SAFETY DATA SHEET

Prolisa™ *C. difficile* GDH EIA

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Identification of the substance or mixture

Product name : Prolisa™ *C. difficile* GDH EIA

		Code
Trade name	Prolisa™ *C. difficile* GDH EIA	PL.2002
	Stop Solution	PL.2103
	Substrate Solution	PL.2104
	20X Wash Buffer	PL.2110
	Positive Control	PL.2112
	Sample Diluent	PL.2113
	Immunoconjugate	PL.2114
	Coated & Stabilized Plate	PL.2115

Identified uses : The Prolisa™ *C. difficile* GDH EIA is a microwell assay for the qualitative detection of *Clostridium difficile* glutamate dehydrogenase (GDH) in fecal specimens. It is intended for use as an aid in the diagnosis of *C. difficile* infections.

Company/undertaking identification

Supplier/Manufacturer : Pro-Lab Diagnostics
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Richmond Hill, ON
Canada L4B 1K3
Tel: +1-905-731-0300
Fax: +1-905-731-0206
www.pro-lab.com

e-mail address of person responsible for this SDS : support@pro-lab.com

Emergency telephone number (with hours of operation) : +44 (0)151 353 1613 -Monday to Friday 9:00 am to 5:00 pm.
+44 (0)7714 429 646 -Outside the above hours.

2. HAZARDS IDENTIFICATION

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification according to Regulation (EC) 1907/2006 (REACH)

Classification	PL.2103	Not classified.
	PL.2104	Not classified.
	PL.2110	Not classified.
	PL.2112	Not classified.
	PL.2113	Not classified.
	PL.2114	Not classified.
	PL.2115	Not classified.
Physical/chemical hazards	PL.2103	Not applicable.
	PL.2104	Not applicable.
	PL.2110	Not applicable.
	PL.2112	Not applicable.
	PL.2113	Not applicable.
	PL.2114	Not applicable.
	PL.2115	Not applicable.
Human health hazards	PL.2103	Not applicable.
	PL.2104	Not applicable.
	PL.2110	Not applicable.
	PL.2112	Not applicable.
	PL.2113	Not applicable.
	PL.2114	Not applicable.
	PL.2115	Not applicable.
Environmental hazards	PL.2103	Not applicable.
	PL.2104	Not applicable.
	PL.2110	Not applicable.
	PL.2112	Not applicable.
	PL.2113	Not applicable.
	PL.2114	Not applicable.
	PL.2115	Not applicable.

See Section 11 for more detailed information on health effects and symptoms.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/mixture : Mixture

Ingredient name	CAS number	%	Number	Classification (according to REACH)
20X Wash Buffer				
Sodium chloride	7647-14-5	10 - 30	231-598-3	Xi; R36 [1]
Disodium hydrogenorthophosphate	7558-79-4	1 - 5	231-448-7	Not classified. [2]

See section 16 for the full text of the R-phrases declared above

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.

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

[3] PBT-substance

[4] vPvB-substance

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

4. FIRST AID MEASURES

Eye contact : Immediately flush eyes with plenty of water for at least 20 minutes, occasionally lifting the upper and lower eyelids. Get medical attention if symptoms occur.

Skin contact : In case of contact, immediately flush skin with plenty of water for at least 20 minutes. Get medical attention if symptoms occur.

Inhalation : Move exposed person to fresh air.

Ingestion : Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

See Section 11 for more detailed information on health effects and symptoms.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable : Use an extinguishing agent suitable for the surrounding fire.

Not suitable : None known.

Special exposure hazards : No specific fire or explosion hazard.

Hazardous decomposition products : Decomposition products may include the following materials: halogenated compounds

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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Provide adequate ventilation. Put on appropriate personal protective equipment (see Section 8).

Environmental precautions : Avoid dispersal of spilt 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 for cleaning up

Small spill : Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : 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. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see section 1 for emergency contact information and section 13 for waste disposal.

7. HANDLING AND STORAGE

Handling : Put on appropriate personal protective equipment (see Section 8). 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. Avoid contact with eyes, skin and clothing. Empty containers retain product residue and can be hazardous.

Storage : Store in accordance with local regulations. 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. Store at 2°C (36°F) to 8°C (46°F).

Packaging materials

Recommended : Use original container.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values

Ingredient name	Occupational exposure limits
20X Wash Buffer Disodium hydrogenorthophosphate	**EU OEL (Europe).** TWA: 10 mg/m³ 8 hour(s). Form: Particulate. TWA: 3 mg/m³ 8 hour(s). Form: Respirable

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

Exposure controls

Occupational exposure controls : No special ventilation requirements. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Hygiene measures : Ensure that eyewash stations and safety showers are close to the workstation location. 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.

Respiratory : Not required under normal conditions of uses. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. Ensure an MSHA/NIOSH-approved respirator or equivalent is used.

Hands : Use gloves appropriate for work or task being performed. Recommended: Natural rubber (latex).

Eyes : Safety eyewear should be used when there is a likelihood of exposure. Recommended: Safety glasses with side shields.

Skin : 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. Recommended: Lab coat.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance

Physical state :

PL.2103	Liquid. [Clear solution.]
PL.2104	Liquid. [Clear solution.]
PL.2110	Liquid. [Hazy liquid.]
PL.2112	Liquid. [Clear solution.]
PL.2113	Liquid. [Clear solution.]
PL.2114	Liquid. [Clear solution.]
PL.2115	Solid. [Material dried on a 96 plates.]

