SAFETY DATA SHEET

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

Contact information

General

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Product identifier

CEDIA® Technology – Powders (Group 1)

Synonyms

EA & ED Reagents for following Assays:
100107, CEDIA® Heroin Metabolite (6-AM) Assay
10015213, CEDIA® Heroin Metabolite (6-AM) Assay
100108, CEDIA® Heroin Metabolite (6-AM) Assay
100186, CEDIA® Heroin Metabolite (6-AM) Assay
10010883, CEDIA® Cannabinoids (THC) OFT Assay
10010888, CEDIA® Cannabinoids (THC) OFT Assay
10018585, CEDIA® Cannabinoids (THC) OFT Assay
10014910, CEDIA® Cannabinoids (THC) OFT Assay

10021737, CEDIA® Cannabinoids (THC) OFT Assay

Trade names

CEDIA® Technology

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.

Issue Date

5 January 2016

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

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

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. EUH032 - Contact with acids liberates very toxic gas.
CLP/GHS precautionary statements	P261 - Avoid breathing dust/mist/vapors/spray. 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

No data specific for the mixture were identified. 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, 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.

Note This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Bovine serum albumin	9048-46-8	N/A	≤55%	SS1: H317, RS1: H334
Potassium phosphate monobasic	7778-77-0	231-913-4	≤3%	SI2: H315; EI2: H319
Potassium phosphate dibasic	7758-11-4	231-834-5	≤3%	SI2: H315; EI2: H319
Sodium azide	26628-22-8	247-852-1	≤1%	ATO2: H300; AA1: H400 , CA1: H410; EUH032
Drug-specific antibody	N/A	N/A	≤0.5%	SS1: H317; RS1: H334

Note The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of CLP/GHS classifications. Product also contains trace levels of antibody conjugate (≤0.01%). The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

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.

SECTION 4 - FIRST AID MEASURES …continued

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 toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/Explosivity	No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited.
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	DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder 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 (see section 9).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing dust.

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
Bovine serum albumin	--	--	--
Potassium phosphate monobasic	--	--	--
Potassium phosphate dibasic	--	--	--

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
Drug-specific antibody	--	--	--

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 dust-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 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.
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	Lyophilized powder
Color	White to off-white
Odor	No information identified.
Odor threshold	No information identified.
pH	Not applicable
Melting point/freezing point	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
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	Soluble in 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.

SECTION 10 - STABILITY AND REACTIVITY …continued

Conditions to avoid Avoid excessive heat.

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note No data for this product/mixture were identified. The following data describe the individual ingredients where applicable.

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Bovine serum albumin	--	--	--	--
Potassium phosphate monobasic	LD_{50}	Oral	Mouse	2820 mg/kg
	LD_{50}	Oral	Rat	3200 mg/kg
	LD_{50}	Dermal	Rabbit	>4640 mg/kg
Potassium phosphate dibasic	LD_{50}	Oral	Rat	>2000 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
Drug-specific antibody	--	--	--	--

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.

Reproductive toxicity Oral doses of up to 1000 mg/kg/day potassium phosphate dibasic were not associated with reproductive toxicity in rats; the NOAEL was 1000 mg/kg/day.

Developmental toxicity Oral doses of up to 1000 mg/kg/day potassium phosphate dibasic were not associated with developmental toxicity in rats; the NOAEL was 1000 mg/kg/day.

Genotoxicity Potassium phosphate dibasic was negative for genotoxic effects in an *in vitro* bacterial cell mutagenicity assay (Ames) and in an *in vitro* chromosomal aberration test.

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.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

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
Bovine serum albumin	--	--	--
Potassium phosphate monobasic	LC_{50}/24h	Dreissena polymorpha (zebra mussel)	92-169 mg/L
Potassium phosphate dibasic	LC_{50}/96h	Oryzias latipes (Japanese rice fish)	> 100 mg/L
	EC_{50}/48h	Daphnia magna (water flea)	118.9 mg/L
	EC_{50}/72h (growth rate reduction)	Pseduokirchneriella subcapitata (green algae)	>100 mg/L
	EC_{50}/72h (biomass)	Pseduokirchneriella subcapitata (green algae)	60 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
Drug-specific antibody	--	--	--

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. 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.
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.

SECTION 15 - REGULATORY INFORMATION …continued

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 H phrases, P phrases and GHS classification	SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. 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; 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.

SECTION 16 - OTHER INFORMATION …continued

Disclaimer …continued

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.

