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

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Product identifier CEDIA® CsA II assay - Powder reagents

Synonyms 100147 CEDIA® Cyclosporine PLUS - EA reagent, ED reagent
10016283 CEDIA® Cyclosporine PLUS - EA reagent, ED reagent

Trade names CEDIA® CsA II assay

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against *In vitro* diagnostic kit. Contains multiple lyophilized powder reagents packaged as separate vials.

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 23 April 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Respiratory sensitizer - Category 1. Skin sensitizer - Category 1. Aquatic toxicity (chronic) - Category 3. Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC Xn - R42 (Respiratory Sens.), R43 (Skin Sens.); R52/53. 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. H412 - Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.

CLP/GHS precautionary statements P261 - Avoid breathing dust/mist/vapor/spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P273 - Avoid release to the environment. 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. R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R32 - Contact with acids liberates very toxic gas.

Safety Advice S2 - Keep out of reach of children. S23 - Do not breathe dust/mist/vapors/spray. S24 - Avoid contact with skin. S29 - Do not empty into drains. S37 - Wear suitable protective gloves. S46 - If swallowed, seek medical advice immediately and show this container or label. S50 - Do not mix with acids. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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).

SECTION 2 - HAZARDS IDENTIFICATION …continued

Other hazards …continued

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.

US Signal word

Danger

US Hazard overview

May cause allergic respiratory reaction. May cause allergic skin reaction. May be harmful to aquatic life with long lasting effects. Mixture not yet fully tested. This product contains bovine serum albumin, which has been associated with occupational sensitization.

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. 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
Bovine serum albumin	9048-46-8	N/A	55%	Harmful - Xn: R42/R43	SS1: H317, RS1: H334
Tributyl phosphate	126-73-8	204-800-2	<1.0%	Harmful - Xn: R20/22; R38; R40	ATO4: H302; ATI4: H332; SI2: H315; Carc2: H351
Sodium azide	26628-22-8	247-852-1	≤1.0%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

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 EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed

Yes

SECTION 4 - FIRST AID MEASURES …continued

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 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/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
Bovine serum albumin	--	--	--
Tributyl phosphate	ACGIH	TLV-TWA (8-HR)	5 mg/m³
	Austria, Belgium, Denmark, Finland, France, Switzerland	8-hour TWA	2.5 mg/m³; 0.2 ppm
	Bulgaria	8-hour TWA	5 mg/m³
	Finland	STEL	5 mg/m³
	Germany	8-hour TWA (MAK)	11 mg/m³ (1 ppm)

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Tributyl phosphate	NIOSH	IDLH (Immediately dangerous to life or health)	30 ppm
	NIOSH	REL - TWA (8-Hr)	2.5 mg/m³; 0.2 ppm
	OSHA	PEL-TWA (8-HR)	5 mg/m³
	Netherlands	MAC	5 mg/m³
	United Kingdom	8-hour TWA	5 mg/m³
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 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	No information identified.
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

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	--	--	--	--
Tributyl phosphate	LD_{50}	Oral	Rat	1552 mg/kg
	LC_{50}	Inhalation	Rat	28000 mg/m³/1h
	LD_{50}	Dermal	Rabbit	>3100 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 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.

Carcinogenicity Tributyl phosphate (TBP) was administered in the diet of male and female mice at concentrations of up to 3500 ppm for 18 months. Survival, clinical signs and hematology parameters were unaffected by treatment at any dose level. Initial weight losses and significant decreases in body weight gain occurred in males and females receiving the high dose. A significant dose-related increase in absolute and relative liver weights was seen in male and female mice which received the two highest doses (1000 and 3500 ppm). The highest doses (1000 and 3500 ppm).

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Carcinogenicity …continued

The incidence of hepatocellular adenomas was significantly increased in male mice treated with 3500 ppm. No other tumors were associated with TBP administration in this study. The NOEL for chronic toxicity was 150 ppm, or 28.9 mg/kg/day for females and 24.1 mg/kg/day for males. Although rats treated chronically with TBP have exhibited urinary bladder hyperplasia and urinary bladder papillomas and transitional cell carcinomas, no urinary bladder alterations attributed to TBP administration occurred in this mouse study. 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
Bovine serum albumin	--	--	--
Tributyl phosphate	LC_{50} 96 h	Carassius auratus (fresh water fish)	8.8 mg/L
	EC_{50} 48h	Daphnia magna (water flea)	3.6 mg/L
	EC_{50} 72h	Desmodesmus subspicatus (green algae)	1.1 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. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
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. Caution. May cause allergic respiratory reaction. May cause allergic skin reaction. May be harmful to aquatic life with long lasting effects. Mixture not fully tested. This product contains bovine serum albumin, which has been associated with occupational sensitization.
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	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn - Harmful. R20/22 - Harmful by inhalation and if swallowed. R38 - Irritating to skin. R40 - Limited evidence of a carcinogenic effect. R42/43 - May cause sensitization by inhalation and skin contact. R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. T+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Full text of H phrases, P phrases and GHS classification	SI2 - Skin irritant Category 2. H315 - Causes skin 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. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATI4 - Acute Toxicity (Inhalation) Category 4. H332 - Harmful if inhaled. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. Carc2 - Carcinogenicity Category 2. H351 - Suspected of causing cancer. 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. H412 - Harmful 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.

