY** or if person has stopped breathing administer CPR.

**MSDS Revision Date: May 28, 2015**

Supersedes MSDS Dated: 09/26/96



**SECTION 5. FIRE FIGHTING MEASURES**

**Extinguishing Media**

Use extinguishing media appropriate for surrounding materials, carbon dioxide (CO<sub>2</sub>), powder or water.

**Unusual Fire and Explosion Hazards**

None known

**Protective Equipment for Fire-Fighting**

Wear full protective clothing and self-contained breathing apparatus (SCBA)

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Wear appropriate protective clothing. Wipe up and transfer into suitable containers for recovery or disposal. This product **MUST NOT** enter drains or waterways. Notify authorities if spill has entered water ways or sewer system or has contaminated soil or vegetation. The product must be disposed of in accordance with federal, state and local regulations for DEA Schedule II controlled substances.

**SECTION 7. HANDLING AND STORAGE**

This product must be stored in original containers and in a cool dry place. The product must be stored in accordance with federal, state and local regulations for DEA Schedule II controlled substances. Avoid contact with skin, eyes and clothing. Wash hands thoroughly after dispensing and before eating, or drinking.

**SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**

Chemical Name	CAS#	Exposure Limits in Air									
		ACGIH-TLVS		OSHA-PELS		NIOSH-RELS		NIOSH	AIHA WEELS		OTHER
		TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	mg/m <sup>3</sup>
Pentobarbital Sodium	57-33-0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ethyl Alcohol	64-17-5	1880	NE	1900	NE	1900	NE	8237 (based on LEL)	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

NE – Not Established

**Respiratory Protection:** A respirator is not required for routine use of this product.

**MSDS Revision Date: May 28, 2015**

Supercedes MSDS Dated: 09/26/96

**Eye Protection:** Eye protection is not needed during normal use. In case of situations in which excessive splashes or sprays may be generated, wear splash goggles.

**Hand Protection:** In case of prolonged skin contact wear rubber gloves, either natural rubber, neoprene or nitrile gloves.

**Body Protection:** Use of lightweight cotton gown or other medical attire is recommended.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical State	Liquid
Color	Clear Blue
Odor	Unknown
pH	9.6-11.0
Boiling Point	Not Applicable
Specific Gravity (H <sub>2</sub> O=1)	1.105
Vapor Pressure	Not Applicable
Solubility in Water	Soluble
Vapor Density	Not Applicable
Flash Point (PMCC)(°C/F)	Not Flammable
Melting Point (°C/F)	Not Applicable
Explosion Limits(%)	Not Applicable

**SECTION 10. STABILITY AND REACTIVITY**

Stability	Stable under normal conditions.
Incompatible Materials /	
Conditions to Avoid	Open flames and high temperatures.
Materials to Avoid	Oxidizing agents
Hazardous Polymerization	Will not occur
Hazardous Decomposition Products	Carbon oxides (CO <sub>x</sub> )

**SECTION 11. TOXICOLOGICAL INFORMATION**

The toxicological properties of this product have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients in this formulation, unless indicated otherwise.

**Acute Toxicity**

Pentobarbital Sodium: Oral LD50 (rat) 118 mg/kg; (dog) 65 mg/kg  
Propylene Glycol: Oral LD50 (rat) 21 to 33.7 g/kg; (dog) 10 to 20 g/kg  
Dermal LD50 (rabbit) 20.8 g/kg



Ethyl Alcohol: Oral LD50 (rat) 7060 mg/kg  
Benzyl Alcohol: Oral LD50 (rat) 1230 mg/kg  
Dermal LD50 (rabbit) 2000 mg/kg  
Inhalation LC50 (rat) 74.187 mg/l, 4h

**Specific Target Organ Systemic Toxicity (single and repeat)**

Pentobarbital Sodium: Causes central nervous system effects similar to alcohol inebriation and adverse liver effects. Ingestion can cause respiratory and cardiovascular depression, coma and death.

Propylene Glycol: Caused no adverse reactions in monkeys or rats after exposure to saturated atmospheres for prolonged periods of time.

Ethyl Alcohol: Chronic exposure can result in adverse liver, heart and central nervous system effects.

Benzyl Alcohol: Can cause adverse central nervous system effects.

**Serious Eye Damage / Eye Irritation**

Propylene Glycol: Causes slight eye irritation.

Ethyl Alcohol: Causes severe eye irritation.

Benzyl Alcohol: Causes moderate to severe eye irritation.

**Skin Corrosion/Irritation**

Propylene Glycol: Causes mild skin irritation.

Ethyl Alcohol: Causes mild skin irritation.

Benzyl Alcohol: Causes mild to moderate skin irritation.

**Respiratory or Skin Sensitization**

No relevant studies identified.

**Carcinogenicity**

This product has not been evaluated for carcinogenicity. Ethyl Alcohol: IARC (International Agency for Research on Cancer) has classified Alcoholic beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

**Mutagenicity / Genotoxicity**

Pentobarbital (base) was positive in the mouse micronucleus assay, mouse cell DNA inhibition test, hamster cytogenetic assay, and in the hamster dominant test.

Propylene Glycol was negative in a bacterial mutagenicity study (Ames).

Benzyl Alcohol in the Ames testing did not show mutagenic activity and mixed results both positive and negative were observed from other in-vitro genotoxicity assays. Benzyl Alcohol showed no genotoxicity during in-vivo testing. The weight of the evidence indicates that it is not mutagenic or clastogenic.

**Reproductive / Developmental Toxicity**

Pentobarbital Sodium: Pentobarbital (base) studies indicate that pentobarbital sodium may affect the developing fetus. Placental transfer in humans has been documented. Neonates from mothers exposed to therapeutic doses of barbiturates have shown blood coagulation disorders and drug withdrawal symptoms. Doses of 600-750 mg administered intravenously to mothers before delivery caused moderate to severe neonatal depression in 40% of the infants with a delay in normal respiration. Doses up to 300 mg showed no appreciable effects.

Propylene Glycol: Caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. It was not teratogenic in rabbits, monkeys or chickens.

Ethyl Alcohol: Ingestion of ethyl alcohol during pregnancy has caused adverse reproductive effects (fetal alcohol syndrome) but only at doses that are maternally toxic.

## SECTION 12. ECOLOGICAL INFORMATION

There is no data for this product or its formulation. The information provided is for the individual ingredients within the product. This product is toxic to wildlife. Birds and mammals feeding on animals treated with this product may be killed.

### **Mobility**

No relevant studies found.

### **Persistence/Degradability**

No relevant studies found.

### **Bio-accumulation**

No relevant studies found.

### **Ecotoxicity**

Pentobarbital Sodium: 96-hr LC50 (fathead minnow) 49.5mg/L

Propylene Glycol: 96-hr LC50 (sheepshead minnow) 23,800 mg/L

Propylene Glycol: 48-hr EC50 (daphnid) >43,500 mg/L

Propylene Glycol: 72-hr EC50 (green algae) >19,000 mg/L

Benzyl alcohol: 96-hr LC50 (Bluegill sunfish) 10mg/L

Benzyl alcohol: 48-hr EC50 (Daphnia Magna) 15.2 mg/L

Benzyl alcohol: 3-hr EC50 (Chlorella pyrenoidosa - Algae) 95 mg/L

## SECTION 13. DISPOSAL CONSIDERATIONS

**MATERIAL WASTE:** Disposal must be in accordance with applicable federal, state and/ or local regulations concerning US DEA Schedule II controlled substances. Incineration is the preferred method of disposal, when appropriate.

**EUTHANIZED ANIMALS:** Animal carcasses must be properly disposed of by deep burial, incineration, or any other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.

**EMPTY CONTAINER DISPOSAL:** Empty containers must be triple rinsed prior to disposal and in accordance with applicable federal, state, and/or local regulations.

**SECTION 14. TRANSPORTATION INFORMATION**

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

**SECTION 15. REGULATORY INFORMATION**
**TSCA LISTING**

INGREDIENT	TSCA
Propylene Glycol	X
Ethyl Alcohol	X
Benzyl Alcohol	X

**U.S. STATE REGULATIONS**

INGREDIENT	CA PROP 65	CARTK	NJRTK	CTRTK	MARTK	PARTK	MNRTK	MIRTK	RIRTK
Pentobarbital Sodium	D		3726						
Propylene Glycol			3595			X	X		X
Ethyl Alcohol	C D	X	0844		X	X	X		X
Benzyl Alcohol					X	X	X		

**SECTION 16. OTHER INFORMATION**

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).



Document No.: SF-FM-Isoflurane/09

**Section – 1: Product and Company Identification**
**Product Name:** Isoflurane

**Synonyms:** 1-chloro-2,2,2-trifluoroethyl difluoromethyl ether;  
 2-Chloro-2-(difluoromethoxy)-1, 1, 1-trifluoroethane, "ISOFOR"

**CAS NO:** 26675-46-7

**Empirical Formulae:**  $C_3H_2ClF_5O$  /  $CF_3CHClOCHF_2$   
**Molecular Weight:** 184.50

**Product Use:** Volatile anaesthetic administered by inhalation

**Company Address:**
**Head Office (Hyderabad)**  
**Piramal Enterprises Limited**  
 5-9-30, Road No.4,  
 Basheerbagh Palace Colony,  
 Basheerbagh, Hyderabad-500 063.  
 Andhra Pradesh, India.

**Site Address:**
**Piramal Enterprises Limited**  
 Digwal Village, Kohir Mandal, Medak District,  
 Andhra Pradesh – 502321, India.

 Emergency telephone: +91-8008788557  
 E mail: [srinivasa.chari@piramal.com](mailto:srinivasa.chari@piramal.com)
**Section – 2: Hazard Identifications**
**GHS Classification**
**Classification of the substance or mixture**
**Classification according to Regulation (EC) No 1272/2008**

Skin Corrosion/Irritation - Category 3

STOT - SE - Category 3

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

Xn Harmful, R67

**Label elements**
**Labelling according Regulation (EC) No 1272/2008**
**Pictogram**

**Signal word:**
**Warning**
**Hazard statement(s)**
**H316** Causes mild skin irritation

**H336** May cause drowsiness or dizziness.

**Precautionary statement(s)**
**P261** Avoid breathing dust/fume/gas/mist/vapors/spray.

**P271** Use only outdoors or in a well-ventilated area.

**P304+P340** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

**P312** Call a POISON CENTER or doctor/physician if you feel unwell.

**P332+P313** If skin irritation occurs: Get medical advice/attention.

**Classification/Specific hazards :**

According to EC criteria, this product is not classified as a "hazardous substance".





Document No.: SF-FM-Isoflurane/09

**Section – 3: Composition / Information on Ingredients**

Name	CAS No.	Molecular Wt
Isoflurane (ISOFOR)	26675-46-7	184.5

**Section – 4: First Aid Measures**

**Inhalation:** Fresh air, rest. Artificial respiration may be needed. Refer for medical attention

**Skin:** Remove contaminated clothes. Rinse and then wash skin with water and soap

**Eyes:** First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.

**Section – 5: Fire Fighting Measures**

**FIRE AND EXPLOSION HAZARDS:** Very negligible fire hazard.

**EXTINGUISHING MEDIA:** carbon dioxide, regular dry chemical

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Do not get water inside container. Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out. Stay away from the ends of tanks. Keep unnecessary people away, isolate hazard area and deny entry. Use extinguishing agents appropriate for surrounding fire. Flood with fine water spray. Cool containers with water spray until well after the fire is out. Apply water from a protected location or from a safe distance. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas. Consider downwind evacuation if material is leaking.

**FLASH POINT:** Will not burn

**Section – 6: Accidental Release Measures**

Collect leaking and spilled liquid in sealable containers as far as possible. Ventilation. Absorb remaining liquid in sand or inert absorbent and remove to safe place. (Extra personal protection: self-contained breathing apparatus.)

**OCCUPATIONAL RELEASE:**

Stop leak if possible without personal risk. Reduce vapors with water spray. Do not get water directly on material. Do not get water inside container. Keep unnecessary people away, isolate hazard area and deny entry.

Small spills: Flood with water. Large spills: Dike for later disposal. Stay upwind and keep out of low areas. Ventilate closed spaces before entering. Evacuation radius: 150 feet

**Section – 7: Handling and Storage**

**Handling (ventilation and fire prevention) ;**

Avoid contact with eyes, skin, and clothing. Avoid generating or breathing product aerosol. Wash after handling.

**Storage (conditions and limitations) ;**

Store tightly closed in original container. Keep containers in a well ventilated, secure location.

**Section – 8: Exposure Controls / Personal Protection**

**Personal Protection:**

**Inhalation:** Ventilation, local exhaust, or breathing protection

**Skin:** Protective gloves- rubber.

**Eyes:** Safety spectacles, or eye protection in combination with breathing protection

**Ingestion:** Do not eat, drink, or smoke during work.





Document No.: SF-FM-Isoflurane/09

**For Unknown Concentrations or Immediately Dangerous to Life or Health** -Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full face piece

**Exposure Control:**

**EXPOSURE LIMITS:**

TLV not established. See Regulatory information.

**INHALATION RISK:**

A harmful contamination of the air can be reached very quickly on evaporation of this substance at 20°C.

