

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

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<b>Product identifier</b>	MAS <sup>®</sup> chemTrak <sup>®</sup> H Liquid Assayed Chemistry Control MAS <sup>®</sup> chemTrak <sup>®</sup> H Liquid Unassayed Chemistry Control MAS <sup>®</sup> chemTrak <sup>®</sup> H Liquid Assayed Chemistry Control for Dimension Vista Systems	
<b>Synonyms</b>	CHA-1 chemTRAK H, Assayed (6x5mL) Level 1 CHA-2 chemTRAK H, Assayed (6x5mL) Level 2 CHA-3 chemTRAK H, Assayed (6x5mL) Level 3 CHA-SP chemTRAK H, Assayed Sample Pack (1x3x5mL) Level 1, 2, 3 CHU-1 chemTRAK H, Unassayed (10x15mL) Level 1 CHU-2 chemTRAK H, Unassayed (10x15mL) Level 2 CHU-3 chemTRAK H, Unassayed (10x15mL) Level 3 CHU-SP chemTRAK H, Unassayed Sample Pack (3x15mL) Level 1, 2, 3 10014150 chemTRAK H, Assayed (6x2mL) Level 1 10014151 chemTRAK H, Assayed (6x2mL) Level 2 10014152 chemTRAK H, Assayed (6x2mL) Level 3	
<b>Trade names</b>	Liquid Assayed Chemistry Control Liquid Unassayed Chemistry Control Liquid Assayed Chemistry Control for Dimension Vista Systems	
<b>Chemical family</b>	Mixture	
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	<i>In vitro</i> diagnostic quality control material.	
<b>Note</b>	The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.	
<b>Issue Date</b>	12 June 2015	

## SECTION 2 - HAZARDS IDENTIFICATION

### Classification of the substance or mixture

**Regulation (EC) 1272/2008 [GHS]**

Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1. Mixture not yet fully tested

**Directive 67/548/EEC or 1999/45/EC**

Xn - R42 (Respiratory Sens.), R43 (Skin Sens.). Mixture not yet fully tested.

### Label elements

**CLP/GHS hazard pictogram**



**CLP/GHS signal word**

Danger

**CLP/GHS hazard statements**

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

**CLP/GHS precautionary statements**

P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/ face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. 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**

S2 - Keep out of reach of children. S23 - Do not breathe spray. S24 - Avoid contact with skin. S37 - Wear suitable protective gloves. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

<b>Other hazards</b>	<p>No data specific for the mixture were identified. The mixture does contain human source material and should be treated/handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.</p> <p>Because the mixture contains a protein (bovine serum albumin) it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract. Bovine serum albumin has been associated with occupational sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).</p>
<b>US Signal word</b>	Danger
<b>US Hazard overview</b>	May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture contains human source material and should be treated/handled as a potential biohazard. Mixture not yet fully tested.
<b>Note</b>	This mixture is classified as hazardous according to Directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US regulations. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The CLP/GHS classifications are based on Regulation (EC) 1272/2008 and on the revised OSHA hazard communication standard. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN</u> <u>CS#</u>	<u>Amount</u>	<u>EU</u> <u>Classification</u>	<u>GHS</u> <u>Classification</u>
Human Source Material	N/A	N/A	40-77%	Not classified	Not classified
Dimethyl sulfoxide	67-68-5	200-664-3	1-2%	Irritant - Xi: R38	SI2: H315
Bovine serum albumin	9048-46-8	N/A	0.9-1.1%	Harmful - Xn: R42/R43	SS1: H317, RS1: H334
Ethosuximide	77-67-8	201-048-7	<0.3%	Toxic - T: R22; R61	ATO4: H302; RT1B: H360D
Carbodiimide Hydrochloride	Proprietary	Proprietary	<0.3%	Irritant - Xi: R36/37/38	SI2: H315; EI2: H319; STOT-SE3: H335

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

<b>Note</b>	The ingredient(s) listed above are considered hazardous. Human source material (human plasma) is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product also contains trace ( $\leq 0.03\%$ ) amounts of various active pharmaceutical ingredients, as well as trace levels of ethanol ( $\leq 0.2\%$ ). See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the CLP/GHS classification is based on Regulation (EC) 1272/2008.
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### SECTION 4 - FIRST AID MEASURES

#### Description of first aid measures

<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>	If swallowed, call a physician immediately. 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.