SECTION 16 - OTHER INFORMATION …continued

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

Revisions

This is the first 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.

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

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1-(703) 527-3887
International access (collect calls accepted)
1-(202) 483-7616 Europe

Product identifier CEDIA® CsA II Assay - Liquid reagents

Synonyms 100147 CEDIA® Cyclosporine PLUS Assay - EARB, EDRB, Lysing reagent
10016283 CEDIA® Cyclosporine PLUS Assay - EARB, EDRB, Lysing reagent

Trade names CEDIA® CsA II Assay

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against *In vitro* diagnostic kit. Contains multiple liquid reagents packaged as separate vials.

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 23 April 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Respiratory sensitizer - Category 1. Skin sensitizer - Category 1. Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC Xn - R42 (Respiratory Sens.), R43 (Skin Sens.). Mixture not yet fully tested.

Label elements

CLP/GHS hazard pictogram	
CLP/GHS signal word	Danger
CLP/GHS hazard statements	H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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.
EU symbol/indication of danger	 Xn - Harmful
Risk (R) Phrase(s)	R42/43 - May cause sensitization by inhalation and skin contact. R32 - Contact with acids liberates very toxic gas.
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. S50 - Do not mix with acids. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

Other hazards

No data specific for the mixture were identified. The mixture contains bovine serum 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

SECTION 2 - HAZARDS IDENTIFICATION …continued

Other hazards …continued

rapid breakdown of proteins in the digestive tract. 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.

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 bovine serum, which has been associated with occupational sensitization.

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
Cyclic oligosaccharides	Proprietary	N/A	<2%	Irritant - Xi: R36/37/38	SI2: H315; EI2: H319; STOT-SE3: H335
Zwitterionic detergent	Proprietary	N/A	<1%	Irritant - Xi: R36/37/38	EI2: H319; SI2: H315; STOT-SE3: H335
Bovine serum (fetal)	N/A	N/A	0.75%	Harmful - Xn: R42/R43	SS1: H317; RS1: H334
Tributyl phosphate	126-73-8	204-800-2	<0.2%	Harmful - Xn: R20/22; R38; R40	ATO4: H302; ATI4: H332; SI2: H315; Carc2: H351
Non-ionic surfactant	Proprietary	N/A	<0.2%	Harmful - R52	AA3: H402
Sodium azide	26628-22-8	247-852-1	<0.13%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032
CsA Antibody	N/A	N/A	<0.1%	Harmful - Xn: R42/43	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 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.
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 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

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Cyclic oligosaccharides	--	--	--
Zwitterionic detergent	--	--	--
Bovine serum (fetal)	--	--	--
Tributyl phosphate	ACGIH	TLV-TWA (8-HR)	5 mg/m³

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Tributyl phosphate	Austria, Belgium, Denmark, Finland, France, Switzerland	8-hour TWA	2.5 mg/m³; 0.2 ppm
	Bulgaria	8-hour TWA	5 mg/m³
	Finland	STEL	5 mg/m³
	Germany	8-hour TWA (MAK)	11 mg/m³; 1 ppm
	NIOSH	IDLH (Immediately dangerous to life or health)	30 ppm
	NIOSH	REL - TWA (8-Hr)	2.5 mg/m³; 0.2 ppm
	OSHA	PEL-TWA (8-HR)	5 mg/m³
	Netherlands	MAC	5 mg/m³
	United Kingdom	8-hour TWA	5 mg/m³
Non-ionic surfactant	--	--	--

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
CsA 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 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	Clear liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	6.0-7.1
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
Cyclic oligosaccharides	--	--	--	--
Zwitterionic detergent	--	--	--	--
Bovine serum (fetal)	--	--	--	--
Tributyl phosphate	LD_{50}	Oral	Rat	1552 mg/kg
	LC_{50}	Inhalation	Rat	28000 mg/m³/1h
	LD_{50}	Dermal	Rabbit	>3100 mg/kg
Non-ionic surfactant	--	--	--	--
Sodium azide	LD_{50}	Oral	Rat	27 mg/kg
	LD_{50}	Oral	Mouse	27 mg/kg
	LD_{50}	Dermal	Rabbit	20 mg/kg
CsA Antibody	--	--	--	--

Irritation/Corrosion No studies identified.