**Section – 9: Physical and Chemical Properties**

**PHYSICAL STATE:** Liquid

**APPEARANCE:** clear

**COLOR:** colorless

**ODOR:** sweet odor

**MOLECULAR WEIGHT:** 184.50

**BOILING POINT:** 120 F (49 C)

**FREEZING POINT:** Not available

**VAPOR PRESSURE:** 330 mmHg @ 25 C

Relative density of the vapour/air-mixture at 20°C (air = 1):1.2

**SPECIFIC GRAVITY** (water=1): 1.496 @ 25 C

**WATER SOLUBILITY:** insoluble

**PH:** Not available

**VOLATILITY:** Not available

**ODOR THRESHOLD:** Not available

**EVAPORATION RATE:** Not available

Octanol/water partition coefficient as log Pow: 2.1

**SOLVENT SOLUBILITY:**

Soluble: oils, fats, organic solvents

**Section – 10: Stability and Reactivity**

**PHYSICAL DANGERS:**

The vapour is heavier than air and may accumulate in lowered spaces causing a deficiency of oxygen.

**CHEMICAL DANGERS:**

On contact with hot surfaces or flames this substance decomposes forming corrosive fumes such as phosgene hydrogen chloride and hydrogen fluoride.

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Minimize contact with material. Avoid inhalation of material or combustion by-products. Containers may rupture or explode if exposed to heat.

**INCOMPATIBILITIES:** No data available.

**HAZARDOUS DECOMPOSITION:**

Thermal decomposition products: halogenated compounds, oxides of carbon

**POLYMERIZATION:** Will not polymerize

**Section – 11: Toxicological Information**

**ROUTES OF EXPOSURE:**

The substance can be absorbed into the body by inhalation of its vapour and by ingestion.

**TOXICITY DATA:**





Document No.: SF-FM-Isoflurane/09

Test	Result	Route	Species
LD50	4470 mg/kg	Oral	Rat
LD50	5080 mg/kg	Oral	Mouse
LC50	16300ppm/3Hrs	Inhalation	Rat
LC50	16800ppm/3Hrs	Inhalation	Mouse
LD50	No established data is available	Dermal	--

**HALOGENATED ANESTHETIC AGENTS:**

2 ppm (15.1 mg/m<sup>3</sup>) NIOSH recommended ceiling 60 minute(s)

**CARCINOGEN STATUS:** IARC: Human Inadequate Evidence, Animal Inadequate Evidence, Group 3

**ACUTE TOXICITY LEVEL:**

Moderately Toxic: ingestion

**TARGET ORGANS:** central nervous system

**MUTAGENIC DATA:** Available.

**REPRODUCTIVE EFFECTS DATA:** Available.

**ADDITIONAL DATA:** Interactions with drugs may occur

**Section – 12: Ecological Information**

Not available

**Section – 13: Disposal Considerations**

Collect leaking and spilled liquid in sealable containers as far as possible. Ventilation. Absorb remaining liquid in sand or inert absorbent and remove to safe place. (Extra personal protection: self-contained breathing apparatus.)

**Section – 14: Transport Information**



Labels Required: MISCELLANEOUS

<b>DOT</b>	Not regulated for inner packagings not exceeding 5.0 L (1.3 gallons) net capacity each. Regulated for inner packagings exceeding 5.0 L (1.3 gallons)
<b>DOT shipping name</b>	Aviation regulated liquid, N.O.S., (Isoflurane)
<b>UN Number</b>	UN3334
<b>Packing group</b>	None
<b>DOT hazard class</b>	9

<b>ICAO/IATA</b>	
<b>IATA proper shipping name</b>	Aviation regulated liquid, N.O.S., (Isoflurane)
<b>IATA UN number</b>	UN3334
<b>IATA primary hazard class</b>	9
<b>IATA packing group</b>	None
<b>IATA packing instruction</b>	964
<b>TDG (Canada)</b>	Not regulated



Document No.: SF-FM-Isoflurane/09

IMO/IMDG	Not regulated
ADR/RID	Not regulated


#### Section – 15: Regulatory Information

##### OCCUPATIONAL EXPOSURE LIMITS:

TLV not established

Check oxygen content before entering area. High concentrations in the air cause a deficiency of oxygen with the risk of unconsciousness or death. Forane is a trade name. MAK value not established but full documentation is available (MAK Iib).

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated

( R ) Risk Phrases	R-36- Irritation to eyes	 [Xn] Irritant
(S) Safety Phrases	S36-Wear suitable protective clothing.	

##### U.S. REGULATIONS:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

##### OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

##### CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product complies with EINECS

#### Section – 16: Other Information

The (M) SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

(M)SDS prepared date: 04/03/2014

(M)SDS review date: 03/03/2016

##### Revision of Change:

1. Company and LOGO name change
2. Packing Instruction changed from 906 to 964 as per abstract of IATA DG Regulations for UN3334
3. Updating of legal classification from Annex 1 of Regulation (EC) 1272/2008

**Disclaimer:** The information above is believed to be accurate and represents the best information currently available to us. Users should make their own investigations to determine the suitability of the information for their particular purposes. This document is intended as a guide to the appropriate precautionary handling of the material by a properly trained person using this product.

Prepared By:  
Manager - EHS

  
04/03/14



## 1. Identification

<b>Product identifier</b>	<b>Vanguard Rapid Resp B</b>
<b>Other means of identification</b>	
<b>Product code</b>	2940
<b>Synonyms</b>	Bordetella Bronchiseptica Vaccine, avirulent live culture
<b>Recommended use</b>	Veterinary vaccine
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	
<b>Company Name (US)</b>	Zoetis Inc. 100 Campus Drive, P.O. Box 651 Florham Park, New Jersey 07932 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Hazard(s) not otherwise classified (HNOC)</b>	In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May cause eye irritation.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Potassium phosphate		7778-77-0	<5
Sucrose		57-50-1	<5
Sodium hydroxide		1310-73-2	<0.1
Bordetella bronchiseptica		68583-00-6	

**Composition comments** In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### 4. First-aid measures

<b>Inhalation</b>	If inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. If symptoms persist, get medical attention.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
<b>Indication of immediate medical attention and special treatment needed</b>	None known.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water spray. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Firefighters should wear full protective clothing including self contained breathing apparatus.
<b>Fire fighting equipment/instructions</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Clean up in accordance with all applicable regulations. Ensure adequate ventilation. Remove sources of ignition. Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Prevent release to the environment.  Never return spills to original containers for re-use. Should not be released into the environment. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Use appropriate containment to avoid environmental contamination.

## 7. Handling and storage

### Precautions for safe handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid dust formation. Avoid breathing dust. Avoid contact with skin and eyes. Avoid accidental injection. Observe good industrial hygiene practices. Wash thoroughly after handling. Handle and open container with care. Avoid release to the environment.

### Conditions for safe storage, including any incompatibilities

Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the SDS). Store as directed by product packaging.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sodium hydroxide (CAS 1310-73-2)	PEL	2 mg/m <sup>3</sup>	
Sucrose (CAS 57-50-1)	PEL	5 mg/m <sup>3</sup> 15 mg/m <sup>3</sup>	Respirable fraction. Total dust.

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m <sup>3</sup>
Sucrose (CAS 57-50-1)	TWA	10 mg/m <sup>3</sup>

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m <sup>3</sup>	
Sucrose (CAS 57-50-1)	TWA	5 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>	Respirable. Total

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Control banding approach

Not available.

### Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields (or goggles).

#### Skin protection

##### Hand protection

Wear impervious gloves if skin contact is possible.

##### Other

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

#### Respiratory protection

No personal respiratory protective equipment normally required. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

#### Thermal hazards

Not applicable.

### General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

Freeze-dried pellet

#### Physical state

Solid.

#### Form

Not available.

#### Color

Not available.

### Odor

Not available.

### Odor threshold

Not available.

<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Direct sources of heat. Contact with incompatible materials. Avoid exposure to light, sunlight and elevated temperatures. Avoid heat, sparks, open flames and other ignition sources.
<b>Incompatible materials</b>	As a precautionary measure, keep away from strong oxidizers.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Sodium hydroxide	Species: Rabbit Severity: Severe
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Sodium hydroxide	Species: Rabbit Severity: Severe

**Ingestion** Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

### Information on toxicological effects



**Acute toxicity**

Components	Species	Test Results
Potassium phosphate (CAS 7778-77-0)		
<u>Acute</u>		
Oral		
LD50	Mouse	1700 mg/kg
Sodium hydroxide (CAS 1310-73-2)		
<u>Acute</u>		
Intraperitoneal		
LD50	Mouse	40 mg/kg
Sucrose (CAS 57-50-1)		
<u>Acute</u>		
Oral		
LD50	Rat	29.7 g/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Sodium hydroxide	Species: Rabbit Severity: Severe	

**Respiratory or skin sensitization**

<b>Respiratory sensitization</b>	Based on available data, the classification criteria are not met.
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Mutagenicity</b>	
Sucrose	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella

**Carcinogenicity**

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not available.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not available.

**Reproductive toxicity**

This product is not expected to cause reproductive or developmental effects.

**Specific target organ toxicity - single exposure**

Not classified.

**Specific target organ toxicity - repeated exposure**

Not classified.

**Aspiration hazard**

Not an aspiration hazard.

**Further information**

The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of microorganisms.

**12. Ecological information****Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Releases to the environment should be avoided.

Components	Species	Test Results
Sodium hydroxide (CAS 1310-73-2)		
<b>Aquatic</b>		
Crustacea	EC50	Water flea (Ceriodaphnia dubia)
		34.59 - 47.13 mg/l, 48 hours

Components	Species	Test Results
Fish	LC50	Western mosquitofish ( <i>Gambusia affinis</i> ) 125 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

### 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Sodium hydroxide (CAS 1310-73-2) Listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

##### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

Sodium hydroxide (CAS 1310-73-2)

**US. Massachusetts RTK - Substance List**

Sodium hydroxide (CAS 1310-73-2)

Sucrose (CAS 57-50-1)

**US. New Jersey Worker and Community Right-to-Know Act**

Sodium hydroxide (CAS 1310-73-2)

**US. Pennsylvania Worker and Community Right-to-Know Law**

Sodium hydroxide (CAS 1310-73-2)

Sucrose (CAS 57-50-1)

**US. Rhode Island RTK**

Sodium hydroxide (CAS 1310-73-2)

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 01-07-2016**Version #** 01

**Disclaimer** Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

# SAFETY DATA SHEET

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ketaved<sup>®</sup> Injection  
**Product No.:** VINV-KETA-0VED  
**GHS Product Identifier:** Not applicable  
**Synonyms:** Ketamine hydrochloride for injection

Molecular Formula: Mixture, not applicable  
Molecular Weight: Mixture, not applicable  
CAS Number: Mixture, not applicable  
Chemical Family: Anesthetic

**Manufacturer:**  
Boehringer Ingelheim Vetmedica, Inc.  
5<sup>th</sup> Street NW  
PO Box 518  
Fort Dodge, IA 50501  
Telephone: (515) 955-4600

**Transportation Emergency:** For Chemical  
Emergency Spill, Leak, Fire, Exposure, or 800  
Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300  
Outside USA and Canada: +1 703-527-3887  
(collect calls accepted)

**Medical Emergency (24HR):** (866) 638-2226  
**Non-Emergency Telephone:** (800) 821-7467

**Intended Use:** Indicated as an anesthetic  
for cats and for restraint in subhuman primates.

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

**Physical State:** Liquid  
**Color:** Yellowish  
**Odor:** Slight



**WARNING! Harmful if swallowed.**  
**For use in felines and subhuman primates only.**

**Not for human use.**

**Allergic reactions can occur.**

**Precautionary Statements:**

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature not exceeding 30°C (86° F).

Store out of direct sunlight.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and incinerate.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, flush with gently flowing fresh water thoroughly.

Dispose of contents and container in accordance with applicable local authority requirements.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

**Potential Health Effects**

**Inhalation:** Not expected to be an inhalation hazard with prescribed use.

**Eye Contact:** Not expected to be a hazard to the eye with prescribed use. May cause eye irritation if exposed. Exposure may cause eye tearing, redness and discomfort.

**Skin Contact:** Not expected to be a hazard to the skin with prescribed use. Prolonged or repeated contact may cause itching, redness, and rash in some individuals or animals.

**Ingestion:** Harmful if swallowed. Exposure may cause vomiting, nausea or other systemic effects. Anesthetics can cause respiratory depression which if not monitored, can cause death.

**Chronic Health Effects:** Prolonged and repeated exposure may cause hypersensitization in sensitive animals. Prolonged and repeated exposure may cause adverse effects to the gastrointestinal tract and kidneys. Possible reproductive hazard – may cause adverse effects on the embryo, fetus or newborn.

**Injection:** Swelling at injection site may occur.

**Target Organ(s):** Central nervous system

**OSHA Regulatory Status:** Hazardous (exempt)

**Environment:** No data available

Components not listed are not hazardous or are below reportable limits.

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ketamine hydrochloride	217-484-6	1867-66-9	< 15%	Xn; R22	----

The full texts for all R-Phrases are displayed in Section 16.

