SAFETY DATA SHEET

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

Contact information

General

Thermo

Microgenics Corporation

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Emergency telephone number

Chemtrec (24-hour availability):

+1 (800) 424-9300 (USA and Canada)

+1 (703) 527-3887 (International; Collect calls accepted)

+1 (202) 483-7616 (Europe)

Product identifier

DRITM Drugs of Abuse Calibrators and Controls

Synonyms

100082 DRI Ecstasy 250 ng/mL Calibrator 100081 DRI Ecstasy 500 ng/mL Calibrator 100080 DRI Ecstasy 750 ng/mL Calibrator 100079 DRI Ecstasy 1000 ng/mL Calibrator

10011207 DRI Ethyl Glucuronide Negative Calibrator (CE) 10011208 DRI Ethyl Glucuronide Calibrator 100 ng/mL (CE) 10011210 DRI Ethyl Glucuronide Calibrator 500 ng/mL (CE) 10011212 DRI Ethyl Glucuronide Calibrator 1000 ng/mL (CE) 10011213 DRI Ethyl Glucuronide Calibrator 2000 ng/mL (CE) 10012135 DRI Ethyl Glucuronide 375 ng/mL Control (CE) 10012136 DRI Ethyl Glucuronide 625 ng/mL Control (CE) 10012137 DRI Ethyl Glucuronide 750 ng/mL Control (CE) 10012138 DRI Ethyl Glucuronide 1250 ng/mL Control (CE) 10015932 DRI Ethyl Glucuronide Negative Calibrator (CJF) 10015933 DRI Ethyl Glucuronide Calibrator 100 ng/mL(CJF) 10015935 DRI Ethyl Glucuronide Calibrator 500 ng/mL (CJF) 10015938 DRI Ethyl Glucuronide Calibrator 1000 ng/mL (CJF) 10015940 DRI Ethyl Glucuronide Calibrator 2000 ng/mL (CJF) 10015934 DRI Ethyl Glucuronide 375 ng/mL Control (CJF) 10015936 DRI Ethyl Glucuronide 625 ng/mL Control (CJF) 10015937 DRI Ethyl Glucuronide 750 ng/mL Control (CJF) 10015939 DRI Ethyl Glucuronide 1250 ng/mL Control (CJF) 100117 DRI Methadone Metabolite 150 ng/mL Calibrator

10016023 DRI Fentanyl 2 ng/mL calibrator (CJF) 10016022 DRI Fentanyl 1 ng/mL control (CJF)

100118 DRI Methadone Metabolite 300 ng/mL Calibrator 100120 DRI Methadone Metabolite 1000 ng/mL Calibrator 100122 DRI Methadone Metabolite 2000 ng/mL Calibrator

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10016024, DRI Fentanyl 3 ng/mL control (CJF)
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10016485, DRI Fentanyl 2 ng/mL calibrator (CE)

10016484, DRI Fentanyl 1 ng/mL control (CE)

10016486, DRI Fentanyl 3 ng/mL control (CE)

