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

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538
Main: (510) 979-5000
Fax: (510) 979-5002
E-mail:
techservice.mgc@thermofisher.com

Emergency telephone number (Chemtrec):
1-(800) 424-9300 (US and Canada)
1-(703) 527-3887
International access (collect calls accepted)
1-(202) 483-7616 Europe

Product identifier DRI® Oxycodone Calibrators and Controls

Synonyms
100250 DRI® Oxycodone Calibrator 100
100251 DRI® Oxycodone Calibrator 300
100252 DRI® Oxycodone Calibrator 500
100253 DRI® Oxycodone Calibrator 1000
100254 DRI® Oxycodone 100 Control Kit
100255 DRI® Oxycodone 300 Control Kit

Trade names DRI® Oxycodone Calibrators and Controls

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against *In vitro* diagnostic kit.

Note 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.

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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

SECTION 2 - HAZARDS IDENTIFICATION …continued

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 vapor/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.

Other hazards

The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.

This product/mixture contains human urine and should be treated/handled as a potential biohazard. All such human urine 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.

The mixture contains bovine serum albumin which has been associated with occupational sensitization. Material produced in compliance with USDA and/or

SECTION 2 - HAZARDS IDENTIFICATION …continued

Other hazards …continued

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).

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. Proteins, in general, can cause skin and/or respiratory sensitization.

US Signal word

Danger

US Hazard overview

May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture not yet fully tested. This product contains human urine and should be treated/ handled as a potential biohazard.

Note

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

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
Urine (Human)	N/A	N/A	8–10%	Not classified	Not classified
Bovine serum albumin	9048-46-8	N/A	0.1-0.3%	Harmful - Xn: R42/R43	SS1: H317, RS1: H334
N,N-Dimethylformamide	68-12-2	200-679-5	≤0.1%	Toxic - T: R61; R20/21; R36; R10	RT1B: H360D; ATD4: H312; ATI4: H332; EI2: H319; FL3: H226
Sodium azide	26628-22-8	247-852-1	≤0.09%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS …continued

Note	The ingredient(s) listed above are considered hazardous. Human urine is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace amounts of active pharmaceutical ingredients (<0.0002%). 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.

SECTION 4 - FIRST AID MEASURES

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	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.
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.

SECTION 5 - FIREFIGHTING MEASURES

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

SECTION 5 - FIREFIGHTING MEASURES …continued

Specific hazards arising from the substance or mixture	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	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

Personal precautions, protective equipment and emergency procedures	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.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	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). Decontaminate the area twice with an appropriate solvent, such as 5% chlorine bleach solution.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	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 vapor/mist/spray.
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.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Urine (Human)	--	--	--
Bovine serum albumin	--	--	--
N,N-Dimethylformamide	ACGIH, Bulgaria, Denmark,	8-hour TWA	10 ppm (skin)
	Austria, Belgium, Poland	8-hour TWA (MAK)	10 ppm (30 mg/m^3)
	EU (2009/161/EU)	8-hour TWA	5 ppm (15 mg/m^3) (skin)
	EU (2009/161/EU)	STEL	10 ppm (30 mg/m^3)
	Finland	8-hour TWA	5 ppm (15 mg/m^3) (skin)
	Finland	STEL	10 ppm (30 mg/m^3)
	France	8-HR TWA (VME)	10 ppm (30 mg/m^3) (skin)
	Germany	8-hour TWA (MAK)	5 ppm (15 mg/m^3)
	Hungary	8-hour TWA	30 mg/m^3(skin)
	Hungary	STEL	120 mg/m^3
	Netherlands	8-Hour TWA (MAC-TGG)	15 mg/m^3 (skin)
	NIOSH	IDLH (Immediately dangerous to life or health)	500 ppm
	NIOSH	REL - TWA (8-Hr)	10 ppm (30 mg/m^3) (skin)
	Poland	8-Hour TWA (MAC)	10 mg/m3
	Poland	STEL(MAC)	60 mg/m^3
	Sweden	8-hour TWA	10 ppm (30 mg/m^3) (skin)
	Sweden	STEL	15 ppm (45 mg/m^3)
	United Kingdom	8-hour TWA	10 ppm (30 mg/m^3) (skin)
	United Kingdom	STEL	20 ppm (61 mg/m3)
	United Kingdom	WEL-TWA	5 ppm (15 mg/m^3)
	US-OSHA	PEL-TWA (8-Hr)	10 ppm (30 mg/m^3) (skin)