#### 4. FIRST AID MEASURES

**General:** Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

**Inhalation:** Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

**Skin Contact:** Wash with soap and water. Get medical attention if symptoms occur.

**Ingestion:** Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

**Injection:** In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

**Note to Physician:** For use in felines and subhuman primates only. Not for human use.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish with water spray, alcohol foam, dry chemical, carbon dioxide

**Unsuitable Extinguishing Media:** None known

**Special Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.

**Unusual Fire & Explosion Hazards:** None known.

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Wear appropriate personal protective equipment (See Section 8).

**Spill Cleanup Methods:** STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible

material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

**Environmental Precautions:** Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

## **7. HANDLING AND STORAGE**

**Handling:** HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

**Storage:** Keep only in the original container. Store at 20°-25° C (68°-77° F). Store out of direct sunlight. Store away from foodstuffs.

## **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Exposure Limits:** None Established.

**Engineering Controls:** Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Respiratory Protection:** Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

**Europe:** Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

**PERSONAL PROTECTIVE EQUIPMENT:** Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

**Eye Protection:** Wear safety glasses with side shields (or goggles).

**Hand Protection:** Wear suitable gloves.

**Skin Protection:** Wear lab coat, apron or appropriate clothing to prevent skin contact.

**Hygiene Measures:** Eye bath, washing facilities

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

**Color:** Yellowish

**Odor:** Not applicable

**Odor Threshold:** No data available

**Physical State:** Liquid

**pH:** 3.5 to 5.5 (acidic)

**Melting Point:** 0°C (32°F) based on data for: Water for injection

**Freezing Point:** Not applicable

**Boiling Point:** 100°C (212°F)

**Flash Point:** Not flammable

**Flammability Limit – Upper (%):** No data available  
**Flammability Limit – Lower (%):** No data available  
**Evaporation rate:** Not applicable  
**Vapor Pressure:** 18 mm of Hg (@ 20°C) (Water for injection)  
**Vapor Density (Air=1):** No data available  
**Viscosity:** Not applicable  
**Specific Gravity:** 1 (water = 1) (Water for injection)  
**Solubility:** Soluble in cold and hot water  
**Partition Coefficient (n-Octanol/water):** No data available  
**Autoignition Temperature:** Not applicable  
**Decomposition Temperature:** Not applicable

## 10. STABILITY AND REACTIVITY

**Stability:** Stable.

**Conditions to Avoid:** High temperatures

**Incompatible Materials:** Strong oxidizing agents, reducing agents

**Hazardous Decomposition Products:** Carbon dioxide, carbon monoxide, nitrogen oxides, hydrogen chloride

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

## 11. TOXICOLOGICAL INFORMATION

### Specified Substances

#### Acute Toxicity

Chemical Name	Test Results
Ketamine hydrochloride	Oral LD50 (rat): 447 mg/kg Oral LD50 (mouse): 617 mg/kg

**Listed Carcinogens:** None listed.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** No data available  
**Persistence and degradability:** No data available  
**Mobility in soil:** No data available  
**Other adverse effects:** No data available




**Germany WGK:** Ketamine hydrochloride: ID 3231: WGK 3 (severely water-endangering)

### 13. DISPOSAL CONSIDERATIONS

**General Information:** Dispose of in accordance with local, state, federal, national or international regulations.

**Disposal Methods:** Drug Enforcement Administration controlled be destroyed following DEA Guidelines for witnessed destruction of the reclamation. Disposal by incineration is recommended. Do not empty Dispose of this material and its container in a safe way. Do not water, food, or feed by disposal.

 is a substance that must be destroyed beyond product beyond into drains. Do not empty. Do not water, food, or feed by disposal. Do not water, food, or feed by disposal.

**RCRA Information:** Not applicable

### 14. TRANSPORT INFORMATION

**DOT:** Not Regulated

**TDG:** Not Regulated

**ADR/RID:** Not Regulated

**IATA:** Not Regulated

**IMDG:** Not Regulated

### 15. REGULATORY INFORMATION

**Canadian Controlled Products Regulations:** This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

**WHMIS Classification:** D1B

**Inventory Status** This material is listed on the following inventories: AICS, EINECS, PICCS and NZIoC.

This material is **not** listed on the following inventories: TSCA, DSL, IECSC, ENCS and KECL. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

#### US Regulations

**FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.**

**CERCLA Hazardous Substance List (40 CFR 302.4):** None listed.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):** None listed.

**Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):** None listed.

**Drug Enforcement Administration (DEA):** Ketamine Hydrochloride is a DEA Schedule III controlled substance.

**SARA Title III****Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):** None listed.**Section 311/312 (40 CFR 370):**

☒ Acute (Immediate)      ☒ Chronic (Delayed)      ☐ Fire  
☐ Reactive      ☐ Pressure Generating

**Section 313 Toxic Release Inventory (40 CFR 372):** None listed.**State Regulations****California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):** None listed.**Massachusetts Right-To-Know List:** None listed.**Minnesota Hazardous Substances List:** None listed.**New Jersey Right-To-Know List:** None listed.**Pennsylvania Right-To-Know List:** None listed.**Rhode Island Right-To-Know List:** None listed.**European Regulations****Austria MAK List (Annex I):** None listed.**Denmark (Annex 3.6):** None listed.**Germany (Dangerous Substances Ordinance 2004, Annex III):** None listed.**Norway (List of Dangerous Substance):** None listed.**Sweden (Annex 3):** None listed.**Switzerland (Toxins List 1):** None listed.

<b>16. OTHER INFORMATION</b>
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**Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	2*	1	0

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ketamine hydrochloride	217-484-6	1867-66-9	< 15%	Xn; R22	----

\* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

**EU Symbol and R Phrase Definitions**

Xn – Harmful

R22 – Harmful if swallowed.

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

AIHA – American Industrial Hygiene Association mppcf – million particles/cubic foot

N/A – Not applicable.

N/E – Not established.

**References:**

- 1 Ketaved<sup>®</sup> Injection MSDS and Package Insert.
- 2 Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3 GHS Manual

**Revision Information:** New SDS**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.

**Issue Date:** 06/01/2015

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## Safety Data Sheet

### Section 1: Identification

#### Product identifier

**Product Name**

- **Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP**

**Product Code**

- AB03534; Core No. 035; NDC 24208--0780-55

**Relevant identified uses of the substance or mixture and uses advised against****Recommended use**

- Finished Pharmaceutical Product; Indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria.

**Restrictions on use**

- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

**Details of the supplier of the safety data sheet****Manufacturer**

- Bausch & Lomb  
1400 North Goodman Street  
Rochester, NY 14609  
United States  
bausch.com

**Telephone (General)** • 1-800-553-5340

**Emergency telephone number****Manufacturer**

- 1-800-535-5053

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

### Section 2: Hazard Identification

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

**Classification of the substance or mixture****UN GHS**

- Skin Sensitization 1B  
Reproductive Toxicity 2

**Label elements****UN GHS****WARNING**

- Hazard statements** • May cause an allergic skin reaction  
Suspected of damaging fertility or the unborn child.

## Precautionary statements

**Prevention** ● Wash thoroughly after handling.

**Response** ● IF ON SKIN: Wash with plenty of soap and water.  
If skin irritation or rash occurs: Get medical advice/attention.  
Wash contaminated clothing before reuse.

**Storage/Disposal** ● Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

## Other hazards

UN GHS

● No data available

## Section 3 - Composition/Information on Ingredients

### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Bacitracin zinc	CAS:1405-89-6 EINECS:215-787-8	< 5%	UN GHS: NDA
Neomycin sulfate	CAS:1405-10-3 EINECS:215-773-1	0.6%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Polymyxin B sulfate	CAS:1405-20-5 EINECS:215-774-7	< 1%	UN GHS: NDA
White mineral oil	CAS:8042-47-5 EINECS:232-455-8	10% TO 20%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
White petrolatum	CAS:8009-03-8 EINECS:232-373-2	85%	UN GHS: NDA

The exact percentage of composition has been withheld as a trade secret.

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

#### Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

#### Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.

#### Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

### Most important symptoms and effects, both acute and delayed

- No data available

## Indication of any immediate medical attention and special treatment needed

### Section 5: Fire-Fighting Measures

#### Extinguishing media

**Suitable Extinguishing Media** • SMALL FIRES: Dry chemical, CO<sub>2</sub>, water spray or regular foam.  
LARGE FIRE: Water spray, fog or regular foam.

**Unsuitable Extinguishing Media** • No data available

#### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards** • None known.

**Hazardous Combustion Products** • None known.

#### Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

### Section 6 - Accidental Release Measures

#### Personal precautions, protective equipment and emergency procedures

**Personal Precautions** • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

**Emergency Procedures** • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

#### Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

#### Methods and material for containment and cleaning up

**Containment/Clean-up Measures** • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

### Section 7 - Handling and Storage

#### Precautions for safe handling

**Handling** • No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

#### Conditions for safe storage, including any incompatibilities

**Storage** • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

**Incompatible Materials or Ignition Sources** • None specified.

### Section 8 - Exposure Controls/Personal Protection

## Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

## Exposure controls

- Engineering Measures/Controls**
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

## Personal Protective Equipment

### Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

### Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

### Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

### Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

## General Industrial Hygiene Considerations

- Wash thoroughly after handling.

## Environmental Exposure Controls

- No data available

## Section 9 - Physical and Chemical Properties

### Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid ointment	Appearance/Description	Translucent, off white to yellowish ointment.
Color	off-white to yellowish.	Particulate Size	Not relevant
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	Heat of Decomposition	Not relevant
pH	Not relevant	Specific Gravity/Relative Density	Not relevant
Density	Not relevant	Water Solubility	Not relevant
Viscosity	Not relevant		
Flammability			
Flash Point	Not relevant	Heat of Combustion ( $\Delta H_c$ )	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Half-Life	Not relevant	Octanol/Water Partition coefficient	Not relevant
Coefficient of water/oil distribution	Not relevant	Bioaccumulation Factor	Not relevant
Bioconcentration Factor	Not relevant	Biochemical Oxygen Demand BOD/BOD5	Not relevant
Chemical Oxygen Demand	Not relevant	Persistence	Not relevant

Degradation	Not relevant		
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## Section 10: Stability and Reactivity

### Reactivity

- No dangerous reaction known under conditions of normal use.

### Chemical stability

- Stable under normal temperatures and pressures.

### Possibility of hazardous reactions

- No data available

### Conditions to avoid

- Extreme heat or cold. Do not freeze.

### Incompatible materials

- No data available

### Hazardous decomposition products

- No data available

## Section 11 - Toxicological Information

### Information on toxicological effects

Components		
Polymyxin B sulfate (< 1%)	1405-20-5	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 790 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Skin Sensitizer 1B
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 2
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

### Potential Health Effects

#### Inhalation

##### Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

##### Chronic (Delayed)

- No data available.

#### Skin



**Acute (Immediate)****Chronic (Delayed)**

- Not expected to cause skin irritation.
- Repeated and prolonged exposure may cause sensitization.

**Eye****Acute (Immediate)****Chronic (Delayed)**

- Non-irritating to the eyes when used as directed.
- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

**Ingestion****Acute (Immediate)****Chronic (Delayed)**

- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- No data available.

**Reproductive Effects**

- Pregnancy Category C. Corticosteroids have been found to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 6 to 18 of gestation and in mice when applied topically at a concentration of 15% on days 10 to 13 of gestation. There are no adequate and well-controlled studies in pregnant women. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

**Section 12 - Ecological Information****Toxicity**

- This material has not been tested for environmental effects.

**Persistence and degradability**

- No data available.

**Bioaccumulative potential**

- No data available

**Mobility in Soil**

- No data available

**Other adverse effects****Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

**Packaging waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

**Section 14 - Transport Information**

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	NDA	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	NDA	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA

ADR/RID	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	NDA	NDA	NDA	NDA	NDA

**Special precautions for user** • No data available

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** • No data available

## Section 15 - Regulatory Information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**SARA Hazard Classifications** • No data available

Inventory					
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	TSCA
White petrolatum	8009-03-8	Yes	No	Yes	Yes
Polymyxin B sulfate	1405-20-5	Yes	No	Yes	No
Bacitracin zinc	1405-89-6	No	Yes	Yes	Yes

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Bacitracin zinc	1405-89-6	Not Listed

## Europe

### Other

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Carc.Cat.2; R45
• Bacitracin zinc	1405-89-6	Not Listed

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	T R:45 S:53-45
• Bacitracin zinc	1405-89-6	Not Listed

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	N
• Bacitracin zinc	1405-89-6	Not Listed

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	S:53-45
• Bacitracin zinc	1405-89-6	Not Listed

## United States

**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Not Listed
• Bacitracin zinc	1405-89-6	Not Listed

**United States - California****Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Not Listed
• Bacitracin zinc	1405-89-6	Not Listed

**U.S. - California - Proposition 65 - Developmental Toxicity**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Not Listed
• Bacitracin zinc	1405-89-6	Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Not Listed
• Bacitracin zinc	1405-89-6	Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**

• Polymyxin B sulfate	1405-20-5	Not Listed
• White petrolatum	8009-03-8	Not Listed
• Bacitracin zinc	1405-89-6	Not Listed

**Section 16 - Other Information****Last Revision Date**

- 14/May/2015

**Preparation Date**

- 14/May/2015

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# SAFETY DATA SHEET

## Sterile Lubricating Jelly

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

### 1. PRODUCT IDENTIFICATION

<b>1.1 TRADE NAME (AS LABELED):</b>	<b>Sterile Lubricating Jelly</b>
<b>SYNONYMS:</b>	Not Available
<b>CAS#:</b>	Mixture
<b>1.2 PRODUCT USE:</b>	Lubricant
<b>CHEMICAL SHIPPING NAME/CLASS:</b>	Non-Regulated
<b>U.N. NUMBER:</b>	N/A
<b>1.3 MANUFACTURER'S NAME:</b>	First Priority, Inc.
<b>ADDRESS:</b>	1590 Todd Farm Drive, Elgin, IL 60123-1287
<b>BUSINESS PHONE:</b>	800-650-4899
<b>EMERGENCY PHONE:</b>	800-424-9300 (Chemtrec U.S. – 24 Hrs)
<b>WEB SITE:</b>	<a href="http://www.prioritycare.com">www.prioritycare.com</a>
<b>DATE OF CURRENT REVISION:</b>	June 22, 2015
<b>DATE OF LAST REVISION:</b>	New

### 2. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** This product is a clear colorless to slightly yellow/beige gel with a pleasant odor.