SAFETY DATA SHEET

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

Contact information

General



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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

CEDIA® Technology - Group B Liquids

Synonyms

EARB & EDRB Reagents for following Assays:
100107, CEDIA® Heroin Metabolite (6-AM) Assay
10015213, CEDIA® Heroin Metabolite (6-AM) Assay
100108, CEDIA® Heroin Metabolite (6-AM) Assay
100186, CEDIA® Heroin Metabolite (6-AM) Assay
10010883, CEDIA® Cannabinoids (THC) OFT Assay
10010888, CEDIA® Cannabinoids (THC) OFT Assay
10018585, CEDIA® Cannabinoids (THC) OFT Assay
10014910, CEDIA® Cannabinoids (THC) OFT Assay

10021737, CEDIA® Cannabinoids (THC) OFT Assay

Trade names

CEDIA® Technology

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.

Issue Date

5 January 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.

Label elements

CLP/GHS hazard pictogram	
CLP/GHS signal word	Warning
CLP/GHS hazard statements	H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. EUH032 - Contact with acids liberates very toxic gas.
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.

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.

Because the mixture contains bovine serum 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 has been associated with occupational sensitization. Although antibody particles are fairly large proteins, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory 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).

SECTION 2 - HAZARDS IDENTIFICATION …continued

Note This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Cyclic oligosaccharides	Proprietary	N/A	≤1%	SI2: H315; EI2: H319; STOT-SE3: H335
Propylene glycol	57-55-6	200-338-0	≤1%	Not classified
Bovine serum	N/A	N/A	≤0.5%	SS1: H317; RS1: H334
Sodium azide	26628-22-8	247-852-1	≤0.15%	ATO2: H300; AA1: H400 , CA1: H410; EUH032
Sodium lauroylsarcosinate	137-16-6	25-281-5	≤0.1%	ATI2: H330; SI2: H315; EI2: H319
Drug-specific antibody	N/A	N/A	<0.1%	SS1: H317; RS1: H334

Note The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of CLP/GHS classifications. The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

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.

SECTION 4 - FIRST AID MEASURES …continued

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

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). 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

Note

Dispose of broken vials/syringes in a sharps container.

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Cyclic oligosaccharides	--	--	--
Propylene glycol	AIHA	TWA-8 HR	10 mg/m³
	Ireland, United Kingdom	TWA-8 HR	150 ppm (total vapor and particulates), 10 mg/m³ (particulates)
	Latvia, Lithuania	TWA-8 HR	7 mg/m³
	United Kingdom	STEL	450 ppm (total particulate and vapor), 30 mg/m³ (particulate)
Bovine serum	--	--	--

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
Sodium lauroylsarcosinate	--	--	--
Drug-specific antibody	--	--	--

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

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. 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 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.
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	Clear liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

pH	6-8
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
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.

SECTION 10 - STABILITY AND REACTIVITY …continued

Chemical stability Stable when stored as recommended.

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid Avoid extreme temperatures.

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

Compound	Type	Route	Species	Dose
Cyclic oligosaccharides	--	--	--	--
Propylene glycol	LD_{50}	Oral	Rat	22000 mg/kg
	LD_{50}	Dermal	Rabbit	20800 mg/kg
Bovine serum	--	--	--	--
Sodium azide	LD_{50}	Oral	Rat	27 mg/kg
	LD_{50}	Oral	Mouse	27 mg/kg
	LD_{50}	Dermal	Rabbit	20 mg/kg
Sodium lauroylsarcosinate	LD_{50}	Inhalation	Rat	0.05-0.5 mg/L
Drug-specific antibody	--	--	--	--

Irritation/Corrosion No studies identified.

Sensitization No data on product formulation. As bovine serum is derived from an animal (foreign) source, there is potential for the material to cause an allergic response in humans. Occupational exposure to bovine serum 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.

Reproductive toxicity No studies identified.

Developmental toxicity No studies identified.

Genotoxicity No studies identified.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

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.

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
Cyclic oligosaccharides	--	--	--
Propylene glycol	--	--	--
Bovine serum	--	--	--
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
Sodium lauroylsarcosinate	EC_{50} (96h)	Danio rerio (zebra fish)	107 mg/L
	LC_{50} (48h)	Daphnia magna	29.7 mg/L
	EC_{50} (72 h)	Desmodesmus subspicatus (green algae)	79 mg/L
	NOEC (respiration inhibition test)	Bacteria (unspecified)	100 mg/L
Drug-specific antibody	--	--	--

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 regulationsAll 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 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.
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.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	SI2 - Skin irritant Category 2. H315 - Causes skin irritation. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation. ATI2 - Acute Toxicity (Inhalation) Category 2. H330 - Fatal if inhaled. 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;

SECTION 16 - OTHER INFORMATION …continued

Abbreviations …continued

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.