

# SAFETY DATA SHEET

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

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### Contact information

#### General



Leucadia Pharmaceuticals  
2325 Camino Vida Roble, Suite A  
Carlsbad, CA 92011  
Main: +1 (844) 538-2231 (Mon-Fri 8:00 AM - 6:00 PM Central)  
Email: info.sds@leucadiapharma.com

#### Emergency telephone number

Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)

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<b>Product identifier</b>	Pentobarbital Sodium Injection, USP
<b>Synonyms</b>	5-ethyl-5-pentan-2-yl-1,3-diazinane-2,4,6-trione; sodium
<b>Trade names</b>	None identified
<b>Chemical family</b>	Barbituric acid 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
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

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## SECTION 2 - HAZARDS IDENTIFICATION

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<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> Consult prescribing/packaging information. <b>The classification and labeling listed below is for bulk drug product.</b>
<b>Globally Harmonized System [GHS]</b>	Specific Target Organ Toxicity (single exposure) - Category 3. Reproductive Toxicity - Category 2.
<b>Label elements</b>	

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**GHS hazard pictogram**



**GHS signal word**

Warning

**GHS hazard statements**

H336 - May cause drowsiness or dizziness. H361d - Suspected of damaging the unborn child.

**GHS precautionary statements**

P201 - Obtain special instructions before use. P261 - Avoid breathing mist/vapors/spray. P271 - Use only outdoors or in a well-ventilated area. P281 - Use personal protective equipment as required. P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308 + P313 - IF exposed or concerned: get medical advice/attention. P312 - Call a Poison Center or doctor/physician if you feel unwell. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations. P312 - Call a Poison Center or doctor/physician if you feel unwell.

**Other hazards**

No data were identified for the mixture. Pentobarbital is a short acting barbiturate that is effective as a sedative, sleep induction, preanesthetic, and anticonvulsant. Common adverse effects reported with use of pentobarbital were sedation, drowsiness, lethargy, vertigo, nausea, vomiting, and headache. A potential for abuse, tolerance, and/or psychological and physical dependence may occur. Abrupt cessation of use may result in withdrawal symptoms.

Newborns exposed during the last trimester of pregnancy may show withdrawal symptoms from 1-14 days after birth. Effects observed may include hyperactivity, restlessness, disturbed sleep, tremor, and hyperreflexia. Pentobarbital is excreted into breast milk. No data were identified following exposure to pentobarbital in breast milk.

**Note**

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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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>
Pentobarbital Sodium	57-33-0	200-323-9	1-5%	ATO3:H301; RT2:H361d; STOT-S3:H336
Propylene glycol	57-55-6	200-338-0	35-50%	Not classified
Ethanol	64-17-5	200-578-6	5-15%	FL2: H225

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## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

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**Note** The ingredient(s) listed above are considered dangerous/hazardous. Propylene glycol is listed because it has OELs. The remaining components are non-hazardous and/or present at amounts below reportable limits. Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. 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

**Immediate Medical Attention Needed**

Yes

**Eye Contact**

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.

**Skin Contact**

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

**Inhalation**

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.

**Ingestion**

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.

**Protection of first aid responders**

See Section 8 for Exposure Controls/Personal Protection recommendations.

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

See Sections 2 and 11.

**Indication of immediate medical attention and special treatment needed, if necessary**

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

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## SECTION 5 - FIREFIGHTING MEASURES

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**Extinguishing media**

Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

**Specific hazards arising from the substance or mixture**

No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and chloride-containing compounds.

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## SECTION 5 - FIREFIGHTING MEASURES ...continued

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<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>	Take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/vapors/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>	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.
<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>	Follow recommendations for handling bulk formulated products (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing vapor/mist/spray.
<b>Conditions for safe storage including any incompatibilities</b>	As a controlled substance, this product should be stored in a designated controlled substance area. Store this product away from incompatible materials. Store at room temperature. Protect from freezing and avoid excessive heat. Keep container upright and tightly closed. Store locked up.
<b>Specific end use(s)</b>	No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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<b>Note</b>	Dispose of broken vials/syringes in a sharps container.
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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**