9. PHYSICAL AND CHEMICAL PROPERTIES

Colour :

PL.2103	Colourless.
PL.2104	Colourless.
PL.2110	Colorless to white.
PL.2112	Colourless.
PL.2113	Amber.
PL.2114	Red.
PL.2115	Not applicable.

Important health, safety and environmental information

pH :

PL.2103	<2
PL.2104	3.7
PL.2110	7.4
PL.2112	6.5
PL.2113	6.2 to 6.7
PL.2114	6.2 to 6.7
PL.2115	Not available.

Solubility : Miscible in water.

10. STABILITY AND REACTIVITY

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.

Materials to avoid : Reactive or incompatible with the following materials: oxidizing materials and acids. Slightly reactive or incompatible with the following materials: metals.

Hazardous decomposition products : Decomposition products may include the following materials: halogenated compounds

11. TOXICOLOGICAL INFORMATION

Toxicokinetics

Absorption : Not available.

Distribution :

PL.2110	Contains material which may cause damage to the following organs: mucous membranes, skin, eyes.

Metabolism : Not available.

Elimination : Not available.

Potential acute health effects

Inhalation :

PL.2103	May give off gas, vapor or dust that is very irritating or corrosive to the respiratory system.
PL.2104	No known significant effects or critical hazards.
PL.2110	No known significant effects or critical hazards.
PL.2112	No known significant effects or critical hazards.
PL.2113	No known significant effects or critical hazards.
PL.2114	No known significant effects or critical hazards.
PL.2115	No known significant effects or critical hazards

Ingestion :

PL.2103	May cause burns to mouth, throat and stomach.
PL.2104	No known significant effects or critical hazards.
PL.2110	No known significant effects or critical hazards.
PL.2112	No known significant effects or critical hazards.
PL.2113	No known significant effects or critical hazards.
PL.2114	No known significant effects or critical hazards.
PL.2115	No known significant effects or critical hazards.

Skin contact :

PL.2103	May cause burns to mouth, throat and stomach.
PL.2104	No known significant effects or critical hazards.
PL.2110	No known significant effects or critical hazards.
PL.2112	No known significant effects or critical hazards.
PL.2113	No known significant effects or critical hazards.
PL.2114	No known significant effects or critical hazards.
PL.2115	No known significant effects or critical hazards.

Eye contact :

PL.2103	May cause burns to mouth, throat and stomach.
PL.2104	No known significant effects or critical hazards.
PL.2110	No known significant effects or critical hazards.
PL.2112	No known significant effects or critical hazards.
PL.2113	No known significant effects or critical hazards.
PL.2114	No known significant effects or critical hazards.
PL.2115	No known significant effects or critical hazards.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
20X Wash Buffer				
Sodium chloride	LD50 Oral	Rat	3000 mg/kg	-
Disodium hydrogenorthophosphate	LD50 Oral	Rat	17000 mg/kg	-

Potential chronic health effects

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
20X Wash Buffer					
Sodium chloride	Eyes - Moderate irritant	Rabbit	-	-	-
	Skin - Mild irritant	Rabbit	-	-	-
Disodium hydrogenorthophosphate	Eyes - Mild irritant	Rabbit	-	-	-
	Skin - Mild irritant	Rabbit	-	-	-

Chronic effects : 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.

Over-exposure signs/symptoms

Inhalation : No specific data.

Ingestion : No specific data.

Skin : No specific data.

Eyes : No specific data.

12. ECOLOGICAL INFORMATION

Ecotoxicity : No known significant effects or critical hazards.

Aquatic ecotoxicity

Product/ingredient name	Result	Species	Exposure
20X Wash Buffer			
Sodium chloride	Acute EC50 402600 to 469200 ug/L Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 >5600 ppm Fresh water	Crustaceans - Asellus communis	48 hours
	Acute LC50 1000000 ug/L Fresh water	Fish - Morone saxatilis - LARVAE	96 hours
Disodium hydrogenorthophosphate	Acute LC50 3580000 ug/L Fresh water	Daphnia - Daphnia magna	48 hours

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

PBT : Not applicable.

P: Not available. B: Not available. T: Not available.

vPvB : Not applicable.

13. DISPOSAL CONSIDERATIONS

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

14. TRANSPORT INFORMATION

International transport regulations

ADR/ADNR/IMDG/IATA : Not regulated.

15. REGULATORY INFORMATION

EU regulations

Classification and labeling according to Regulation (EC) 1907/2006 (REACH)

Classification and labeling have been determined according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use.

Risk phrases	:	This product is not classified according to EU legislation.
Product use	:	Industrial applications.
Europe inventory	:	Not determined.
Black List Chemicals	:	Not listed
Priority List Chemicals	:	Not listed
Integrated pollution prevention and control list (IPPC) - Air	:	Not listed
Integrated pollution prevention and control list (IPPC) - Water	:	Not listed

Other EU regulations

Additional warning phrases : Safety data sheet available for professional user on request.

International regulations

Chemical Weapons Convention List Schedule I Chemicals	:	Not listed
Chemical Weapons Convention List Schedule II Chemicals	:	Not listed
Chemical Weapons Convention List Schedule III Chemicals	:	Not listed

16. OTHER INFORMATION

Full text of R-phrases referred to in sections 2 and 3 - United Kingdom (UK)	:	R36- Irritating to eyes.
Full text of classifications referred to in sections 2 and 3 - United Kingdom (UK)	:	Xi - Irritant

History

Date of issue (dd/mm/yyyy)	:	01/11/2010
Version	:	1

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.