0404 DRI Cotinine Calibrator Kit

0460 DRI Cotinine Low Control Kit

0470 DRI Cotinine High Control Kit

0235 DRI THC Urine Calibrator 20 ng/mL

1397 DRI THC Urine Calibrator 20 ng/mL

0042 DRI THC Urine Calibrator 50 ng/mL

1398 DRI THC Urine Calibrator 50 ng/mL

0044 DRI THC Urine Calibrator 100 ng/mL

1399 DRI THC Urine Calibrator 100 ng/mL

0206 DRI THC Urine Calibrator 200 ng/mL

1400 DRI THC Urine Calibrator 200 ng/mL

0170 DRI THC Urine 40 ng/mL Control

1401 DRI THC Urine 40 ng/mL Control

0168 DRI THC Urine 60 ng/mL Control

1402 DRI THC Urine 60 ng/mL Control

0214 DRI THC Urine 75 ng/mL Control

1404 DRI THC Urine 125 ng/mL Control

0212 DRI THC Urine 125 ng/mL Control

1588 DRI Multi Drug Calibrator 1

1597 DRI Multi Drug Calibrator 4

1589 DRI Multi Drug Calibrator 1

1598 DRI Multi Drug Calibrator 4

1591 DRI Multi Drug Calibrator 2

1664 DRI Negative Urine Calibrator

1592 DRI Multi Drug Calibrator 2

1388 DRI Negative Urine Calibrator

1594 DRI Multi Drug Calibrator 3

1595 DRI Multi Drug Calibrator 3

0034 DRI Drugs of Abuse Low Calibrator

0036 DRI Drugs of Abuse High Calibrator

1609 DRI Opiate Urine Calibrator 1

1610 DRI Opiate Urine Calibrator 2

10018079 DRI Hydrocodone Assay Calibrator 100

10018080 DRI Hydrocodone Assay Calibrator 300

10018081 DRI Hydrocodone Assay Calibrator 500

10018082 DRI Hydrocodone Assay Calibrator 1000

10018149 DRI Hydrocodone Assay Control Kit

10026302 DRI Hydromorphone Control

1662848 CEDIATM Propoxyphene/Methadone Cut Off Calibrator

1662856 CEDIA™ Propoxyphene/Methadone Intermediate Calibrator

1662864 CEDIA™ Propoxyphene/Methadone High Calibrator

1815440 CEDIATM Specialty Control Set

100200 MGC Primary DAU Control Set

100201 MGC Clinical DAU Control Set

100202 MGC Select DAU Control Set

10021390 CEDIA™ Negative Calibrator II

10020799 CEDIATM Buprenorphine II Calibrator 10ng/mL

10020800 CEDIA™ Buprenorphine II Calibrator 20ng/mL

10020801 CEDIA™ Buprenorphine II Calibrator 50ng/mL

10020802 CEDIA™ Buprenorphine II Calibrator 100ng/mL

10020804 CEDIATM Buprenorphine II Control

10022930 CEDIATM Negative Calibrator III (1 x 10 mL) CJF 10022931 CEDIA™ AB-PINACA 5 ng/mL Calibrator (1 x 5mL) CJF 10022932 CEDIATM AB-PINACA 20 ng/mL Calibrator (1 x 5mL) CJF 10022933 CEDIA™ AB-PINACA 50 ng/mL Calibrator (1 x 5mL) CJF 10022934 CEDIA™ AB-PINACA 100 ng/mL Calibrator (1 x 5mL) CJF 10022935 CEDIA™ AB-PINACA Control Set (2 x 5mL each) CJF 10022753 CEDIATM Negative Calibrator II (1 x 7.5 mL) CJF 10023466 CEDIATM Negative Calibrator III (CE) 10023467 CEDIATM AB-PINACA 5 ng/mL Calibrator (CE) 10023468 CEDIATM AB-PINACA 20 ng/mL Calibrator (CE) 10023469 CEDIATM AB-PINACA 50 ng/mL Calibrator (CE) 10023470 CEDIATM AB-PINACA 100 ng/mL Calibrator (CE) 10023471 CEDIATM AB-PINACA Control Set (CE) 10022754 CEDIATM UR-144 10 ng/mL Calibrator (1 x 5 mL) 10022755 CEDIA™ UR-144 20 ng/mL Calibrator (1 x 5 mL) 10022756 CEDIATM UR-144 40 ng/mL Calibrator (1 x 5 mL) 10022759 CEDIATM UR-144 60 ng/mL Calibrator (1 x 5 mL) 10022760 CEDIA™ UR-144 Control Set (2 x 5 mL) 10024435 DRI MDA 650 ng/mL Control 10026590 CEDIA™ Mitragynine (Kratom) 20 ng/mL Calibrator 10026591 CEDIA™ Mitragynine (Kratom) 50 ng/mL Calibrator 10026592 CEDIATM Mitragynine (Kratom) 100 ng/mL Calibrator 10026593 CEDIATM Mitragynine (Kratom) 200 ng/mL Calibrator

10026594 CEDIATM Mitragynine (Kratom) Control Set

Trade names

DRI THC (Cannabinoids) Controls and Calibrators, DRI Ecstasy Calibrators DRI Methadone Metabolite Calibrators, DRI Ethyl Glucuronide Controls and Calibrators, DRI Fentanyl Controls and Calibrators, DRI Cotinine Controls and Calibrators, DRI Opiate Calibrators, DRI Multi- Drug Calibrators, DRI Negative Urine Calibrators, DRI Hydrocodone Assay Calibrators and Controls, DRI Hydromorphone Control, CEDIA Propoxyphene/Methadone Calibrators, MGC Primary DAU Controls, CEDIA Specialty Control Set, MGC Clinical DAU Controls, MGC Select DAU Controls, CEDIA Buprenorphine II Calibrators and Control, CEDIA AB-PINACA Calibrators and Controls, CEDIA UR-144 Calibrators and Controls, DRI MDA Control. CEDIA Mitragynine (Kratom).