**Health Hazards:** Repeated or prolonged exposure may cause slight irritation to skin. May cause slight irritation to eyes upon contact.

**Flammability Hazards:** This product is a non-combustible liquid with a flash point > 200°F (93°C)

**Reactivity Hazards:** None known

**Environmental Hazards:** The Environmental effects of this product have not been investigated. Release of this product may have adverse effects in the aquatic environment.

US DOT SYMBOLS

Non-Regulated

CANADA (WHMIS) SYMBOLS

Complies with WHMIS 2015

EUROPEAN and (GHS) Hazard Symbols

None

Signal Word: Not Applicable

#### 2.1 GHS LABELING AND CLASSIFICATION:

CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does not meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

#### EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:

Index Number:

**EC# 231-791-2 This substance is not classified in the Annex VI of Directive 67/548/EEC**

**EC# 200-338-0 This substance is not classified in the Annex VI of Directive 67/548/EEC**

Substances not listed either individually or in group entries must be self classified.

#### Component(s) Contributing to Classification(s)

All Ingredients

#### 2.2 LABEL ELEMENTS:

##### GHS Hazard Classification(s):

None Applicable

##### Hazard Statement(s):

None Applicable

##### Precautionary Statement(s):

None Applicable

# SAFETY DATA SHEET

## Sterile Lubricating Jelly

### 2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

**SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:** The most significant routes of overexposure for this product are by contact with skin or eyes, inhalation and ingestion. The symptoms of overexposure are described below.

#### ACUTE:

**INHALATION:** Inhalation of mist or spray may cause respiratory irritation.

**CONTACT WITH SKIN:** Prolonged or repeated contact may cause slight irritation.

**EYE CONTACT:** Contact may cause slight eye irritation.

**INGESTION:** Under normal conditions of intended use, this material is not expected to be an ingestion hazard.

**CHRONIC:** No data available

**TARGET ORGANS:** Acute: Eyes, Skin Chronic: N/A

## 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS#	EINECS #	GHS Hazard Classification
Water	75 – 90%	7732-18-5	231-791-2	Not Classified
Propylene Glycol	7 – 14%	57-55-6	200-338-0	Not Classified
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the CFR and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard JIS Z 7250: 2000.

## 4. FIRST-AID MEASURES

### 4.1 DESCRIPTION OF FIRST AID MEASURES:

**EYE CONTACT:** If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation persists or blurred vision occurs.

**SKIN CONTACT:** Wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

**INHALATION:** If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

**INGESTION:** If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Some individuals may develop skin sensitization from exposure.

### 4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Contact with skin and eyes may cause slight irritation.

### 4.3 RECOMMENDATIONS TO PHYSICIANS:

Treat symptoms and eliminate overexposure.

## 5. FIRE-FIGHTING MEASURES

### 5.1 FIRE EXTINGUISHING MATERIALS:

**FIRE EXTINGUISHING MATERIALS:** Use fire extinguishing methods below:

<u>Water Spray:</u> Yes	<u>Carbon Dioxide:</u> Yes
<u>Foam:</u> Yes	<u>Dry Chemical:</u> Yes
<u>Halon:</u> Yes	<u>Other:</u> Any "C" Class

### 5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

This product is a non-combustible liquid with a flash point >200°F (93°C).

Explosion Sensitivity to Mechanical Impact: No

Explosion Sensitivity to Static Discharge: No

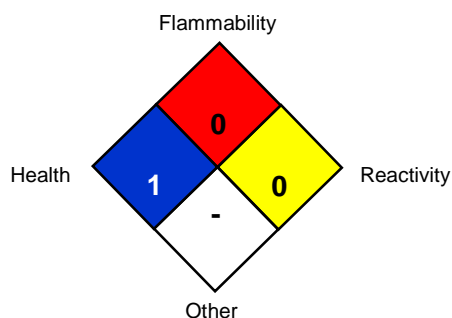
# SAFETY DATA SHEET

## Sterile Lubricating Jelly

### 5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

#### NFPA RATING SYSTEM



#### HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM	
HEALTH HAZARD (BLUE)	1
FLAMMABILITY HAZARD (RED)	0
PHYSICAL HAZARD (YELLOW)	0
PROTECTIVE EQUIPMENT	
EYES	RESPIRATORY
See Sect 8	See Sect 8
HANDS	BODY
See Sect 8	See Sect 8
For Routine Industrial Use and Handling Applications	

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe \* = Chronic hazard

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

Use cautious judgment when cleaning up spill. Wear suitable protective clothing, gloves, and eye/face protection.

### 6.2 ENVIRONMENTAL PRECAUTIONS:

Stop leak. Contain spill if possible and safe to do so. Prevent product from entering drains.

### 6.3 SPILL AND LEAK RESPONSE:

Stop the flow of material, if this can be done safely. Dike and contain the spill with inert material (sand, earth, fuller's earth, etc.) and if appropriate, transfer the liquid and solid dike material to containers for disposal. Remove contaminated clothing promptly and wash affected skin areas with soap and water. Wash clothing before reuse. Keep spill out of all sewers and open bodies of water. Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces, those of Australia, Japan and EU Member States (see Section 13, Disposal Considerations).

## 7. HANDLING and STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING:

Use good hygiene practices. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Use good hygiene practices.

### 7.2 STORAGE AND HANDLING PRACTICES:

Store in original container. Keep container closed. Store in a cool, dry location. Avoid exposure to ignition sources and incompatible materials.

### 7.3 SPECIFIC USES:

See section 1.2 for details.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

### 8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Water	7732-18-5	Not Listed	Not Listed
Propylene Glycol	57-55-6	Not Listed	Not Listed

# SAFETY DATA SHEET

## Sterile Lubricating Jelly

### **8.2 EXPOSURE CONTROLS:**

**VENTILATION AND ENGINEERING CONTROLS:** Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

*The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.*

**RESPIRATORY PROTECTION:** Maintain airborne contaminant concentrations below guidelines listed above. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

**EYE PROTECTION:** Safety glasses or chemical splash goggles are recommended to avoid contact. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

**HAND PROTECTION:** Chemical resistant gloves are recommended to prevent contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

**BODY PROTECTION:** Use as appropriate to prevent skin contact. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

## **9. PHYSICAL and CHEMICAL PROPERTIES**

### **9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:**

**APPEARANCE (Physical State) and COLOR:** This product is a clear colorless to slightly yellow/beige gel.

**ODOR:** Pleasant odor.

**ODOR THRESHOLD:** Not Available

**pH:** 6.00-7.00

**MELTING/FREEZING POINT:** Not Available

**BOILING POINT:** Not Available

**FLASH POINT:** >200°F (93°C).

**EVAPORATION RATE (n-BuAc=1):** Not Available

**FLAMMABILITY (SOLID, GAS):** Non-Flammable

**UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS:** Not Available

**VAPOR PRESSURE (mm Hg @ 20°C (68°F):** Not Available

**VAPOR DENSITY:** Not Available

**RELATIVE DENSITY:** Not Available

**DENSITY:** Not Available

**SOLUBILITY IN WATER:** Soluble

**SPECIFIC GRAVITY:** 1.00

**WEIGHT PER GALLON:** 3.3kg(3.3lbs)

**PARTITION COEFFICIENT (n-octanol/water):** Not Available

**AUTO-IGNITION TEMPERATURE:** Not Available

**DECOMPOSITION TEMPERATURE:** Not Available

**VISCOSITY:** 22,000 CPS- 50,000 CPS

**VOC g/l / Lb/gal:** Not Available

### **9.2 OTHER INFORMATION:**

No additional information available

## **10. STABILITY and REACTIVITY**

### **10.1 REACTIVITY:**

This product is not reactive.

### **10.2 STABILITY:**

Stable under conditions of normal storage and use.



# SAFETY DATA SHEET

Sterile Lubricating Jelly

## **10.3 POSSIBILITY OF HAZARDOUS REACTIONS:**

Will not occur.

## **10.4 CONDITIONS TO AVOID:**

Incompatible materials.

## **10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:**

Strong oxidizing agents.

## **10.6 HAZARDOUS DECOMPOSITION PRODUCTS:**

Not expected to occur.

## 11. TOXICOLOGICAL INFORMATION

### **11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:**

#### **TOXICITY DATA:**

No LD 50 Data Available

**SUSPECTED CANCER AGENT:** None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore not are considered to be, or suspected to be, cancer-causing agents by these agencies.

**IRRITANCY OF PRODUCT:** This product may be irritating to skin and eyes.

**SENSITIZATION TO THE PRODUCT:** This product is not a sensitizer.

**REPRODUCTIVE TOXICITY INFORMATION:** No information concerning the effects of this product and its components on the human reproductive system.

**SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:** Eye contact – may cause irritation.

**SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:** Prolonged exposure can be irritating to the skin.

**ASPIRATION HAZARD:** None

## 12. ECOLOGICAL INFORMATION

### **12.1 TOXICITY:**

No toxicity data available.

### **12.2 PERSISTENCE AND DEGRADABILITY:**

No specific data available on this product.

### **12.3 BIOACCUMULATIVE POTENTIAL:**

No specific data available on this product.

### **12.4 MOBILITY IN SOIL:**

No specific data available on this product.

### **12.5 RESULTS OF PBT AND vPvB ASSESSMENT:**

No specific data available on this product.

### **12.6 OTHER ADVERSE EFFECTS:**

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

### **12.7 WATER ENDANGERMENT CLASS:**

Not water endangering in accordance with EU Guideline 91/155-EWG.

### **12.8 SPECIFIC AVAILABLE COMPONENT INFORMATION:**

No additional data available.

## 13. DISPOSAL CONSIDERATIONS

### **13.1 WASTE TREATMENT METHODS:**

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

### **13.2 EU Waste Code:**

Not determined



# SAFETY DATA SHEET

Sterile Lubricating Jelly

## 14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

**U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:** This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows:

**14.1 PROPER SHIPPING NAME:** Not Regulated

**14.2 HAZARD CLASS NUMBER and DESCRIPTION:** N/A

**14.3 UN IDENTIFICATION NUMBER:** N/A

**14.4 PACKING GROUP:** N/A

**14.5 DOT LABEL(S) REQUIRED:** N/A

**NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER:** N/A

**RQ QUANTITY:** None

**14.6 MARINE POLLUTANT:** The components of this product are not designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

**14.7 SPECIAL PRECAUTIONS FOR USER:**

None

**14.8 INTERNATIONAL TRANSPORTION:**

**INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA):** This product is not considered as dangerous goods.

**INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO):** This product is not considered as dangerous goods.

**14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:**

**EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):** This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

## 15. REGULATORY INFORMATION

**15.1 UNITED STATES REGULATIONS:**

**U.S. SARA REPORTING REQUIREMENTS:** The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

**U.S. SARA THRESHOLD PLANNING QUANTITY:** There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

**U.S. CERCLA REPORTABLE QUANTITY (RQ):** None

**U.S. TSCA INVENTORY STATUS:** The components of this product are listed on the TSCA Inventory or are exempted from listing.

**OTHER U.S. FEDERAL REGULATIONS:** None

**CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):** Ingredients within this product are not on the Proposition 65 Lists.

**15.2 CANADIAN REGULATIONS:**

**CANADIAN DSL/NDL INVENTORY STATUS:** The components of this product are on the DSL Inventory, or are exempted from listing.

**OTHER CANADIAN REGULATIONS:** Not applicable.

**CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

**CANADIAN WHMIS CLASSIFICATION and SYMBOLS:** Complies with WHMIS 2015.

**15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:**

This product does not meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

**15.4 AUSTRALIAN INFORMATION FOR PRODUCT:** The components of this product are listed on the International Chemical Inventory list.

