

# 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



Impax Laboratories, Inc.  
31153 San Antonio Street, Hayward, CA 94544  
24 Hr Phone: 1-877-99-IMPAX [1-877-99-46729]  
E-mail: [Inquiries@impaxlabs.com](mailto:Inquiries@impaxlabs.com)

**Emergency telephone number** Chemtel: +1 (800) 255-3924

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<b>Product identifier</b>	Epinephrine Injection, USP Autoinjector
<b>Synonyms</b>	Epinephrine Injection
<b>Trade names</b>	Adrenaclick <sup>®</sup>
<b>Chemical family</b>	Mixture
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product packaged in final form for patient use; indicated for the emergency treatment of severe acute allergic reactions, asthma, and chronic pulmonary disease.
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product. This SDS will be revisited if more data become available.

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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> Please consult the prescribing/packaging information. <b>The classification and labeling listed below is for bulk Epinephrine Injection.</b>
<b>Globally Harmonized System [GHS]</b>	Not classified
<b>Label elements</b>	
<b>GHS hazard pictogram</b>	None required

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

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**GHS signal word** None required  
**GHS hazard statements** None required  
**GHS precautionary statements** None required

**Other hazards** Epinephrine (*i.e.*, adrenaline) is an endogenous neurotransmitter hormone. Its primary effects are vasoconstriction, cardiac stimulation, and smooth muscle relaxation. The most common adverse effects reported with therapeutic use include transient/moderate anxiety, feelings of over stimulation, restlessness, headache, tremor, weakness, shakiness, dizziness, sweating, increased heart rate, palpitations, paleness, nausea, vomiting, and difficulty breathing. Other symptoms, such as high blood pressure, cardiac arrhythmias, and cerebral bleeding, have occurred. As epinephrine can cross the placenta, it may adversely affect the fetus (*e.g.*, reduce fetal oxygen levels due to constriction of blood vessels).

**Note** This mixture does not meet criteria for classification 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). Nevertheless, it should be handled with caution as it contains pharmacologically active ingredients.

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

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Epinephrine	51-43-4	200-098-7	≤ 0.1 %	ATO2: H300; ATD2: H310; ATI2: H330; STOT-R1: H372; RT1B: H360Df; CA3: H412
Chlorbutanol	57-15-8	200-317-6	≤ 0.5%	ATO4: H302
Sodium bisulfite	7631-90-5	231-548-0	≤ 0.2%	ATO4: H302; EUH031

**Note** The ingredient(s) listed above are considered hazardous. GHS classifications for sodium bisulfite are based on EU - CLP Annex VI - Table 3.1. The remaining components are 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**

**Immediate Medical Attention Needed** No. If exposed or concerned: Get medical advice/attention.

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

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<b>Eye Contact</b>	In the event of a chemical exposure, immediately irrigate eyes with copious quantities of water for at least 15 minutes. Remove contact lenses as soon as practical. Do not delay irrigation while waiting for contact lens removal. 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>	Contains epinephrine, a potent vasoconstricting-agent. Medical conditions aggravated by exposure: cardiovascular diseases, hypertension, and hypersensitivity. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine. 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. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and sulfur, nitric and sulfuric acid, hydrochloric acid, and other nitrogen-, sulfur-, and/or chlorine-containing compounds.
<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>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. 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 product is released or spilled, 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 formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing mist/spray.
<b>Conditions for safe storage including any incompatibilities</b>	Protect from light. Epinephrine is light sensitive and should be stored in the carrying-case provided to protect it from light. Store at room temperature (20° to 25°C (68° to 77°F)); excursions permitted to 15° to 30°C (59° to 86°F). Keep container upright - promptly discard unused portion.
<b>Specific end use(s)</b>	No information identified.

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

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**Note** Dispose of broken vials/autoinjectors in a sharps container.

**Control****Parameters/Occupational Exposure Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Epinephrine	--	--	--
Chlorbutanol	--	--	--
Sodium bisulfite	ACGIH	8-hour TWA	5 mg/m <sup>3</sup>

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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 must 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 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 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 in autoinjector
<b>Color</b>	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>	2.2-5
<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>	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 in water
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-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>	No information identified.
<b>Chemical stability</b>	Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Replace epinephrine injection, USP auto-injector if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles.
<b>Possibility of hazardous reactions</b>	No information identified.
<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 toxicology data for the product/mixture were identified. The following data describe the active ingredient or other individual 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>
Epinephrine	LD <sub>50</sub>	Intravenous	Rat	150 µg/kg*
	LD <sub>50</sub>	Intravenous	Mouse	217 µg/kg
	LD <sub>50</sub>	Intravenous	Dog	100 µg/kg
	LD <sub>50</sub>	Dermal	Rat	62 mg/kg
	LD <sub>LO</sub>	Oral	Mouse	50 mg/kg
	LD <sub>LO</sub>	Oral	Rat	30 mg/kg
Chlorbutanol	LD <sub>50</sub>	Oral	Rat	510 mg/kg
	LD <sub>50</sub>	Oral	Mouse	150 mg/kg
Sodium bisulfite	LD <sub>50</sub>	Oral	Rat	2150-3160 mg/kg

**Additional acute toxicity information** \*To err on the side of caution (due to the high potency of this substance), it is assumed that toxicity *via* inhalation may be comparable to the intravenous route.