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-STEL	0.3 mg/m³
	New Zealand, Portugal	Ceiling	0.29 mg/m³

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-TWA	0.1 mg/m³
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m³
	Germany	OEL-STEL	0.4 mg/m³
	Germany	OEL-TWA	0.2 mg/m³

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.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Respiratory protection	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 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.
Environmental Exposure Controls	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.
Other protective measures	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

Appearance	Liquid
Color	Light yellow
Odor	No information identified.
Odor threshold	No information identified.
pH	5.9-6.1
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Miscible with water.
Solvent solubility	No information identified.
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	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures ≥ 25° C.
Incompatible materials	No information identified.

SECTION 10 - STABILITY AND REACTIVITY …continued

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

Compound	Type	Route	Species	Dose
Urine (Human)	--	--	--	--
Bovine serum albumin	--	--	--	--
N,N-Dimethylformamide	LD_{50}	Dermal	Rabbit	4720 mg/kg
	LD_{50}	Dermal	Rat	>3.2 g/kg
	LC_{50}	Inhalation	Mouse	9.4-10 g/m^3
	LC_{50} (1 hour)	Inhalation	Rat	3421 ppm/1H
	LC_{50} (4 hour)	Inhalation	Mouse	1948 ppm/4H
	LD_{50}	Oral	Mouse	2900-3750 mg/kg
	LD_{50}	Oral	Rabbit	5000 mg/kg
	LD_{50}	Oral	Rat	2000-4000 mg/kg
Sodium azide	LD_{50}	Oral	Rat	27 mg/kg
	LD_{50}	Oral	Mouse	27 mg/kg
	LD_{50}	Dermal	Rabbit	20 mg/kg

Irritation/Corrosion No studies identified.

Sensitization No studies identified. 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 The acute toxicity of N,N-Dimethylformamide (DMF) in a number of species, following oral, dermal, inhalation, or parenteral administration is relatively low, with lethal doses typically in the g/kg range for the oral, dermal, & parenteral routes and in the g/m^3 for inhalation exposures. Animals given large single doses of DMF or exposed to high air concentrations exhibited general depression, anesthesia, loss of appetite, loss of body weight, tremors, labored breathing, convulsions, hemorrhage of the nose & mouth, liver injury, & coma immediately preceding death.

STOT-repeated exposure/Repeat-dose toxicity In rats administered DMF at 0, 25, 100 or 400 ppm in air by whole body vapor exposure for 6 hours/day, 5 days/week over two years, exposure to the highest concentration reduced body weight gain in both sexes but did not affect survival. The highest concentration also increased liver weights in both sexes. In both sexes of the two highest dose groups, incidence of minimal to mild centrilobular hepatocellular hypertrophy and centrilobular accumulation of lipofuscin/ hemosiderin was increased.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Reproductive toxicity

Male and female mice were exposed to DMF in drinking water at doses of 0, 1,000, 4,000, & 7,000 ppm. At 1000 ppm, there was increased relative liver weight for males and females and increased relative kidney plus adrenal weights for females. Of those animals noted to have hepatic lesions, centrilobular hepatic hypertrophy was present and was considered treatment related. Reproductive toxicity was observed primarily at the mid- and high-dose levels. At 4,000 and 7,000 ppm, fertility & fecundity were reduced; pups were also observed to have various craniofacial malformations.

Developmental toxicity

Rabbits, rats and mice have been treated with DMF via oral (gavage), dermal, inhalation or intraperitoneal administration during organogenesis. In rats treated dermally with 94 mg/kg or greater, teratogenicity was increased without maternal toxicity. Teratogenicity in mice was found at 944 mg/kg via intraperitoneal dosing. In rabbits exposed dermally to 400 mg/kg, teratogenicity was found. The defects were generally changes in the ribs and vertebrae. In rats exposed to air concentrations of DMF 6 hours daily of up to 300 ppm during gestation days 6-15, maternal and fetal toxicity was observed, but without any increase in defects. In mice exposed to DMF in drinking water at doses of up to 7,000 ppm, at doses of 4,000 ppm and greater pup survival was decreased and at a dose of 1,000 ppm pup weights were reduced. Defects of ossification in cranium and sternebrae occurred.