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## Sterile Lubricating Jelly

### **15.5 JAPANESE INFORMATION FOR PRODUCT:**

**JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:** The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

**JAPANESE ENCS INVENTORY:** The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

**POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:** No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

### **15.6 INTERNATIONAL CHEMICAL INVENTORIES:**

Listing of the components on individual country Chemical Inventories is as follows:

Asia-Pac: Listed

Australian Inventory of Chemical Substances (AICS): Listed

Korean Existing Chemicals List (ECL): Listed

Japanese Existing National Inventory of Chemical Substances (ENCS): Listed

Philippines Inventory of Chemicals and Chemical Substances (PICCS): Listed

Swiss Giftlist List of Toxic Substances: Listed

U.S. TSCA: Listed

## 16. OTHER INFORMATION

**PREPARED BY:** Paul Eigbrett – **(GHS MSDS Compliance PLUS)**

**DATE OF PRINTING:** June 22, 2015

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. First Priority, Inc assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, First Priority, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

**END OF SDS SHEET**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Selamectin topical solution- Single dose tubes

**Trade Name:** REVOLUTION; STRONGHOLD; PARADYNE  
**Synonyms:** Selamectin formulation  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as Antiparasitic (veterinary); endectocide  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to pale yellow solution

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (single exposure): Category 3  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2  
Flammable liquids- Category 2

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H225 - Highly flammable liquid and vapor  
H336 - May cause drowsiness and dizziness  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child  
H411 - Toxic to aquatic life with long lasting effects

## SAFETY DATA SHEET

Material Name: Selamectin topical solution- Single dose tubes  
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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P264 - Wash hands thoroughly after handling  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P273 - Avoid release to the environment  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
P370 + P378 - In case of fire: Use CO<sub>2</sub>, dry chemical or foam for extinction  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P405 - Store locked up  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

Short Term:

Long Term:

Not acutely toxic (based on components) . May cause slight skin irritation.  
Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin). Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver, reproductive system, and the developing fetus.  
Hazardous Substance. Dangerous Goods.

### Australian Hazard Classification (NOHSC):

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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## SAFETY DATA SHEET

Material Name: Selamectin topical solution- Single dose tubes  
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	72 - 86
Selamectin	220119-17-5	Not Listed	Repr.2 (H361) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	7 - 15
Dipropylene glycol methyl ether	34590-94-8	252-104-2	Not Listed	<1.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	<1.0

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry chemical, or foam

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Highly flammable. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire. Use spark-proof tools and explosion-proof equipment

## SAFETY DATA SHEET

Material Name: Selamectin topical solution- Single dose tubes  
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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

##### Measures for Cleaning / Collecting:

Contain the source of the spill if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly. Prevent discharge to drains.

##### Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use water spray to disperse vapors and dilute spill to a nonflammable mixture. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Take precautionary measures against static discharges. Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

##### Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Store away from direct sunlight. Keep container tightly closed when not in use. Keep out of reach of children. Store as directed by product packaging.

##### Storage Temperature:

Store at or below 30°C (86°F).

##### Specific end use(s):

Veterinary product used as Antiparasitic (veterinary); endectocide

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)

200 ppm

ACGIH Threshold Limit Value (STEL)

400 ppm

ACGIH - Biological Exposure Limit:

40 mg/L

Australia STEL

500 ppm

1230 mg/m<sup>3</sup>



## SAFETY DATA SHEET

Material Name: Selamectin topical solution- Single dose tubes  
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	400 ppm 983 mg/m <sup>3</sup>
Austria OEL - MAKs	200 ppm 500 mg/m <sup>3</sup>
Belgium OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Bulgaria OEL - TWA	980.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	500 mg/m <sup>3</sup>
Denmark OEL - TWA	200 ppm 490 mg/m <sup>3</sup>
Estonia OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
Finland OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m <sup>3</sup>
Germany (DFG) - MAK	200 ppm 500 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm 980 mg/m <sup>3</sup>
Hungary OEL - TWA	500 mg/m <sup>3</sup>
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	350 mg/m <sup>3</sup>
Lithuania OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	900 mg/m <sup>3</sup>
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm 200 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Slovenia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m <sup>3</sup>
Switzerland OEL - TWAs	200 ppm 500 mg/m <sup>3</sup>
Selamectin	
Zoetis OEL TWA 8-hr	200 µg/m <sup>3</sup>
Dipropylene glycol methyl ether	
ACGIH Threshold Limit Value (TWA)	100 ppm
ACGIH Threshold Limit Value (STEL)	150 ppm

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Material Name: Selamectin topical solution- Single dose tubes  
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>ACGIH - Skin Absorption Designation</b>	Skin - potential significant contribution to overall exposure by the cutaneous route
<b>Australia TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	50 ppm
	307 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	308.0 mg/m <sup>3</sup>
	50 ppm
<b>Cyprus OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	270 mg/m <sup>3</sup>
<b>Denmark OEL - TWA</b>	50 ppm
	309 mg/m <sup>3</sup>
<b>Estonia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Finland OEL - TWA</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>France OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Germany - TRGS 900 - TWAs</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	50 ppm
	310 mg/m <sup>3</sup> mixture of isomers
<b>Greece OEL - TWA</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	308 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Italy OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	50 ppm
	300 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	300 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>OSHA - Final PELs - Skin Notations:</b>	prevent or reduce skin absorption
<b>Poland OEL - TWA</b>	240 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	100 ppm
<b>Romania OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
	18 ppm
	300 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	50 ppm 308 mg/m <sup>3</sup>
Sweden OEL - TWAs	50 ppm 300 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 ppm 300 mg/m <sup>3</sup>

#### Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Yellow to colorless
<b>Odor:</b>	Characteristic alcohol odor	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Miscible: Water		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	84		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Selamectin

Measured Log P 3.1

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: 0.815 - 0.847

Viscosity: No data available

#### Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): 19

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

#### Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Prevent vapor accumulation. Vapours may form explosive mixture with air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: inhalation , skin contact , eye contact

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg

Mouse Oral LD50 650 mg/kg

Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

##### Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg

Mouse Oral LD50 3600 mg/kg

Rat Inhalation LC50-8h 16,000 ppm

Rabbit Dermal LD50 12800 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 30mg/L

#### Dipropylene glycol methyl ether

Dog Oral LD50 7500 mg/kg

Rat Oral LD 50 5400 µL/kg

Rabbit Dermal LD 50 10 mL/kg

#### Selamectin

Rat Oral LD50 > 1600 mg/kg

Mouse Oral LD50 > 1600mg/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Inhalation Acute Toxicity

May be harmful if inhaled. May cause respiratory tract and mucous membrane irritation. Based on components, inhalation may cause irritation, headache, drowsiness, and symptoms of drunkenness.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

##### Isopropyl alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

##### Dipropylene glycol methyl ether

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

##### Selamectin

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Minimal

Skin Sensitization - GPMT Guinea Pig Negative

**Irritation / Sensitization Comments:** May cause eye irritation.

**Skin Irritation / Sensitization** May cause mild skin irritation. based on components.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system

104 Week(s) Rat Inhalation 5000 ppm Kidney

##### Selamectin

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### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Oral 5 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral 40 mg/kg/day	NOAEL	None identified

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Butylated hydroxytoluene**

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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##### **Isopropyl alcohol**

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

##### **Selamectin**

Reproductive & Fertility	Rat	10 mg/kg/day	NOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	10 mg/kg/day	NOAEL	Developmental toxicity
Prenatal & Postnatal Development	Rat	Oral 40 mg/kg/day	NOAEL	Maternal Toxicity,

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Isopropyl alcohol**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

##### **Selamectin**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells HGPRT	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

##### **Butylated hydroxytoluene**

IARC: Group 3 (Not Classifiable)

##### **Isopropyl alcohol**

IARC: Group 3 (Not Classifiable)



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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. This mixture contains material that is toxic to aquatic life. Bioaccumulation and/or long term effects are not expected. Releases to the environment should be avoided.

**Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Selamectin

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 26 ng/L

*Mysidopsis bahia* (Mysid Shrimp) LC50 96 Hours 28 ng/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours > 28 ug/L

*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours >763 ug/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 266 ug/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

##### Selamectin

Measured Log P 3.1

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number:</b>	UN 1219
<b>UN proper shipping name:</b>	Isopropanol Solution
<b>Transport hazard class(es):</b>	3
<b>Packing group:</b>	II
<b>Environmental Hazard(s):</b>	Marine Pollutant (Selamectin)
<b>Flash Point (°C):</b>	19

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See "excepted quantity" provisions if applicable. Marine pollutant requirements apply only to quantities >5 Liters for liquids / >5 Kilograms for solids (per inner package) when shipped as per IMDG or ADR (effective year 2015 or greater) regulations. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Flash Point (°C): 19

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

##### Selamectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

##### Dipropylene glycol methyl ether

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	252-104-2

##### Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting	Not Listed
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-881-4

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness  
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Selamectin topical solution- Single dose tubes

**Trade Name:** REVOLUTION; STRONGHOLD; PARADYNE  
**Synonyms:** Selamectin formulation  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as Antiparasitic (veterinary); endectocide  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to pale yellow solution

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (single exposure): Category 3  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2  
Flammable liquids- Category 2

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H225 - Highly flammable liquid and vapor  
H336 - May cause drowsiness and dizziness  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child  
H411 - Toxic to aquatic life with long lasting effects

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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P264 - Wash hands thoroughly after handling  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P273 - Avoid release to the environment  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
P370 + P378 - In case of fire: Use CO<sub>2</sub>, dry chemical or foam for extinction  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P405 - Store locked up  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

Short Term:

Long Term:

Not acutely toxic (based on components) . May cause slight skin irritation.  
Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin). Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver, reproductive system, and the developing fetus.  
Hazardous Substance. Dangerous Goods.

### Australian Hazard Classification (NOHSC):

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	72 - 86
Selamectin	220119-17-5	Not Listed	Repr.2 (H361) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	7 - 15
Dipropylene glycol methyl ether	34590-94-8	252-104-2	Not Listed	<1.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	<1.0

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry chemical, or foam

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Highly flammable. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire. Use spark-proof tools and explosion-proof equipment



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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

##### Measures for Cleaning / Collecting:

Contain the source of the spill if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly. Prevent discharge to drains.

##### Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use water spray to disperse vapors and dilute spill to a nonflammable mixture. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Take precautionary measures against static discharges. Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

##### Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Store away from direct sunlight. Keep container tightly closed when not in use. Keep out of reach of children. Store as directed by product packaging.

##### Storage Temperature:

Store at or below 30°C (86°F).

##### Specific end use(s):

Veterinary product used as Antiparasitic (veterinary); endectocide

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)

200 ppm

ACGIH Threshold Limit Value (STEL)

400 ppm

ACGIH - Biological Exposure Limit:

40 mg/L

Australia STEL

500 ppm

1230 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	400 ppm 983 mg/m <sup>3</sup>
Austria OEL - MAKs	200 ppm 500 mg/m <sup>3</sup>
Belgium OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Bulgaria OEL - TWA	980.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	500 mg/m <sup>3</sup>
Denmark OEL - TWA	200 ppm 490 mg/m <sup>3</sup>
Estonia OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
Finland OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m <sup>3</sup>
Germany (DFG) - MAK	200 ppm 500 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm 980 mg/m <sup>3</sup>
Hungary OEL - TWA	500 mg/m <sup>3</sup>
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	350 mg/m <sup>3</sup>
Lithuania OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	900 mg/m <sup>3</sup>
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm 200 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Slovenia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m <sup>3</sup>
Switzerland OEL - TWAs	200 ppm 500 mg/m <sup>3</sup>
Selamectin	
Zoetis OEL TWA 8-hr	200 µg/m <sup>3</sup>
Dipropylene glycol methyl ether	
ACGIH Threshold Limit Value (TWA)	100 ppm
ACGIH Threshold Limit Value (STEL)	150 ppm

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>ACGIH - Skin Absorption Designation</b>	Skin - potential significant contribution to overall exposure by the cutaneous route
<b>Australia TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	50 ppm
	307 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	308.0 mg/m <sup>3</sup>
	50 ppm
<b>Cyprus OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	270 mg/m <sup>3</sup>
<b>Denmark OEL - TWA</b>	50 ppm
	309 mg/m <sup>3</sup>
<b>Estonia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Finland OEL - TWA</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>France OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Germany - TRGS 900 - TWAs</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	50 ppm
	310 mg/m <sup>3</sup> mixture of isomers
<b>Greece OEL - TWA</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	308 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Italy OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	50 ppm
	300 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	300 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>OSHA - Final PELs - Skin Notations:</b>	prevent or reduce skin absorption
<b>Poland OEL - TWA</b>	240 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	100 ppm
<b>Romania OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
	18 ppm
	300 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	50 ppm 308 mg/m <sup>3</sup>
Sweden OEL - TWAs	50 ppm 300 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 ppm 300 mg/m <sup>3</sup>

#### Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Yellow to colorless
<b>Odor:</b>	Characteristic alcohol odor	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Miscible: Water		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	84		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Selamectin

Measured Log P 3.1

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: 0.815 - 0.847

Viscosity: No data available

#### Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): 19

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

#### Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Prevent vapor accumulation. Vapours may form explosive mixture with air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: inhalation, skin contact, eye contact

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg

Mouse Oral LD50 650 mg/kg

Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

##### Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg

Mouse Oral LD50 3600 mg/kg

Rat Inhalation LC50-8h 16,000 ppm

Rabbit Dermal LD50 12800 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 30mg/L

#### Dipropylene glycol methyl ether

Dog Oral LD50 7500 mg/kg

Rat Oral LD 50 5400 µL/kg

Rabbit Dermal LD 50 10 mL/kg

#### Selamectin

Rat Oral LD50 > 1600 mg/kg

Mouse Oral LD50 > 1600mg/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Inhalation Acute Toxicity

May be harmful if inhaled. May cause respiratory tract and mucous membrane irritation. Based on components, inhalation may cause irritation, headache, drowsiness, and symptoms of drunkenness.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

##### Isopropyl alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

##### Dipropylene glycol methyl ether

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

##### Selamectin

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Minimal

Skin Sensitization - GPMT Guinea Pig Negative

**Irritation / Sensitization Comments:** May cause eye irritation.

**Skin Irritation / Sensitization** May cause mild skin irritation. based on components.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system

104 Week(s) Rat Inhalation 5000 ppm Kidney

##### Selamectin

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### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Oral 5 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral 40 mg/kg/day	NOAEL	None identified

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Butylated hydroxytoluene**

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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##### **Isopropyl alcohol**

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

##### **Selamectin**

Reproductive & Fertility	Rat	10 mg/kg/day	NOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	10 mg/kg/day	NOAEL	Developmental toxicity
Prenatal & Postnatal Development	Rat	Oral 40 mg/kg/day	NOAEL	Maternal Toxicity,

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Isopropyl alcohol**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

##### **Selamectin**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells HGPRT	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

##### **Butylated hydroxytoluene**

IARC: Group 3 (Not Classifiable)

##### **Isopropyl alcohol**

IARC: Group 3 (Not Classifiable)



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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. This mixture contains material that is toxic to aquatic life. Bioaccumulation and/or long term effects are not expected. Releases to the environment should be avoided.

**Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Selamectin

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 26 ng/L

*Mysidopsis bahia* (Mysid Shrimp) LC50 96 Hours 28 ng/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours > 28 ug/L

*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours >763 ug/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 266 ug/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

##### Selamectin

Measured Log P 3.1

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number:</b>	UN 1219
<b>UN proper shipping name:</b>	Isopropanol Solution
<b>Transport hazard class(es):</b>	3
<b>Packing group:</b>	II
<b>Environmental Hazard(s):</b>	Marine Pollutant (Selamectin)
<b>Flash Point (°C):</b>	19

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See "excepted quantity" provisions if applicable. Marine pollutant requirements apply only to quantities >5 Liters for liquids / >5 Kilograms for solids (per inner package) when shipped as per IMDG or ADR (effective year 2015 or greater) regulations. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Flash Point (°C): 19

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

##### Selamectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

##### Dipropylene glycol methyl ether

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	252-104-2

##### Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting	Not Listed
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-881-4

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness  
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Selamectin topical solution- Single dose tubes

**Trade Name:** REVOLUTION; STRONGHOLD; PARADYNE  
**Synonyms:** Selamectin formulation  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as Antiparasitic (veterinary); endectocide  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to pale yellow solution

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (single exposure): Category 3  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2  
Flammable liquids- Category 2

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H225 - Highly flammable liquid and vapor  
H336 - May cause drowsiness and dizziness  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child  
H411 - Toxic to aquatic life with long lasting effects

## SAFETY DATA SHEET

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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P264 - Wash hands thoroughly after handling  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P273 - Avoid release to the environment  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
P370 + P378 - In case of fire: Use CO<sub>2</sub>, dry chemical or foam for extinction  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P405 - Store locked up  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

Short Term:

Long Term:

Not acutely toxic (based on components) . May cause slight skin irritation.  
Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin). Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver, reproductive system, and the developing fetus.  
Hazardous Substance. Dangerous Goods.

### Australian Hazard Classification (NOHSC):

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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## SAFETY DATA SHEET

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	72 - 86
Selamectin	220119-17-5	Not Listed	Repr.2 (H361) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	7 - 15
Dipropylene glycol methyl ether	34590-94-8	252-104-2	Not Listed	<1.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	<1.0

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry chemical, or foam

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Highly flammable. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire. Use spark-proof tools and explosion-proof equipment

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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

##### Measures for Cleaning / Collecting:

Contain the source of the spill if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly. Prevent discharge to drains.

##### Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use water spray to disperse vapors and dilute spill to a nonflammable mixture. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Take precautionary measures against static discharges. Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

##### Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Store away from direct sunlight. Keep container tightly closed when not in use. Keep out of reach of children. Store as directed by product packaging.

##### Storage Temperature:

Store at or below 30°C (86°F).

##### Specific end use(s):

Veterinary product used as Antiparasitic (veterinary); endectocide

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)

200 ppm

ACGIH Threshold Limit Value (STEL)

400 ppm

ACGIH - Biological Exposure Limit:

40 mg/L

Australia STEL

500 ppm

1230 mg/m<sup>3</sup>



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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	400 ppm 983 mg/m <sup>3</sup>
Austria OEL - MAKs	200 ppm 500 mg/m <sup>3</sup>
Belgium OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Bulgaria OEL - TWA	980.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	500 mg/m <sup>3</sup>
Denmark OEL - TWA	200 ppm 490 mg/m <sup>3</sup>
Estonia OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
Finland OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m <sup>3</sup>
Germany (DFG) - MAK	200 ppm 500 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm 980 mg/m <sup>3</sup>
Hungary OEL - TWA	500 mg/m <sup>3</sup>
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	350 mg/m <sup>3</sup>
Lithuania OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	900 mg/m <sup>3</sup>
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm 200 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Slovenia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m <sup>3</sup>
Switzerland OEL - TWAs	200 ppm 500 mg/m <sup>3</sup>
Selamectin	
Zoetis OEL TWA 8-hr	200 µg/m <sup>3</sup>
Dipropylene glycol methyl ether	
ACGIH Threshold Limit Value (TWA)	100 ppm
ACGIH Threshold Limit Value (STEL)	150 ppm

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>ACGIH - Skin Absorption Designation</b>	Skin - potential significant contribution to overall exposure by the cutaneous route
<b>Australia TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	50 ppm
	307 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	308.0 mg/m <sup>3</sup>
	50 ppm
<b>Cyprus OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	270 mg/m <sup>3</sup>
<b>Denmark OEL - TWA</b>	50 ppm
	309 mg/m <sup>3</sup>
<b>Estonia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Finland OEL - TWA</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>France OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Germany - TRGS 900 - TWAs</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	50 ppm
	310 mg/m <sup>3</sup> mixture of isomers
<b>Greece OEL - TWA</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	308 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Italy OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	50 ppm
	300 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	300 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>OSHA - Final PELs - Skin Notations:</b>	prevent or reduce skin absorption
<b>Poland OEL - TWA</b>	240 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	100 ppm
<b>Romania OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
	18 ppm
	300 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	50 ppm 308 mg/m <sup>3</sup>
Sweden OEL - TWAs	50 ppm 300 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 ppm 300 mg/m <sup>3</sup>

#### Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Yellow to colorless
<b>Odor:</b>	Characteristic alcohol odor	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Miscible: Water		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	84		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Selamectin

Measured Log P 3.1

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: 0.815 - 0.847

Viscosity: No data available

#### Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): 19

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

#### Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Prevent vapor accumulation. Vapours may form explosive mixture with air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: inhalation , skin contact , eye contact

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg

Mouse Oral LD50 650 mg/kg

Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

##### Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg

Mouse Oral LD50 3600 mg/kg

Rat Inhalation LC50-8h 16,000 ppm

Rabbit Dermal LD50 12800 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 30mg/L

#### Dipropylene glycol methyl ether

Dog Oral LD50 7500 mg/kg

Rat Oral LD 50 5400 µL/kg

Rabbit Dermal LD 50 10 mL/kg

#### Selamectin

Rat Oral LD50 > 1600 mg/kg

Mouse Oral LD50 > 1600mg/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Inhalation Acute Toxicity

May be harmful if inhaled. May cause respiratory tract and mucous membrane irritation. Based on components, inhalation may cause irritation, headache, drowsiness, and symptoms of drunkenness.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

##### Isopropyl alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

##### Dipropylene glycol methyl ether

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

##### Selamectin

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Minimal

Skin Sensitization - GPMT Guinea Pig Negative

**Irritation / Sensitization Comments:** May cause eye irritation.

**Skin Irritation / Sensitization** May cause mild skin irritation. based on components.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system

104 Week(s) Rat Inhalation 5000 ppm Kidney

##### Selamectin

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### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Oral 5 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral 40 mg/kg/day	NOAEL	None identified

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Butylated hydroxytoluene**

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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##### **Isopropyl alcohol**

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

##### **Selamectin**

Reproductive & Fertility	Rat	10 mg/kg/day	NOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	10 mg/kg/day	NOAEL	Developmental toxicity
Prenatal & Postnatal Development	Rat	Oral 40 mg/kg/day	NOAEL	Maternal Toxicity,

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Isopropyl alcohol**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

##### **Selamectin**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells HGPRT	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

##### **Butylated hydroxytoluene**

IARC: Group 3 (Not Classifiable)

##### **Isopropyl alcohol**

IARC: Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. This mixture contains material that is toxic to aquatic life. Bioaccumulation and/or long term effects are not expected. Releases to the environment should be avoided.

**Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Selamectin

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 26 ng/L

*Mysidopsis bahia* (Mysid Shrimp) LC50 96 Hours 28 ng/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours > 28 ug/L

*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours >763 ug/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 266 ug/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

##### Selamectin

Measured Log P 3.1

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number:</b>	UN 1219
<b>UN proper shipping name:</b>	Isopropanol Solution
<b>Transport hazard class(es):</b>	3
<b>Packing group:</b>	II
<b>Environmental Hazard(s):</b>	Marine Pollutant (Selamectin)
<b>Flash Point (°C):</b>	19



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See "excepted quantity" provisions if applicable. Marine pollutant requirements apply only to quantities >5 Liters for liquids / >5 Kilograms for solids (per inner package) when shipped as per IMDG or ADR (effective year 2015 or greater) regulations. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Flash Point (°C): 19

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

##### Selamectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

##### Dipropylene glycol methyl ether

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	252-104-2

##### Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting	Not Listed
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-881-4

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness  
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Selamectin topical solution- Single dose tubes

**Trade Name:** REVOLUTION; STRONGHOLD; PARADYNE  
**Synonyms:** Selamectin formulation  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as Antiparasitic (veterinary); endectocide  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to pale yellow solution

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (single exposure): Category 3  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2  
Flammable liquids- Category 2

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H225 - Highly flammable liquid and vapor  
H336 - May cause drowsiness and dizziness  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child  
H411 - Toxic to aquatic life with long lasting effects

## SAFETY DATA SHEET

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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P264 - Wash hands thoroughly after handling  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P273 - Avoid release to the environment  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
P370 + P378 - In case of fire: Use CO<sub>2</sub>, dry chemical or foam for extinction  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P405 - Store locked up  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

Short Term:

Long Term:

Not acutely toxic (based on components) . May cause slight skin irritation.  
Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin). Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver, reproductive system, and the developing fetus.  
Hazardous Substance. Dangerous Goods.

### Australian Hazard Classification (NOHSC):

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	72 - 86
Selamectin	220119-17-5	Not Listed	Repr.2 (H361) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	7 - 15
Dipropylene glycol methyl ether	34590-94-8	252-104-2	Not Listed	<1.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	<1.0

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry chemical, or foam

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Highly flammable. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire. Use spark-proof tools and explosion-proof equipment

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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

##### Measures for Cleaning / Collecting:

Contain the source of the spill if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly. Prevent discharge to drains.

##### Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use water spray to disperse vapors and dilute spill to a nonflammable mixture. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Take precautionary measures against static discharges. Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

##### Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Store away from direct sunlight. Keep container tightly closed when not in use. Keep out of reach of children. Store as directed by product packaging.

##### Storage Temperature:

Store at or below 30°C (86°F).