Sensitization No studies identified. As bovine serum is derived from animal (foreign) protein, 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.

Carcinogenicity Tributyl phosphate (TBP) was administered in the diet of male and female mice at concentrations of up to 3500 ppm for 18 months. Survival, clinical signs and hematology parameters were unaffected by treatment at any dose level. Initial weight losses and significant decreases in body weight gain occurred in males and females receiving the high dose. A significant dose-related increase in absolute and relative liver weights was seen in male and female mice which received the two highest doses (1000 and 3500 ppm). The incidence of hepatocellular adenomas was significantly increased in male mice treated with 3500 ppm.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Carcinogenicity …continued

No other tumors were associated with TBP administration in this study. The NOEL for chronic toxicity was 150 ppm, or 28.9 mg/kg/day for females and 24.1 mg/kg/day for males.

Although rats treated chronically with TBP have exhibited urinary bladder hyperplasia and urinary bladder papillomas and transitional cell carcinomas, no urinary bladder alterations attributed to TBP administration occurred in this mouse study. None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

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	--	--	--
Zwitterionic detergent	--	--	--
Bovine serum (fetal)	--	--	--
Tributyl phosphate	LC_{50} 96 h	Carassius auratus (fresh water fish)	8.8 mg/L
	EC_{50} 48h	Daphnia magna (water flea)	3.6 mg/L
	EC_{50} 72h	Desmodesmus subspicatus (green algae)	1.1 mg/L
Non-ionic surfactant	EC_{50} (time not specified)	Not specified	> 1 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
CsA 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.

SECTION 12 - ECOLOGICAL INFORMATION …continued

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

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	Caution. Mixture not fully tested. This product contains bovine serum, which has been associated with occupational sensitization.
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	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	X_i - Irritant. R36/37/38 - Irritating to eyes, respiratory system and skin. R38 - Irritating to skin. Xn - Harmful. R20/22 - Harmful by inhalation and if swallowed. R40 - Limited evidence of a carcinogenic effect. R42/43 - May cause sensitization by inhalation and skin contact. R52 - Harmful to aquatic organisms. T+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
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. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory 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. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATI4 - Acute Toxicity (Inhalation) Category 4. H332 - Harmful if inhaled. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. Carc2 - Carcinogenicity Category 2. H351 - Suspected of causing cancer. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. AA3- Acute aquatic toxicity Category 3. H402 - Harmful 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

SECTION 16 - OTHER INFORMATION …continued

Abbreviations …continued

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

Revisions

This is the first 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.

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 CEDIA® Cyclosporine PLUS Assay - High and Low Calibrators

Synonyms 100147 CEDIA® Cyclosporine PLUS Assay - High and Low Calibrators
10016283 CEDIA® Cyclosporine PLUS Assay - High and Low Calibrators

Trade names CEDIA® Cyclosporine PLUS Assay - High and Low Calibrators

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 23 April 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Respiratory sensitizer - Category 1. Skin sensitizer - Category 1. Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC Xn - R42 (Respiratory Sens.), R43 (Skin Sens.). Mixture not yet fully tested.

Label elements

CLP/GHS hazard pictogram	
CLP/GHS signal word	Danger
CLP/GHS hazard statements	H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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.
EU symbol/indication of danger	 Xn - Harmful
Risk (R) Phrase(s)	R42/43 - May cause sensitization by inhalation and skin contact. R32 - Contact with acids liberates very toxic gas.
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. S50 - Do not mix with acids. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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.

SECTION 2 - HAZARDS IDENTIFICATION …continued

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 bovine serum albumin, which has been associated with occupational sensitization.

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. 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
Bovine serum albumin	9048-46-8	N/A	18%	Harmful - Xn: R42/R43	SS1: H317, RS1: H334
Sodium azide	26628-22-8	247-852-1	≤0.13%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

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 EU and CLP/GHS classifications. Product also contains trace levels of ethanol (< 0.5%) and proprietary pharmaceutical ingredients (< 0.001%). 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.

SECTION 4 - FIRST AID MEASURES …continued

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 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.

SECTION 6 - ACCIDENTAL RELEASE MEASURES …continued

Methods and material for containment and cleaning up	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	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
Bovine serum albumin	--	--	--
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 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	Clear liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	7.0
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	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.

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

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	--	--	--	--
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.

Reproductive toxicity No studies identified.

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.

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	--	--	--
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.

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

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.

SECTION 14 - TRANSPORT INFORMATION …continued

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	Caution. Mixture not fully tested. This product contains bovine serum albumin, which has been associated with occupational sensitization.
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	Not listed
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+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 16 - OTHER INFORMATION …continued

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.
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
Revisions	This is the first 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.