Chemical family Mixture

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

Criminal, Forensic, and Justice kits

The pharmacological, toxicological, and ecological properties of this

product/mixture have not been fully characterized. This SDS will be updated as

more data become available.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Note

Globally Harmonized

System [GHS]

Respiratory sensitizer - Category 1. Skin sensitizer - Category 1.

Other/Supplemental Mixture not yet fully tested

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ... continued

GHS hazard pictogram



GHS signal word

Danger

GHS hazard statements

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

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.

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 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.

Note

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

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS#	EINECS/ELIN	Amount Amount	<u>GHS</u>
		<u>CS#</u>		Classification
Urine (Human)	N/A	N/A	8-10%	Not classified
Bovine serum albumin	9048-46-8	N/A	0.1-0.3%	SS1: H317;
				RS1: H334
Sodium azide	26628-22-8	247-852-1	≤0.09%	ATO2: H300;
				AA1: H400;
				CA1: H410;
				EUH032

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 also contains trace amounts of active pharmaceutical ingredients (<0.01%), as well as methanol (<0.001%) and DMF (<0.02%). See Section 16 for full text of GHS classifications.

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.

Specific hazards arising from the substance or mixture

No information identified. May emit 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. Do not breathe mist/spray.

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 <u>OEL</u> **Type** <u>Issuer</u> Urine (Human) --Bovine serum albumin

Australia,

Sodium azide ACGIH, **OEL-STEL** 0.3 mg/m^3

> 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

New Zealand, Ceiling

 0.29 mg/m^3

Portugal

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

Control

Parameters/Occupational Exposure Limit Values

...continued

Compound	<u>Issuer</u>	Type	<u>OEL</u>		
Sodium azide	ACGIH,	OEL-TWA	0.1 mg/m^3		
	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.SCalifornia				
	OSHA, United				
	Kingdom				
	NIOSH,	Ceiling	0.3 mg/m^3		
	U.SCalifornia				
	OSHA				
	Germany	OEL-STEL	0.4 mg/m^3		
	~	OFF THE	00		

Germany

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. Laboratory operations should be conducted within a laboratory hood or biological safety cabinet if feasible. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

 0.2 mg/m^3

OEL-TWA

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

Choice of respiratory protection should be appropriate to the task and the level of Respiratory protection

existing engineering controls. If handling outside of containment device, an approved and properly fitted air-purifying respirator with HEPA filters should be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure airsupplied 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.

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.

Wear safety glasses with side shields, chemical splash goggles, or full face shield, Eye/face protection

> 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.

Controls

Environmental Exposure 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

> Liquid **Appearance**

Light yellow Color

Odor No information identified.

Odor threshold No information identified.

5.9-6.1 рH

Melting point/freezing

point

No information identified.

Initial boiling point and No information identified.

boiling range

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ... continued

Flash point No information identified.

Evaporation rate No information identified.

Flammability (solid, gas) No information identified.

Upper/lower No information identified.

flammability or explosive

limits

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 formula Not applicable (Mixture)

Molecular weight 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 $\geq 25^{\circ}$ C.

Incompatible materials No information identified.

Hazardous decomposition

No information identified.

products

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>	Species Species	<u>Dose</u>
Urine (Human)				
Bovine serum albumin				
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 No studies identified.

STOT-repeated

exposure/Repeat-dose

toxicity

No studies identified.

No studies identified. Reproductive toxicity **Developmental toxicity** No studies identified.

Genotoxicity No studies identified.

Carcinogenicity No studies identified. 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.

No studies identified **Aspiration hazard**

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

<u>Compound</u>	<u>Type</u>	<u>Species</u>	Concentration
Urine (Human)			
Bovine serum albumin			
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

SECTION 12 - ECOLOGICAL INFORMATION ... continued

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.

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. 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

Based on the available data, this product/mixture is not regulated as a hazardous **Transport**

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

Avoid release to the environment.

SECTION 14 - TRANSPORT INFORMATION ... continued

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

SECTION 15 - REGULATORY INFORMATION

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 All components of mixture are on TSCA Inventory or are exempt.

SARA section 313 Not listed.

California proposition 65 Not listed.

Additional information Federal German Government Water Hazard Classification:

WHC 3

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications

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.

Sources of data

Information from published literature and internal company data.

Abbreviations

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# -Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT -Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA -International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT

SECTION 16 - OTHER INFORMATION ... continued

Abbreviations ... continued

Persistent, Bioaccumulative, and Toxic; 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; vPvB - Very Persistent and Very Bioaccumulative;
 WHMIS - Workplace Hazardous Materials Information System

Issue Date

11 January 2019

Revisions

This is the second 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/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.