##### Specific end use(s):

Veterinary product used as Antiparasitic (veterinary); endectocide

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)

200 ppm

ACGIH Threshold Limit Value (STEL)

400 ppm

ACGIH - Biological Exposure Limit:

40 mg/L

Australia STEL

500 ppm

1230 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	400 ppm 983 mg/m <sup>3</sup>
Austria OEL - MAKs	200 ppm 500 mg/m <sup>3</sup>
Belgium OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Bulgaria OEL - TWA	980.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	500 mg/m <sup>3</sup>
Denmark OEL - TWA	200 ppm 490 mg/m <sup>3</sup>
Estonia OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
Finland OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m <sup>3</sup>
Germany (DFG) - MAK	200 ppm 500 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm 980 mg/m <sup>3</sup>
Hungary OEL - TWA	500 mg/m <sup>3</sup>
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	350 mg/m <sup>3</sup>
Lithuania OEL - TWA	150 ppm 350 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	900 mg/m <sup>3</sup>
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm 200 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Slovenia OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain OEL - TWA	200 ppm 500 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m <sup>3</sup>
Switzerland OEL - TWAs	200 ppm 500 mg/m <sup>3</sup>
Selamectin	
Zoetis OEL TWA 8-hr	200 µg/m <sup>3</sup>
Dipropylene glycol methyl ether	
ACGIH Threshold Limit Value (TWA)	100 ppm
ACGIH Threshold Limit Value (STEL)	150 ppm



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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>ACGIH - Skin Absorption Designation</b>	Skin - potential significant contribution to overall exposure by the cutaneous route
<b>Australia TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	50 ppm
	307 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	308.0 mg/m <sup>3</sup>
	50 ppm
<b>Cyprus OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	270 mg/m <sup>3</sup>
<b>Denmark OEL - TWA</b>	50 ppm
	309 mg/m <sup>3</sup>
<b>Estonia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Finland OEL - TWA</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>France OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Germany - TRGS 900 - TWAs</b>	50 ppm
	310 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	50 ppm
	310 mg/m <sup>3</sup> mixture of isomers
<b>Greece OEL - TWA</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	308 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Italy OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	50 ppm
	300 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	300 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	100 ppm
	600 mg/m <sup>3</sup>
<b>OSHA - Final PELs - Skin Notations:</b>	prevent or reduce skin absorption
<b>Poland OEL - TWA</b>	240 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	100 ppm
<b>Romania OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
	18 ppm
	300 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	50 ppm
	308 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	50 ppm 308 mg/m <sup>3</sup>
Sweden OEL - TWAs	50 ppm 300 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 ppm 300 mg/m <sup>3</sup>

#### Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Yellow to colorless
<b>Odor:</b>	Characteristic alcohol odor	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Miscible: Water		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	84		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Selamectin

Measured Log P 3.1

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: 0.815 - 0.847

Viscosity: No data available

#### Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): 19

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

#### Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Prevent vapor accumulation. Vapours may form explosive mixture with air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: inhalation , skin contact , eye contact

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg

Mouse Oral LD50 650 mg/kg

Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

##### Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg

Mouse Oral LD50 3600 mg/kg

Rat Inhalation LC50-8h 16,000 ppm

Rabbit Dermal LD50 12800 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 30mg/L

#### Dipropylene glycol methyl ether

Dog Oral LD50 7500 mg/kg

Rat Oral LD 50 5400 µL/kg

Rabbit Dermal LD 50 10 mL/kg

#### Selamectin

Rat Oral LD50 > 1600 mg/kg

Mouse Oral LD50 > 1600mg/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Inhalation Acute Toxicity

May be harmful if inhaled. May cause respiratory tract and mucous membrane irritation. Based on components, inhalation may cause irritation, headache, drowsiness, and symptoms of drunkenness.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

##### Isopropyl alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

##### Dipropylene glycol methyl ether

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

##### Selamectin

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Minimal

Skin Sensitization - GPMT Guinea Pig Negative

**Irritation / Sensitization Comments:** May cause eye irritation.

**Skin Irritation / Sensitization** May cause mild skin irritation. based on components.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system

104 Week(s) Rat Inhalation 5000 ppm Kidney

##### Selamectin

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### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Oral 5 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral 40 mg/kg/day	NOAEL	None identified

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Butylated hydroxytoluene**

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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##### **Isopropyl alcohol**

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

##### **Selamectin**

Reproductive & Fertility	Rat	10 mg/kg/day	NOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	10 mg/kg/day	NOAEL	Developmental toxicity
Prenatal & Postnatal Development	Rat	Oral 40 mg/kg/day	NOAEL	Maternal Toxicity,

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Isopropyl alcohol**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

##### **Selamectin**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells HGPRT	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

##### **Butylated hydroxytoluene**

IARC: Group 3 (Not Classifiable)

##### **Isopropyl alcohol**

IARC: Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. This mixture contains material that is toxic to aquatic life. Bioaccumulation and/or long term effects are not expected. Releases to the environment should be avoided.

**Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Selamectin

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 26 ng/L

*Mysidopsis bahia* (Mysid Shrimp) LC50 96 Hours 28 ng/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours > 28 ug/L

*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours >763 ug/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 266 ug/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

##### Selamectin

Measured Log P 3.1

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number:</b>	UN 1219
<b>UN proper shipping name:</b>	Isopropanol Solution
<b>Transport hazard class(es):</b>	3
<b>Packing group:</b>	II
<b>Environmental Hazard(s):</b>	Marine Pollutant (Selamectin)
<b>Flash Point (°C):</b>	19

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See "excepted quantity" provisions if applicable. Marine pollutant requirements apply only to quantities >5 Liters for liquids / >5 Kilograms for solids (per inner package) when shipped as per IMDG or ADR (effective year 2015 or greater) regulations. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Flash Point (°C): 19

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

##### Selamectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

##### Dipropylene glycol methyl ether

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	252-104-2

##### Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting	Not Listed
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-881-4

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness  
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**





# SAFETY DATA SHEET

## Sentinel Spectrum® (milbemycin oxime/lufenuron/praziquantel)

### 1. IDENTIFICATION

<b>Product Name</b>	Sentinel Spectrum® (milbemycin oxime/lufenuron/praziquantel)
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Identified uses</b>	Chewable Tablets for Worm and Flea Prevention and Control in Dogs and Puppies
<b>Restrictions on Use</b>	Not for human use.
<b>Company Identification</b>	Virbac AH, Inc. P.O. Box 162059 Fort Worth, Texas 76161 (800) 338-3659
<b>Customer Information Number</b>	
<b>Emergency Telephone Number</b>	
<b>CHEMTREC Number</b>	(800) 424-9300
<b>Other Emergency Number:</b>	1-800-338-3659 for medical emergencies
<b>Issue Date</b>	April 10, 2015
<b>Supersedes Date</b>	This is the first issue.

*Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*

### 2. HAZARDS IDENTIFICATION

#### Hazard Classification

Acute Hazards to the Aquatic Environment – Category 1 (OSHA non-mandatory)

#### Label Elements

Hazard Symbols



Signal Word: Warning

#### Hazard Statements

Very toxic to aquatic life.

#### Precautionary Statements

##### Prevention

Avoid release to the environment.

##### Response

Collect spillage.

##### Storage

None

##### Disposal

Dispose of contents/container in accordance with local regulation.



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## 2. HAZARD IDENTIFICATION

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### Other Hazards

None

### Specific Concentration Limits

The values listed below represent the percentages of ingredients of unknown toxicity.

Acute oral toxicity	<10%
Acute dermal toxicity	<10%
Acute inhalation toxicity	20 - 30%
Acute aquatic toxicity	>90%

---

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

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### Synonyms:

This product is a mixture.

Component Name	CAS Number	Concentration
Milbemycin oxime	122674-17-3	<1%
Lufenuron	103055-07-8	5 – 10%
Praziquantel	55268-74-1	1 – 5%
Starch	NA	25 – 35%

Each flavored chew contains:

2.3, 5.75, 11.5 or 23.0 mg of Milbemycin oxime

46, 115, 230, or 460 mg of Lufenuron

22.8, 57, 114, or 228 mg of Praziquantel

---

## 4. FIRST - AID MEASURES

---

### Description of necessary first-aid measures

#### Eyes

Not an expected route of entry. If tablet contacts eye, flush thoroughly with water. If pain or irritation persists contact a physician.

#### Skin

Wash skin with soap and water.

#### Ingestion

Contact a physician immediately if ingested. Physician may call a poison control center for advice concerning human ingestion.

#### Inhalation

Not applicable

### Most important symptoms/effects, acute and delayed

Aside from the information found under Description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

### Indication of immediate medical attention and special treatment needed

#### Notes to Physicians

Treat symptomatically.



---

## **5. FIRE - FIGHTING MEASURES**

---

### **Extinguishing Media**

Use extinguishing media appropriate for surrounding materials.

### **Unusual Fire and Explosion Hazards**

Can release hazardous vapors during a fire.

### **Protective Equipment for Fire-Fighting**

Wear full protective clothing and self-contained breathing apparatus.

---

## **6. ACCIDENTAL RELEASE MEASURES**

---

### **Personal precautions, protective equipment and emergency procedures**

Wear appropriate protective clothing.

### **Environmental Precautions**

Prevent the material from entering drains or watercourses.

### **Methods and materials for containment and cleaning up**

Sweep and dispose of small amounts in trash. Large amounts should be disposed of in a sanitary landfill.

---

## **7. HANDLING AND STORAGE**

---

### **Precautions for safe handling**

Wear appropriate protective clothing.

### **Conditions for safe storage**

Store in original container at controlled room temperatures between 59°F and 77°F (15°C - 25° C). Keep out of sunlight. Keep away from children. Wash hands after dispensing to dog and before eating, drinking or smoking.

---

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

---

### **Control parameters**

Exposure limits are listed below, if they exist.

#### **Milbemycin Oxime**

Manufacturer's recommended limit: 0.12 mg/m<sup>3</sup> 8h TWA

#### **Lufenuron**

Manufacturer's recommended limit: 0.15mg/m<sup>3</sup> 8h TWA

#### **Praziquantel**

None established

#### **Starch**

ACGIH: TLV 10mg/m<sup>3</sup> 8h TWA

OSHA: PEL 15 mg/m<sup>3</sup> total dust, 5 mg/m<sup>3</sup> respirable fraction

### **Appropriate engineering controls**

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.



---

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

---

### Individual protection measures

#### Respiratory Protection

Not required under normal conditions of use.

#### Skin Protection

Not required under normal conditions of use. Workers should wash hands before eating, drinking or smoking.

#### Eye/Face Protection

Not required under normal conditions of use.

#### Body Protection

Normal work wear.

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

---

### Appearance

**Physical State** Solid

**Color** Brown

**Odor** Characteristic beef- bacon flavor

**Odor Threshold** No data available

**pH** Not applicable

**Density** No data available

**Boiling Range/Point (°C/F)** Not applicable

**Melting Point (°C/F)** Not applicable

**Flash Point (°C/F)** Not applicable

**Vapor Pressure** Not applicable

**Evaporation Rate (BuAc=1)** Not applicable

**Solubility in Water** Soluble

**Vapor Density (Air = 1)** Not applicable

**VOC** Not applicable

**Partition coefficient (n-octanol/water)** Not applicable

**Viscosity** Not applicable

**Auto-ignition Temperature** No data available

**Decomposition Temperature** No data available

**Upper explosive limit** No data available

**Lower explosive limit** No data available

**Flammability (solid, gas)** No data available

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## 10. STABILITY AND REACTIVITY

---

### Reactivity

Data is not available

### Chemical Stability

Stable under normal conditions.

### Possibility of hazardous reactions

Hazardous polymerization will not occur.

### Conditions to Avoid

Heat - high temperatures



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## 10. STABILITY AND REACTIVITY

---

### Incompatible Materials

None known.

### Hazardous Decomposition Products

None known.

---

## 11. TOXICOLOGICAL INFORMATION

---

See product insert and/or packaging for additional information.

### Acute Toxicity

#### Milbemycin oxime

Oral LD50 (rat) >2000 mg/kg

Dermal LD50 (rat) >2000 mg/kg

Inhalation LD50 (rat) 1220 mg/m<sup>3</sup> 4h

#### Lufenuron

Oral LD50 (rat) >2000 mg/kg

Dermal LD50 (rat) >2000 mg/kg

Inhalation LD50 (rat) >2350 mg/m<sup>3</sup> 4h

#### Praziquantel

Oral LD50 (rat) 2840 mg/kg

Dermal LD50 (rat) >2000 mg/kg

### Specific Target Organ Toxicity (STOT) – single exposure

Praziquantel: Acute overexposure (ingestion) may cause dizziness, headache, drowsiness, malaise, abdominal pain.

### Specific Target Organ Toxicity (STOT) – repeat exposure

Praziquantel: Chronic overexposure may cause nausea, lethargy, diarrhea, itching, fever and rash.

### Serious Eye damage/Irritation

Milbemycin oxime: Not irritating to eyes in rabbit studies.

Lufenuron: Not irritating to eyes in rabbit studies.

Praziquantel: Not irritating to eyes in rabbit studies.

### Skin Corrosion/Irritation

Milbemycin oxime: Not irritating to skin in rabbit studies.

Lufenuron: Not irritating to skin in rabbit studies.

Praziquantel: Not irritating to skin in rabbit studies.

### Respiratory or Skin Sensitization

Milbemycin oxime: Not sensitizing in guinea pig study.

Lufenuron: Sensitizing in guinea pig in Maximisation Test.

Praziquantel: Not sensitizing in guinea pig study.

### Carcinogenicity

Product: Not considered carcinogenic by NTP, IARC, and OSHA.

Praziquantel: Long term studies in rats and golden hamsters did not reveal any carcinogenic effect.

Lufenuron: Not carcinogenic in rat and mouse studies.



---

## 11. TOXICOLOGICAL INFORMATION

---

### **Germ Cell Mutagenicity**

Milbemycin oxime: Negative results for in vivo and in vitro animal studies.

Lufenuron: Negative results for in vivo and in vitro animal studies.

Praziquantel: Negative results for in vivo and in vitro animal studies.

### **Reproductive Toxicity**

Praziquantel: Studies in rats and rabbits have shown no evidence of impaired fertility or harm to the fetus. An increase of the abortion rate was found in rats at three times the single human therapeutic dose.

Lufenuron: Did not show teratogenic effects in animal experiments.

Milbemycin oxime: Not teratogenic in rat and rabbit studies.

### **Aspiration Hazard**

Not an aspiration hazard.

---

## 12. ECOLOGICAL INFORMATION

---

### **Ecotoxicity**

#### Lufenuron

LC50 (Rainbow Trout) >73 mg/l 96hr

LC50 (Daphnia magna) 0.0011 – 0.0013 mg/l 48hr

EC50 (green algae) 10 mg/l 72hr

#### Milbemycin Oxime

LC50 (Common carp) 0.059 mg/l 48hr

LC50 (Daphnia pulex) >300 mg/l 3hr

### **Mobility in soil**

Ivermectin: Ivermectin is metabolized in the soil. Water solubility is limited and it binds to soil very tightly. It does not bioconcentrate in fish and is not taken up from soil into plants.