### SECTION 5 - FIREFIGHTING MEASURES

<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
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## SECTION 5 - FIREFIGHTING MEASURES ...continued

<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<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.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

<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.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	Surround spill with absorbents and place a damp cloth or towel over the area to minimize entry into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Disinfect the area twice with an appropriate solvent, such as 5% chlorine bleach solution.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

## SECTION 7 - HANDLING AND STORAGE

<b>Precautions for safe handling</b>	This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
<b>Conditions for safe storage including any incompatibilities</b>	Store frozen at -25°C to -15°C away from incompatible materials.
<b>Specific end use(s)</b>	No information identified.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control

### Parameters/Occupational

### Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Human Source Material	--	--	--
Dimethyl sulfoxide	AIHA	WEEL-TWA	250 ppm
	Austria,	MAK	50 ppm, 160 mg/m <sup>3</sup>
	Germany,		
	Switzerland		
	Estonia,	STEL	150 ppm, 500 mg/m <sup>3</sup>
	Lithuania,		
	Sweden		
	Estonia,	TWA	50 ppm, 150 mg/m <sup>3</sup>
	Lithuania		
	Sweden	TLV	50 ppm, 150 mg/m <sup>3</sup>
Bovine serum albumin	Finland	TWA	50 ppm
	Switzerland	STEL	100 ppm, 320 mg/m <sup>3</sup>
	Germany	Ceiling	100 ppm, 320 mg/m <sup>3</sup>
	Denmark	TWA	50 ppm, 160 mg/m <sup>3</sup>
	Slovenia	TWA	160 mg/m <sup>3</sup>
	Denmark	TWA	50 ppm, 160 mg/m <sup>3</sup>
Ethosuximide	--	--	--
Carbodiimide Hydrochloride	--	--	--

### Exposure/Engineering controls

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.

### Respiratory protection

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.

### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

### Skin protection

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.

### Eye/face protection

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.

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

<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 product/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). Decontaminate all protective equipment following use.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	Clear liquid
<b>Color</b>	Yellow to amber
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	5-8
<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
<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.

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

**Partition coefficient  
(*n*-octanol/water)** No information identified.

**Auto-ignition  
temperature** No information identified.

**Decomposition  
temperature** No information identified.

**Viscosity** No information identified.

**Explosive properties** No information identified.

**Oxidizing properties** No information identified.

### Other information

**Molecular weight** No information identified.

**Molecular formula** No information identified.

## SECTION 10 - STABILITY AND REACTIVITY

**Reactivity** No information identified.

**Chemical stability** Stable when stored as recommended.

**Possibility of hazardous  
reactions** Not expected to occur.

**Conditions to avoid** Avoid temperatures  $\geq 25^{\circ}\text{C}$ ; excess heat.  
Avoid prolonged exposure to light.  
Avoid prolonged exposure to oxygen.

**Incompatible materials** No information identified.

**Hazardous decomposition  
products** No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 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>
Human Source Material	--	--	--	--
Dimethyl sulfoxide	LD <sub>50</sub>	Oral	Rat	14.5 g/kg
	LD <sub>50</sub>	Oral	Rat	28.3 g/kg
	LD <sub>50</sub>	Oral	Mouse	7.9 g/kg



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

...continued

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
	LD <sub>50</sub>	Oral	Mouse	21.4 g/kg
Bovine serum albumin	--	--	--	--
Ethosuximide	LD <sub>50</sub>	Oral	Mouse	1530 mg/kg
	LD <sub>50</sub>	Oral	Rat	1820 mg/kg
	LD <sub>50</sub>	Intravenous (IV)	Mouse	780 mg/kg
Carbodiimide Hydrochloride	LD <sub>50</sub>	Intravenous	Mouse	56 mg/kg

**Additional acute toxicity information** No studies identified.

**Irritation/Corrosion** No data on product formulation. Dimethyl sulfoxide is a skin irritant in humans and animals.

**Sensitization** No data on product formulation. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.

**STOT-single exposure** No data on product formulation. Male rats were exposed to an aerosol of 1600 mg/m<sup>3</sup> DMSO for 4 hr. Groups were sacrificed immediately after exposure, another 24 hours after exposure, and the third group was observed for 2 weeks after exposure before sacrifice. There was no mortality and none of the animals displayed outward signs of toxicity during and after exposure to DMSO. Organs appeared normal at necropsy

Single intravenous injections of undiluted DMSO were administered to groups of male and female rats. Dose levels were 2.5, 5.0, and 10 g/kg. Each dose was administered over a 1-minute interval. Animals were observed for 14 days following DMSO administration. With one exception, deaths occurred within the first 24 hours. Non-lethal doses of DMSO produced decreased motor activity and myasthenia.

**STOT-repeated exposure/Repeat-dose toxicity** No data on product formulation. Male rats were exposed to 200 mg/m<sup>3</sup> DMSO for 7 hours/day, 5 days a week, over 6 weeks for 30 exposures. There were no outward toxic signs noted in any of the exposed animals throughout the experimental period of 6 weeks and no effects on blood parameters were reported.

