

# SAFETY DATA SHEET

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

### Contact information

#### General



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<b>Product identifier</b>	Aplisol® (Tuberculin Purified Protein Derivative, Diluted [Stabilized Solution], 5TU/0.1 ml) in multi-dose vials.
<b>Synonyms</b>	Tuberculin PPD, Diluted
<b>Trade names</b>	Aplisol®
<b>Chemical family</b>	Mixture - contains tuberculin purified protein derivative
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical mixture product packaged in final form for patient use. Used as diagnostic tool for the detection of <i>Mycobacterium tuberculosis</i> infection.
<b>Note</b>	The physical, chemical, toxicological and ecological properties of this product/mixture have not been fully characterized. This SDS will be revisited as more data become available.
<b>Issue Date</b>	19 May 2015

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## 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 Aplisol® (Tuberculin Purified Protein Derivative, Diluted [Stabilized Solution] 5TU/0.1 ml) in multi-dose vials.</b>
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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**Regulation (EC) 1272/2008 [GHS]** Skin sensitizer - Category 1. Respiratory sensitizer - Category 1.

**Directive 67/548/EEC or 1999/45/EC** Xn - R42/R43

**Label elements**

**CLP/GHS hazard pictogram**



**CLP/GHS signal word**

Danger

**CLP/GHS hazard statements**

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H317 - May cause allergic skin reaction.

**CLP/GHS precautionary statements**

P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear eye/face protection. P285 - In case of inadequate ventilation wear respiratory protection. P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**EU symbol/indication of danger**



Xn - Harmful

**Risk (R) Phrase(s)**

R42/43 - May cause sensitization by inhalation and skin contact.

**Safety Advice**

S23 - Do not breathe vapor/spray. S24 - Avoid contact with skin. S36/37 - Wear suitable protective clothing and gloves. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

**Other hazards**

Aplisol (tuberculin PPD, diluted) is a sterile aqueous solution of a purified protein fraction isolated from a human strain of *Mycobacterium tuberculosis* for intradermal administration as an aid in the diagnosis of tuberculosis. Common adverse effects associated with use include local, as well as, systemic hypersensitivity reactions (redness, rash, swelling, itching, anaphylaxis).

In a workplace setting, the likelihood of systemic effects following accidental

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

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**Other hazards**  
...continued                    ingestion is low, due to the rapid breakdown of proteins in the digestive tract. Although purified protein particles are fairly large in size, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory sensitization.

**US Signal word**                    Danger

**US Hazard overview**                Contains a purified protein. May cause an allergic respiratory reaction. May cause an allergic skin reaction.

**Note**                                    This mixture is classified as dangerous according to directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US communication regulations. See Section 16 for full text of EU and GHS classifications. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC.

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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>EU Classification</u>	<u>GHS Classification</u>
Tuberculin Purified Protein Derivative	92129-86-7	295-888-1	0.1-1 %	Harmful - Xn: R42, R43	RS1:H334; SS1:H317
Phenol	108-95-2	203-632-7	0.1-0.3 %	Corrosive - C: R34; Toxic - T: R23/24/25, R48/ R20/21/22, R68	SC1B: H314; AT3: H331, H311, H301; STOT-R2: H373; GCM2: H341

**Note**                                    The ingredient(s) listed above are considered dangerous/hazardous and/or are pharmacologically active. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

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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.

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

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<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 known or reported. 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. May emit toxic fumes of carbon monoxide and carbon dioxide, and nitrogen-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>	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 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 dust/mist/vapors/spray.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES ...continued**

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**Methods and material for containment and cleaning up** 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).

**Reference to other sections** See Sections 8 and 13 for more information.

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**SECTION 7 - HANDLING AND STORAGE**

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**Precautions for safe handling** Avoid breathing dust/mist/spray. Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.

**Conditions for safe storage including any incompatibilities** Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed. Protect from light.

**Specific end use(s)** No information identified.

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

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

**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Tuberculin Purified Protein Derivative	--	--	--
Phenol	ACGIH	TLV-TWA	5 ppm (skin)
	OSHA	PEL	5 ppm (skin)
	NIOSH	REL - TWA	20 mg/m <sup>3</sup>
	NIOSH	REL-Ceiling	60 mg/m <sup>3</sup>

**Exposure/Engineering controls** None required for normal handling of packaged product. If vials are crushed or broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. High-energy operations should be done within an approved emission control or containment system.

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

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<b>Respiratory protection</b>	None required for normal handling of packaged product. If vials are crushed or 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 fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or 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 a lower level of respiratory protection may not provide adequate protection.
<b>Hand protection</b>	None required for the normal handling of packaged product. If vials are crushed or broken: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.
<b>Skin protection</b>	None required for the normal handling of packaged product. If vials are crushed or broken: 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>	None required for the normal handling of packaged product. If vials are crushed or broken: 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). SENSITIZING AGENT: extra care should be taken to minimize direct contact.

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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>	Odorless
<b>Odor threshold</b>	No information identified.
<b>pH</b>	7.1 to 7.5

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

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<b>Melting point/ freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.
<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.
<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 (<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 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>	No information identified.

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**SECTION 10 - STABILITY AND REACTIVITY ...continued**

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<b>Possibility of hazardous reactions</b>	None expected under normal conditions.
<b>Conditions to avoid</b>	No information identified.
<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 this mixture were identified. The following data describe the active ingredient and/or the 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>
Tuberculin Purified Protein Derivative	--	--	--	--
Phenol	LD <sub>50</sub>	Oral	Rodents	300-600 mg/kg
	LD <sub>50</sub>	Dermal	Rat/Rabbit	670-1400 mg/kg
	LC <sub>50</sub> (8 hour)	Inhalation	Rat	>900 mg/m <sup>3</sup>

**Irritation/Corrosion** Phenol can be corrosive to skin.

**Sensitization** No studies identified.

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

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified for the active ingredient. Inhalation of phenol at moderate doses (0.02 to 1 ppm) for 2 months produced changes in blood enzyme activity and adverse lung effects (including pneumonia and hyperplasia) in rats. In two additional rat studies, NOAELs of 40 and 60 mg/kg/day (details not specified) were identified. A NOAEL of 140 mg/kg/day (details not specified) was also identified in a mouse study.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

**Genotoxicity** No studies identified for the active ingredient. Phenol was not mutagenic in bacterial cells, but has caused mutations, chromosomal damage, and DNA effects in mammalian cells. It was also positive in some *in vivo* mouse micronucleus assays at high doses.

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

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<b>Carcinogenicity</b>	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 studies identified
<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>
Tuberculin Purified Protein Derivative	--	--	--

<b>Persistence and Degradability</b>	No data identified.
<b>Bioaccumulative potential</b>	No data identified.
<b>Mobility in soil</b>	No data identified.
<b>Results of PBT and vPvB assessment</b>	Not performed.
<b>Other adverse effects</b>	No data identified.
<b>Note</b>	The environmental characteristics of this 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.

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

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<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>	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 complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Yes. Danger. Contains a purified protein. May cause an allergic respiratory reaction. May cause an allergic skin reaction.
<b>WHMIS classification</b>	Not required. Drugs are not subject to WHMIS. 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.
<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 R phrases and EU Classifications</b>	C - Corrosive. T - Toxic. Xn - Harmful. R34 - Causes burns. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R42/43 - May cause sensitization by inhalation and skin contact.
<b>Full text of H phrases, P phrases and GHS classification</b>	RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction.

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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; 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>Revisions</b>	Updated contact information and concentration in Section 1; Updated ingredient composition in Section 3 and data in Section 11.
<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>