### **Persistence/Degradability**

Lufenuron: Not readily biodegradable.

### **Bioaccumulative Potential**

No relevant studies identified.

### **Other adverse effects**

No relevant studies identified.

---

## 13. DISPOSAL CONSIDERATIONS

---

Dispose of in accordance with all applicable local and national regulations.

---

## 14. TRANSPORT INFORMATION

---

Contact supplier for transport information.



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**15. REGULATORY INFORMATION**

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**United States TSCA Inventory**

This product is a drug and therefore is not regulated under the US EPA Toxic Substance Control Act.

**Canada DSL Inventory**

This product contains ingredients that are not listed on the Domestic Substance List (DSL).

**California Proposition 65**

This product contains the following materials which the State of California has found to cause cancer, birth defects or other reproductive harm: Butylated Hydroxyanisole (BHA) (<0.05%)

**SARA Title III Sect. 311/312 Categorization**

None

**SARA Title III Sect. 313**

This product contains a chemical that is listed in Section 313 at or above de minimis concentrations. The following listed chemicals are present: None

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**16. OTHER INFORMATION**

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**Legend**

ACGIH: American Conference of Governmental Industrial Hygienists

CAS#: Chemical Abstracts Service Number

IARC: International Agency for Research on Cancer

LD50: Lethal Dose 50%

NA: Denotes no information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

VOC: Volatile Organic Compounds

Revision Date: April 10, 2015

Replaces: This is the first issue.

Changes made: Not applicable

**Prepared By:** EnviroNet LLC.

The information and recommendations presented in this SDS are based on sources believed to be accurate. Virbac AH, Inc. assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the material for their particular purposes. In particular, we make NO WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, with respect to such information, and we assume no liability resulting from its use. Users should ensure that any use or disposal of the material is in accordance with applicable Federal, State, and local laws and regulations.

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Butorphanol Tartrate Injection

**Trade Name:** TORBUTROL; TORBUGESIC

**Chemical Family:** Opioid analgesic

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical active used as opioid analgesic

**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Solution

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1B  
Effects on or via lactation

#### EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2

EU Symbol: Xn  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H360D - May damage the unborn child  
H362 - May cause harm to breast-fed children



## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Injection  
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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P263 - Avoid contact during pregnancy/while nursing  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

#### Short Term:

Harmful if swallowed (based on animal data) .

#### Long Term:

Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

#### Known Clinical Effects:

Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Butorphanol tartrate	58786-99-5	261-443-5	Xn;R22 Repr.Cat.2;R61 R64	Acute Tox. 4,H302; Repr. 1B,H360D; Lact.,H362	0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium citrate	68-04-2	200-675-3	Not Listed	Not Listed	*
Citric Acid	77-92-9	201-069-1	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Benzethonium chloride	121-54-0	204-479-9	Not Listed	Not Listed	*

## SAFETY DATA SHEET

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**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Sodium chloride

Latvia OEL - TWA

5 mg/m<sup>3</sup>

Lithuania OEL - TWA

5 mg/m<sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Butorphanol tartrate

Zoetis OEB

OEB 4 (control exposure to the range of 1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Solution

#### Color:

No data available.

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

## SAFETY DATA SHEET

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available  
pH: No data available.  
Melting/Freezing Point (°C): No data available  
Boiling Point (°C): No data available.  
Partition Coefficient: (Method, pH, Endpoint, Value)  
No data available  
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available  
Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

**Flammability:**

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

### 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: None  
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.  
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers  
Hazardous Decomposition Products: No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Sodium chloride**

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

**Benzethonium chloride**

Rat	Oral	LD50	368mg/kg
Rat	Subcutaneous	LD50	119mg/kg
Rat	IV	LD50	19mg/kg

**Butorphanol tartrate**

Rat	Oral	LD50	315 mg/kg
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## SAFETY DATA SHEET

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### 11. TOXICOLOGICAL INFORMATION

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Citric Acid**

Eye Irritation	Rabbit	Irritant
Skin Irritation	Rabbit	Non-irritating

##### **Sodium chloride**

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

##### **Benzethonium chloride**

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Mild

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Butorphanol tartrate**

Reproductive & Fertility	Rat	Oral 2.5 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Oral Dose not specified	NOAEL	Not Teratogenic
Reproductive & Fertility	Rat	Subcutaneous 1 mg/kg/day	LOAEL	Fetal mortality

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Butorphanol tartrate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Unscheduled DNA Synthesis	Human fibroblast cells	Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Butorphanol tartrate**

2 Year(s)	Rat	Oral 60 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral 60 mg/kg/day	NOAEL	Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## SAFETY DATA SHEET

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### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### **WHMIS hazard class:**

D2a very toxic materials

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



## SAFETY DATA SHEET

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### 15. REGULATORY INFORMATION

#### Sodium citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3

#### Citric Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

#### Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

#### Butorphanol tartrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	261-443-5

#### Benzethonium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-479-9

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

## SAFETY DATA SHEET

**Material Name:** Butorphanol Tartrate Injection  
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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child  
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Toxic to Reproduction: Category 2  
Xn - Harmful

R22 - Harmful if swallowed.  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**



**SDS: Butorphanic® Injection CIV  
(butorphanol tartrate)**

058323

058324

Verified 2/17

**SAFETY DATA SHEET****1. Identification**

**Product Identifier:** Butorphanic® Injection CIV (butorphanol tartrate)

**Synonyms:** (-)-17-(cyclobutylmethyl) morphinan-3, 14-diol [S-(R\*,R\*)] - 2,3 - dihydroxy butanedioate (1:1) (salt).

**National Drug Code (NDC):** 59399-112-20

**Recommended Use:** Veterinary Injection.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.  
**Health Hazards:** Not classifiable.  
**Symbol(s):** None.  
**Signal Word:** None.  
**Hazard Statement(s):** None.  
**Precautionary Statement(s):**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash hands thoroughly after handling.

P314 Get medical advice/attention if you feel unwell.

P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
+  
P351  
+  
P338

P337 If eye irritation persists: Get medical  
+  
advice/attention.  
P313

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

SDS: Butorphanic® Injection CIV  
(butorphanol tartrate)3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Butorphanol Tartrate	58786-99-5	(-)-17-(cyclobutylmethyl) morphinan-3, 14-diol [S-(R*,R*)] - 2,3 - dihydroxy butanedioate (1:1) (salt).	C <sub>21</sub> H <sub>29</sub> NO <sub>2</sub> •C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>	477.55	1%

\*The formula also contains Citric Acid, 3.3 mg; Sodium Citrate, 6.4 mg; Sodium Chloride, 4.7 mg; Benzethonium Chloride, 1.0 mg; and Water for injection.

4. First Aid Measures**Ingestion:**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. The management of suspected butorphanol overdosage includes maintenance of adequate ventilation, peripheral perfusion, normal body temperature, and protection of the airway. Patients should be under continuous observation with adequate serial measures of mental state, responsiveness and vital signs. Oxygen and ventilatory assistance should be available with continual monitoring by pulse oximetry if indicated. In the presence of coma, placement of an artificial airway may be required. An adequate intravenous portal should be maintained to facilitate treatment of hypotension associated with vasodilation. The use of a specific opioid antagonist such as naloxone should be considered. As the duration of butorphanol action usually exceeds the duration of action of naloxone, repeated dosing with naloxone may be required. In managing cases of suspected butorphanol overdosage, the possibility of multiple drug ingestion should always be considered.

**Eye Contact:**

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:**

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	None anticipated from normal handling of this product. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. In clinical use, the most frequent adverse effects include sedation, tiredness, dizziness, nausea, vomiting, constipation, abdominal pain, heart palpitations, sweating/clammy skin, vasodilation, palpitations, hypotension, skin rashes, hallucinations, euphoria, visual disturbances, headache, and pinpoint pupils. Butorphanol affects the central nervous system and can cause respiratory depression. Chronic use may lead to dependence.
<b>Medical Conditions Aggravated by Exposure:</b>	Not determined.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

### 5. Firefighting Measures

<b>Flammability:</b>	None anticipated for this aqueous product.
<b>Suitable Extinguishing Media:</b>	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

#### Specific Hazards Arising from the Chemical:

<b>Hazardous Combustion Products:</b>	Not determined.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment/Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

<b>Personal Precautions:</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.

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- Methods for Cleaning Up:** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water.
- Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.
- Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

- Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. In the United States, butorphanol tartrate is a Schedule IV controlled substance. Additional training and procedures may be required for proper handling of this product. Handle in accordance with good industrial hygiene and safety practices.
- Conditions for Safe Storage, Including Any Incompatibilities:** For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
- Specific End Use:** Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Butorphanol Tartrate	2 mcg/m <sup>3</sup> TWA

- Engineering Controls:** Engineering controls are normally not needed during the normal use of this product.
- Respiratory Protection:** Respiratory protection is normally not needed during intended product use. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
- Eyes Protection:** Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
- Hand Protection:** Not required for the normal use of this product. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling

## SDS: Butorphanic® Injection CIV (butorphanol tartrate)

practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:**

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Clear colorless liquid solution.
<b>Odor:</b>	None.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	4.5 (3.0 – 5.5).
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	180:1 at pH 7.5.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	No data available.
<b>Incompatible Materials:</b>	Oxidizers, acids, and bases.
<b>Hazardous Decomposition Products:</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

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### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion:** May be harmful if swallowed.

**Skin Contact:** May be harmful if absorbed through the skin. May cause irritation.

**Eye Contact:** May cause eye irritation.

#### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### **Delayed and Immediate Effects of Exposure:**

No data available.

#### **Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Butorphanol Tartrate	Rat	Oral	LD <sub>50</sub>	315 mg/kg
Butorphanol Tartrate	Mouse	Oral	LD <sub>50</sub>	395 mg/kg
Butorphanol Tartrate	Dog	Oral	LD <sub>50</sub>	>50 mg/kg
Butorphanol Tartrate	Monkey	Oral	LD <sub>50</sub>	>50 mg/kg
Butorphanol Tartrate	Rat	Intravenous	LD <sub>50</sub>	17 mg/kg
Butorphanol Tartrate	Mouse	Intravenous	LD <sub>50</sub>	36 mg/kg
Butorphanol Tartrate	Dog	Intravenous	LD <sub>50</sub>	10 mg/kg

LD<sub>50</sub>: Dosage that produces 50% mortality.

#### **Acute Toxicity – Dermal:**

No data available.

#### **Acute Toxicity – Inhalation:**

No data available.

#### **Corrosivity:**

None anticipated from normal handling of this product.

#### **Dermal Irritation:**

None anticipated from normal handling of this product.

#### **Eye Irritation:**

None anticipated from normal handling of this product.

#### **Dermal or Respiratory Sensitization:**

None anticipated from normal handling of this product. Butorphanol tartrate is not a dermal sensitizer.

#### **Toxicokinetics/Metabolism:**

No data available.

#### **Target Organ Effects:**

Based on clinical use, possible target organs include, the central nervous system, cardiovascular system, respiratory system, and the gastrointestinal system.

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(butorphanol tartrate)**

<b>Reproductive Effects:</b>	None anticipated from normal handling of this product. In fertility studies, rats treated orally with a dosage of 160 mg/kg/day had a reduced pregnancy rate. However, a similar effect was not observed with at a subcutaneous dosage of 2.5 mg/kg/day. Reproduction studies in mice, rats, and rabbits treated with butorphanol during organogenesis did not show any teratogenic potential. However, pregnant rats treated subcutaneously with butorphanol at 1 mg/kg had a higher frequency of stillbirths than controls. Butorphanol given at oral dosages of 30 mg/kg and 60 mg/kg also showed higher incidences of post-implantation loss in rabbits.
<b>Carcinogenicity:</b>	Two-year carcinogenicity studies were conducted in mice (up to 2 mg/kg/day via oral gavage) and rats given butorphanol tartrate in the diet up to 60 mg/kg/day. There was no evidence of treatment-related carcinogenicity in either species in these studies.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	Butorphanol was not genotoxic in <i>S. typhimurium</i> or <i>E. coli</i> assays or in unscheduled DNA synthesis and repair assays conducted in cultured human fibroblast cells.
<b>Aspiration Hazard:</b>	None anticipated from normal handling of this product.

**12. Ecological Information****Ecotoxicity**

**Aquatic:** Not determined for product. Information for butorphanol tartrate is provided below:

Compound	Species	Test Type	Dose
Butorphanol Tartrate	Daphnia magna	EC <sub>50</sub> (48hr)	38.1 mg/L
Butorphanol Tartrate	Inhibition of respiration in activated sludge.	EC <sub>50</sub> (3hr)	878 mg/L

<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	Not determined for product. Information for butorphanol tartrate is provided below:  Butorphanol tartrate degraded < 10% in a 28-day biodegradation assay. Based on these results, butorphanol tartrate is not considered readily biodegradable.

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Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

**13. Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

**14. Transport Information**

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

**15. Regulatory Information****US Federal Regulations:**

Toxic Substance Control Act (TSCA):	Exempt.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

**State Regulations**

California Proposition 65:	Not listed.
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**16. Other Information**

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