DMSO was administered dermally to rabbits for 30 days at a dose of 1 or 5 g/kg/day. Rabbits received dermal applications of DMSO to normal and abraded skin for a period of 23 weeks, when ocular changes were observed. Treatment was withheld from animals showing ocular changes; the remaining animals continued to receive DMSO applications for the scheduled 26 weeks (6 months). Mortality

## SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

<b>STOT-repeated exposure/Repeat-dose toxicity ...continued</b>	<p>was high in all groups, however there was no significant differences in mortality between groups. There were no clinical signs to suggest systemic toxicity.</p> <p>DMSO was administered as a 90% solution to rhesus monkeys by gastric intubation, 7 days a week for up to 87 weeks. Dosages administered were equivalent to 990, 2970, and 8910 mg/kg/day. The principal physical signs seen in the animals given DMSO orally included excess salivation and emesis. These signs occurred sporadically and did not appear to be related to the dose except in the group receiving higher volume of compound. Anorexia occurred at high oral doses but was not evident at the 2 lower dose levels. No DMSO-related changes were found in the treated monkeys during physical examinations.</p>
<b>Reproductive toxicity</b>	<p>No data on product formulation. DMSO has been extensively used as a cryoprotectant in the freezing of early experimental animal and human embryos. The viability and apparent normalcy of frozen embryos after thawing suggests that DMSO exposure is not toxic to the early embryo.</p>
<b>Developmental toxicity</b>	<p>No data on product formulation. Increased frequencies of skeletal, central nervous system, and other anomalies were observed among the offspring of rats, mice, hamsters, and rabbits treated during pregnancy with ethosuximide in doses, respectively, &lt;1-25, 6-36, &lt;1-18, and &lt;1-7 times those used in humans. Behavioral alterations were seen among the offspring of rats treated during pregnancy with ethosuximide in doses similar to those used clinically.</p> <p>DMSO has been associated with teratogenic and/or embryotoxic effects in the hamster, rat, mouse, and chick at high doses. In the hamster, the injection of 500 to 800 mg/kg on the 8th day of gestation was associated with a wide variety of congenital defects, including exencephaly, microphthalmia, bone and limb abnormalities, and as cleft lip. Increased frequencies of fetal death were observed when pregnant rats or rabbits were treated with doses of 5-10 or 1-3 g/kg/day, respectively. However, fetal death was not increased in another study after intraperitoneal treatment of pregnant rats with 6.9 g/kg/day of dimethyl sulfoxide. No malformations were observed in the offspring of rats treated with dimethyl sulfoxide at doses of 0.2-5 g/kg/day during pregnancy.</p>
<b>Genotoxicity</b>	<p>No data on product formulation. Dimethyl sulfoxide was negative for genotoxicity in an Ames bacterial cell mutagenicity assay and a sister chromatid exchange assay in Chinese hamster ovary cells.</p>
<b>Carcinogenicity</b>	<p>No data on product formulation. None of the 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.</p>
<b>Aspiration hazard</b>	<p>No data available.</p>
<b>Human health data</b>	<p>See "Section 2 - Other Hazards"</p>
<b>Additional information</b>	<p>The pharmacological and toxicological properties of this mixture have not been fully characterized.</p>

## SECTION 12 - ECOLOGICAL INFORMATION

### Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Human Source Material	--	--	--
Dimethyl sulfoxide	EC <sub>50</sub> /96h	Skeletonema costatum (Diatom)	12.35 - 25.5 g/L
	LC <sub>50</sub> /96h	Pimephales promelas	34 g/L
	LC <sub>50</sub> /96h	Oncorhynchus mykiss	33-37 g/L (static)
	LC <sub>50</sub> /96h	Lepomis macrochirus	>40 g/L (static)
	LC <sub>50</sub> /96h	Cyprinus carpio	41.7 g/L
	EC <sub>50</sub> /24h	Daphnia magna	7 g/L
Bovine serum albumin	--	--	--
Ethosuximide	--	--	--
Carbodiimide Hydrochloride	--	--	--

**Persistence and Degradability** No data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Results of PBT and vPvB assessment** No data available.

**Other adverse effects** No data available.

**Note** The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Waste treatment methods** Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. 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.

## SECTION 14 - TRANSPORT INFORMATION

**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.

## SECTION 14 - TRANSPORT INFORMATION ...continued

<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>	Mixture not fully tested - avoid exposure.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15 - REGULATORY INFORMATION

<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 or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Yes. Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture contains human source material and should be treated/handled as a potential biohazard. Mixture not fully tested.
<b>WHMIS classification</b>	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>	Not listed
<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.

## SECTION 16 - OTHER INFORMATION

<b>Full text of R phrases and EU Classifications</b>	Xn - Harmful. R42 - May cause sensitization by inhalation. R43 - May cause sensitization by skin contact.
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## SECTION 16 - OTHER INFORMATION ...continued

<b>Full text of H phrases, P phrases and GHS classification</b>	SS1 - Skin sensitizer Category 1. RS1 - Respiratory Sensitizer Category 1. H317 - May cause an allergic skin reaction. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled.
<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>	This is the fifth 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. 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/diagnostic 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>