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**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Pentobarbital Sodium	--	--	--
Propylene glycol	AIHA	TWA-8 HR	10 mg/m <sup>3</sup>
	Ireland, United Kingdom	TWA-8 HR	150 ppm (total vapor and particulates), 10 mg/m <sup>3</sup> (particulates)
	Latvia, Lithuania	TWA-8 HR	7 mg/m <sup>3</sup>
	United Kingdom	STEL	450 ppm (total particulate and vapor), 30 mg/m <sup>3</sup> (particulate)
Ethanol	ACGIH, NIOSH	TWA-8 HR	1000 ppm
	NIOSH	IDLH (Immediately dangerous to life or health)	3300 ppm
	Austria, Belgium, Denmark, Estonia, Finland, France, Greece, Ireland, Portugal, Romania, Slovenia, Spain, United Kingdom, Mexico, Singapore	TWA-8 HR	1000 ppm
	Austria	STEL (3 x 60 min)	2000 ppm
	Bulgaria, Czech Republic, Latvia	TWA-8 HR	1000 mg/m <sup>3</sup>
	Czech Republic	Ceiling	3000 mg/m <sup>3</sup>
	Estonia, Lithuania, Sweden	STEL	1000 ppm

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

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**Control Parameters/  
Occupational Exposure  
Limit Values**

...continued

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
	Estonia, Germany, Lithuania, Netherlands, Slovak Republic, Sweden	TWA-8 HR	500 ppm
	Finland	STEL	1300 ppm
	France, Romania	STEL	5000 ppm
	Germany, Lithuania	Ceiling	1000 ppm
	Hungary	STEL	7600 mg/m <sup>3</sup>
	Hungary, Poland	TWA-8 HR	1900 mg/m <sup>3</sup>
	Slovak Republic	Ceiling	1920 mg/m <sup>3</sup>
	Slovenia	STEL	4000 ppm
	United Kingdom	STEL	3000 ppm
	Brazil	TWA-8 HR	780 ppm

**Exposure/Engineering  
controls**

None required for normal handling of packaged product. If handling bulk mixture or if vials are broken: Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Utilize closed and sealed systems whenever possible. Solutions used for procedures where aerosolization may occur (e.g., spraying, pumping, open transfers,) must be handled using an engineered local exhaust ventilation (LEV) and/or enclosure or isolator system. Control the potential for spills and leaks by securing all connections. Use clean-in-place systems.

**Respiratory  
protection**

None required for normal handling of packaged product. If handling bulk mixture or if vials are broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required when performing aerosol generating operations. An airline respirator or self-contained breathing apparatus (SCBA) and disposable outerwear is required for spill cleanup.

**Hand protection**

Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.

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

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<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 mixture, 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
<b>Color</b>	Clear, colorless.
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	~9.5
<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>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.

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

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<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>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	Not applicable (Mixture)
<b>Molecular weight</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	Stable under recommended storage conditions.
<b>Chemical stability</b>	Stable under recommended storage conditions.
<b>Possibility of hazardous reactions</b>	No information identified.
<b>Conditions to avoid</b>	Do not freeze or heat.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	Not available.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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<b>Note</b>	As limited data for the mixture were identified, the data below describes the ingredient(s).
<b>Information on toxicological effects</b>	
<b>Route of entry</b>	May be absorbed by inhalation, skin contact and ingestion.



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


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**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Pentobarbital Sodium	LD <sub>50</sub>	Oral	Rat	118 mg/kg
	LD <sub>50</sub>	Oral	Mouse	239 mg/kg
	LD <sub>50</sub>	Intravenous (IV)	Rat	65 mg/kg
	LD <sub>50</sub>	IV	Mouse	65 mg/kg
	LD <sub>50</sub>	IV	Dog	50 mg/kg
	Propylene glycol	LD <sub>50</sub>	Oral	Rat
LD <sub>50</sub>		Oral	Mouse	22000 mg/kg
LD <sub>50</sub>		Oral	Rabbit	18500 mg/kg
LD <sub>50</sub>		Oral	Dog	22000 mg/kg
LD <sub>50</sub>		Oral	Guinea Pig	18350 mg/kg
LD <sub>50</sub>		Dermal	Rabbit	20800 mg/kg
LC <sub>50</sub> (4 hour)		Inhalation	Rat	>44.9 g/m <sup>3</sup> /4H
Ethanol	LD <sub>50</sub>	Oral	Rat	7060 mg/kg
	LD <sub>50</sub>	Oral	Mouse	3400 mg/kg
	LC <sub>50</sub>	Inhalation	Rat	20000 ppm/10 hours
	LC <sub>50</sub>	Inhalation	Mouse	39 g/m <sup>3</sup> /4 hours