DMF caused maternal toxicity and embryotoxicity, including teratogenicity, in rabbits after oral administration via gavage at 200 µl/kg/day from day 6-18 after conception. All animals in the dose group became pregnant and showed reduced food intake and weight gain. Placental weights were significantly lower and three abortions occurred. The fetuses showed weight reduction.

Genotoxicity

DMF was negative in the Ames bacterial cell mutagenicity assay, with and without metabolic activation.

Carcinogenicity

In rats administered DMF at 0, 25, 100 or 400 ppm in air by whole body vapor exposure for 6 hours/day, 5 days/week over two years, no increase in tumors occurred, but a 14.8% incidence of uterine endometrial stromal polyps in high-dose females was observed compared to 1.7% in controls.. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard

No data available.

Human health data

See "Section 2 - Other Hazards"

Additional information

The toxicological properties of this mixture have not been fully characterized.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Urine (Human)	--	--	--
Bovine serum albumin	--	--	--
N,N-Dimethylformamide	LC_{50}/48h	Pimephales promelas, fathead minnow	12463-14322 mg/L

SECTION 12 - ECOLOGICAL INFORMATION …continued

Toxicity …continued

Compound	Type	Species	Concentration
N,N-Dimethylformamide	LC_{50}/72h	Pimephales promelas, fathead minnow	6968-16957 mg/L
	LC_{50}/96 h	Pimephales promelas, fathead minnow	5714-18967 mg/L
	LC_{50}/72h	Oncorhynchus mykiss, rainbow trout	9100-11000 mg/L
	LC_{50}/96 h	Oncorhynchus mykiss, rainbow trout	9000-10700 mg/L
	LC_{50}/48h	Daphnia magna (Water flea)	15920 mg/L
	LC_{50}/24h	Lepomis macrochimus (bluegill sunfish)	7200-7800 mg/L
	LC_{50}/48h	Lepomis macrochimus (bluegill sunfish)	7200-7800 mg/L
	LC_{50}/72h	Lepomis macrochimus (bluegill sunfish)	7000-7700 mg/L
	LC_{50}/96h	Lepomis macrochimus (bluegill sunfish)	6700-7500 mg/L
	EC_{50}/24h	Daphnia magna (Water flea)	23400-29600 mg/L
	EC_{50}/48h	Daphnia magna (Water flea)	13300-15900 mg/L
	EC_{50}/48h	Oncorhynchus mykiss, rainbow trout	9000-10700 mg/L
	EC_{50}/96h	Oncorhynchus mykiss, rainbow trout	9000-10700 mg/L
Sodium azide	LC_{50}/96h	Oncorhynchus mykiss	0.8 mg/L
	LC_{50}/96h	Lepomis macrochirus	0.7 mg/L
	LC_{50}/96h	Pimephales promelas	5.46 mg/L

Additional toxicity information Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.

Persistence and Degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment Not performed.

Other adverse effects No data available.

SECTION 12 - ECOLOGICAL INFORMATION …continued

Note	The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. 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. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner.

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.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
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	Mixture not fully tested - avoid exposure.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	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.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Yes. Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture not fully tested. This product contains human urine and should be treated/handled as a potential biohazard.
WHMIS classification	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.
TSCA status	All components of mixture are on TSCA Inventory or are exempt
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn - Harmful. R42/43 - May cause sensitization by inhalation and skin contact. T- Toxic. T+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. R36 - Irritating to eyes. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R61 - May cause harm to the unborn child. R20/21 - Harmful by inhalation and in contact with skin. R10 - Flammable.
Full text of H phrases, P phrases and GHS classification	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. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Aquatic toxicity (chronic) - Category 1. H410 - Very toxic to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas. RT1B - Reproductive Toxicity: H360D - May damage the unborn child. ATD4 - Acute Toxicity (Dermal) Category 4. H312 - Harmful in contact with skin. ATI4 - Acute Toxicity (Inhalation) Category 4. H332 - Harmful if inhaled. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. FL3 - Flammable Liquid Category 3. H226 - 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

SECTION 16 - OTHER INFORMATION …continued

Abbreviations …continued

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

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/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.