

SAFETY DATA SHEET

Prolisa™ *C. difficile* GDH EIA

Section 1. Identification

GHS product identifier : Prolisa™ *C. difficile* GDH EIA

Other means of identification : Not available.

Trade name : Prolisa™ *C. difficile* GDH EIA
 Stop Solution
 Substrate Solution
 20X Wash Buffer
 Positive Control
 Sample Diluent
 Immunoconjugate
 Coated & Stabilized Plate

Code

PL.2002
 PL.2103
 PL.2104
 PL.2110
 PL.2112
 PL.2113
 PL.2114
 PL.2115

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : The Prolisa™ *C. difficile* GDH EIA is a microwell assay for the qualitative detection of *Clostridium difficile* glutamate dehydrogenase (GDH) in faecal specimens. It is intended for use as an aid in the diagnosis of *C. difficile* infections. This test detects GDH and will not differentiate between toxigenic and non-toxigenic strains of *C. difficile*. Like alternative *C. difficile* tests, results should be considered in conjunction with patient history and additional laboratory investigations.

Supplier's details : Pro-Lab Diagnostics
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Emergency telephone number (with hours of operation) : 905-731-0300 –Monday to Friday 8:30 am to 5:00 pm Eastern Standard Time.
 416-230-0692 –Outside the above hours.

Section 2. Hazards identification

Classification of the substance or mixture : Not classified.

PL.2110	SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2
PL.2113	Not classified.
PL.2103	SKIN CORROSION/IRRITATION - Category 1
	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 1
PL.2104	Not classified.
PL.2112	SKIN SENSITIZATION - Category 1
PL.2115	Not classified.
PL.2114	Not classified.

GHS label elements

Section 2. Hazards identification

Signal word	: PL.2110	Warning
	PL.2113	No signal word.
	PL.2103	Danger
	PL.2104	No signal word.
	PL.2112	Warning
	PL.2115	No signal word.
	PL.2114	No signal word.
Hazard statements	: PL.2110	May cause damage to organs through prolonged or repeated exposure.
	PL.2113	No known significant effects or critical hazards.
	PL.2103	Causes severe skin burns and eye damage.
	PL.2104	No known significant effects or critical hazards.
	PL.2112	May cause an allergic skin reaction.
	PL.2115	No known significant effects or critical hazards.
	PL.2114	No known significant effects or critical hazards.
<u>Precautionary statements</u>		
Prevention	: Not applicable.	
Response	: Not applicable.	
Storage	: Not applicable.	
Disposal	: Not applicable.	
Physical hazards not otherwise classified (PHNOC)	: None known.	
Health hazards not otherwise classified (HHNOC)	: None known.	

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Not available.

CAS number/other identifiers

CAS number	: Not applicable.
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Ingredient name	%	CAS number
PL.2110 Disodium hydrogenorthophosphate Thiomersal	≥1 - ≤3 <0.25	7558-79-4 54-64-8
PL.2112 Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	<0.06	55965-84-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
halogenated compounds
metal oxide/oxides

Section 5. Fire-fighting measures

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store at 2°C to 8°C. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : PL.2110 Liquid. [Hazy liquid.]
 PL.2113 Liquid. [Clear solution.]
 PL.2103 Liquid. [Clear solution.]
 PL.2104 Liquid. [Clear solution.]
 PL.2112 Liquid. [Clear solution.]
 PL.2115 Solid. [Material dried on a 96 well plate.]
 PL.2114 Liquid. [Translucent solution.]

Color : PL.2110 Colorless to white.
 PL.2113 Amber.
 PL.2103 Colorless.
 PL.2104 Colorless to light yellow.
 PL.2112 Colorless.
 PL.2115 Not applicable.
 PL.2114 Brown.

Odor : Not available.

Section 9. Physical and chemical properties

Odor threshold	: Not available.
pH	: PL.2110 7.4 PL.2113 6.6 to 7.2 PL.2103 <2 PL.2104 3.7 PL.2112 6.5 PL.2115 Not available. PL.2114 6.2 to 6.7
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Miscible in water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
PL.2110 Disodium hydrogenorthophosphate	LD50 Oral	Rat	17000 mg/kg	-
Thiomersal	LD50 Oral	Rat	75 mg/kg	-
PL.2112 Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	LD50 Oral	Rat	53 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
PL.2110 Disodium hydrogenorthophosphate	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
Thiomersal	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Mild irritant	Rabbit	-	8 µg	-

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
PL.2110 Thiomersal	Category 2	Not determined	Not determined

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Section 11. Toxicological information

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
PL.2110 Disodium hydrogenorthophosphate	Acute LC50 3580000 µg/L Fresh water	Daphnia - Daphnia magna	48 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
PL.2110 Disodium hydrogenorthophosphate	-5.8	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	TDG	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Canadian lists

Canadian NPRI : None of the components are listed.
CEPA Toxic substances : None of the components are listed.
Canada inventory : Not determined.

International lists

National inventory

Australia : Not determined.
China : Not determined.
Europe : Not determined.
Japan : **Japan inventory (ENCS):** Not determined.
Japan inventory (ISHL): Not determined.
Malaysia : Not determined.

Section 15. Regulatory information

New Zealand	: Not determined.
Philippines	: Not determined.
Republic of Korea	: Not determined.
Taiwan	: Not determined.

Section 16. Other information

History

Date of issue	: 11/15/2017
Version	: 1
Prepared by	: KMK Regulatory Services Inc.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.