**Irritation/Corrosion** No data available.

**Sensitization** No data available.

**STOT-single exposure** No data available.

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

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<b>STOT-repeated exposure/Repeat-dose toxicity</b>	In 13-week inhalation studies, increased respiratory rate, changes in respiratory epithelium, and increased heart/adrenal gland weight were observed in rats and mice exposed to 40 mg/m <sup>3</sup> epinephrine (duration not specified). Additionally, degenerative lesions of the laryngeal muscle were seen in rats exposed to concentrations ≥20 mg/m <sup>3</sup> . In mice, inflammation of the glandular stomach and uterine atrophy were observed at concentrations ≥10 and 40 mg/m <sup>3</sup> , respectively.
<b>Reproductive toxicity</b>	In hamsters, epinephrine caused a decrease in reproductive success at 500 µg/kg (route of administration not specified). In mice, epinephrine decreased sexual receptivity in female mice at subcutaneous (SC) doses of 40 µg (~1.6 mg/kg), but implantation success was not affected.
<b>Developmental toxicity</b>	Epinephrine was teratogenic in rabbits, mice, and hamsters at SC doses as low as 1.2, 1 and 0.5 mg/kg, respectively; however, it was not teratogenic in mice at a lower SC dose of 0.5 mg/kg.  Uterine vasoconstriction and impaired fetal gas exchange were observed in pregnant monkeys treated with intravenous (IV) doses of 0.5-20 µg/kg/min for 1-18 minutes. Additionally, fetal asphyxia was observed after epinephrine administration to pregnant monkeys at doses similar to those used in humans.
<b>Genotoxicity</b>	Epinephrine was negative in the Ames bacterial mutagenicity assay and an <i>in vivo</i> micronucleus assay (species not specified). Although both negative and equivocal effects were observed in a chromosomal aberration assay with Chinese hamster ovary cells in the presence and absence of metabolic activation, respectively, the overall weight of evidence suggests a low genotoxicity potential.
<b>Carcinogenicity</b>	Epinephrine was not carcinogenic in rats and mice exposed by inhalation to concentrations up to 5 and 3 mg/m <sup>3</sup> , respectively. None of the components 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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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Epinephrine	EC <sub>50</sub> /24h	Daphnia magna	40.0 mg/L
	EC <sub>50</sub> /48h	Daphnia magna	31.7 mg/L
Chlorbutanol	LC <sub>50</sub> (time not specified)	Pimephales promelas (fathead minnow)	130-141 mg/L
Sodium bisulfite	NOEC (34d)	Danio rerio (Zebrafish)	≥316 mg/L (sodium sulfite)
	EC <sub>50</sub> /48h	Daphnia magna (crustacea)	89 mg/L (disodium disulfite)



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**SECTION 12 - ECOLOGICAL INFORMATION ...continued**

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**Toxicity ...continued**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
	NOEC (21 days)	Daphnia magna (crustacea)	>10 mg/L (disodium disulfite)
	EC <sub>50</sub> /72h	Desmodesmus subspicatus (algae, green)	43.8 mg/L (disodium disulfite)

**Persistence and Degradability** No data identified.

**Bioaccumulative potential** No data identified.

**Mobility in soil** No data identified.

**Results of PBT and vPvB assessment** Not performed.

**Other adverse effects** No data identified.

**Note** The environmental characteristics of this mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Releases to the environment should be avoided.

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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**Waste treatment methods** Epinephrine is a RCRA listed hazardous waste, code P042.

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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**Transport** 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.

**UN number** None assigned.

**UN proper shipping name** None assigned.

**Transport hazard classes and packing group** None assigned.

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**SECTION 14 - TRANSPORT INFORMATION ...continued**

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**Environmental hazards** Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

**Special precautions for users** Due to lack of data, avoid release to the environment.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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

**Chemical safety assessment** Not conducted.

**TSCA status** Drugs are exempt from TSCA.

**SARA section 313** Not listed.

**California proposition 65** Not listed.

**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** ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. ATD2 - Acute Toxicity (Dermal) Category 2. H310 - Fatal in contact with skin. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. H372 - Causes damage to the cardiovascular system through prolonged or repeated exposure. RT1B - Reproductive toxicity Category 1B. H360Df - May damage the unborn child. Suspected of damaging fertility. CA3 - Aquatic toxicity (chronic) - Category 3. H412 - Harmful to aquatic life with long lasting effects. EUH031 - Contact with acids liberates very toxic gas. (Specific concentration limit: ≥5%)

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

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

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**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** 19 April 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 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.