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** Increased frequencies of skeletal and craniofacial anomalies as well as of fetal death were observed among the offspring of mice treated during pregnancy with ~25 times the human sedative dose of pentobarbital. No increase in malformations, but an increased frequency of fetal death were observed among the offspring of pregnant rabbits treated with 20 times the human sedative dose of pentobarbital. Long-lasting alterations of behavior and decreased brain/body weight ratios were observed among the offspring of rats treated with 20-40 times the usual human sedative dose of pentobarbital during pregnancy. Pentobarbital sodium has been rated by the FDA as Pregnancy Category D - positive evidence of risk.

**Genotoxicity** Pentobarbital sodium was non-genotoxic in a mouse micronucleus assay, DNA inhibition assays, and DNA mutation tests.

**Carcinogenicity** Ethyl alcohol (ethanol) as contained in alcoholic beverages (and consumed) is listed as a group I IARC carcinogen (carcinogenic to humans). ACGIH lists ethanol as TLV-A3 (animal carcinogen). None of the other components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

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


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<b>Aspiration hazard</b>	No studies identified
<b>Human health data</b>	See "Section 2 - Other Hazards"
<b>Additional information</b>	The toxicological properties of this mixture have not been fully characterized.

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**SECTION 12 - ECOLOGICAL INFORMATION**


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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Pentobarbital Sodium	--	--	--
Propylene glycol	EC <sub>50</sub> (96h)	Green algae ( <i>Selenastrum capricornutum</i> )	19,600 mg/L
	LC <sub>50</sub> (48 h)	<i>Daphnia magna</i> (water flea)	43,500 mg/L
	LC <sub>50</sub> (24 h)	<i>Carassius auratus</i> (fresh water fish)	>5000 mg/L
	LC <sub>50</sub> (96 h)	<i>Lepomis macrochirus</i> , bluegill sunfish	>10,000 ppm
	LC <sub>50</sub> (96 h)	<i>Oncorhynchus mykiss</i> (rainbow trout)	51,600 mg/L
	LC <sub>50</sub> (96 h)	<i>Pimephales promelas</i> (fathead minnow)	54,900 mg/L
Ethanol	LC <sub>50</sub> /96h	Rainbow trout	12900 mg/L (flow through)
	LC <sub>50</sub> /96h	Fathead minnow	15000 mg/L
	EC <sub>50</sub> /48h	<i>Daphnia magna</i>	9268 mg/L
	EC <sub>50</sub> /5-30 min	<i>Photobacterium phosphoreum</i>	~35000 mg/L

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<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>	Ecological characteristics of this mixture were not available. 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 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>	This 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>TSCA status</b>	Drugs are exempt from TSCA.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Ethyl alcohol (ethanol) as contained in alcoholic beverages (and consumed) is listed as a reproductive toxicant, but this is not applicable with normal use of this product.

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**SECTION 15 - REGULATORY INFORMATION** ...continued

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**Additional information** No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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**Full text of H phrases and GHS classifications** ATO3 - Acute Toxicity (Oral) Category 3. H301 - Toxic if swallowed. RT2 - Reproductive toxicity Category 2. H361d - Suspected of damaging the unborn child. STOT-S3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H336 - May cause drowsiness or dizziness. FL2 - Flammable Liquid Category 2. H225 - Highly flammable liquid and vapor.

**Sources of data** Information from published literature and internal company data.

**Abbreviations** 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

**Issue Date** 20 December 2017

**Revisions** This is the first version of this SDS.

**Disclaimer** 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.

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

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Disclaimer ...continued**

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.