

SAFETY DATA SHEET

Proflow™ *C. difficile* GDH

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Product name	: Proflow™ <i>C. difficile</i> GDH	Code
Trade name	: Proflow™ <i>C. difficile</i> GDH Proflow™ <i>C. difficile</i> GDH Cassette <i>C. difficile</i> GDH Sample Diluent <i>C. difficile</i> GDH Positive Control	PL.3001 PL.3101 PL.3102 PL.3103
Product description	: Not available.	
Product type	: Liquid.	
Other means of identification	: Not available.	

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

Identified uses	: The Proflow™ <i>C. difficile</i> GDH is a qualitative lateral flow test for the detection of <i>Clostridium difficile</i> glutamate dehydrogenase (GDH) in faecal specimens. It is intended for use as an aid in the diagnosis of <i>C. difficile</i> infections. The test detects GDH and will not differentiate between toxigenic and non-toxigenic strains of <i>C. difficile</i> . The results should be considered in conjunction with patient history and additional laboratory investigations. This test is intended for laboratory use only.
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1.3 Details of the supplier of the safety data sheet

Supplier's details	: Pro-Lab Diagnostics 20 Mural Street, Unit 4 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

1.4 Emergency telephone number

National advisory body/Poison Centre

Emergency telephone number (with hours of operation)	: +44 (0)151 353 1613 - Monday to Friday 9:00 am to 5:00 pm GMT +44 (0)7714 429 646 – Outside the above hours
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

C. difficile GDH Sample Diluent

Skin Sens. 1, H317

PL.3101 The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

PL.3102 The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

PL.3103 The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

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

2.2 Label elements

Hazard pictograms :



Signal word : **PL.3101** No signal word.
PL.3102 Warning
PL.3103 No signal word.

Hazard statements : **PL.3101** No known significant effects or critical hazards.
PL.3102 H317 - May cause an allergic skin reaction.
PL.3103 No known significant effects or critical hazards.

Precautionary statements

Prevention : P280 - Wear protective gloves.
P261 - Avoid breathing vapour.
P272 - Contaminated work clothing should not be allowed out of the workplace.

Response : P302 + P352 - IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 - If skin irritation or rash occurs: Get medical attention.

Storage : Not applicable.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazardous ingredients : **C. difficile GDH Sample Diluent**
Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one

Supplemental label elements : Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

SECTION 2: Hazards identification

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
C. difficile GDH Sample Diluent Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one	CAS: 55965-84-9 Index: 613-167-00-5	<0.06	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) See Section 16 for the full text of the H statements declared above.	[1]

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, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern
- [6] Additional disclosure due to company policy

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

SECTION 4: First aid measures

4.1 Description of 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. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

SECTION 4: First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both 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** : May cause an allergic skin reaction.
- 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** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : No specific fire or explosion hazard.
- Hazardous combustion products** : No specific data.

SECTION 5: Firefighting measures

5.3 Advice for firefighters

- 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. 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.

SECTION 6: Accidental release measures

6.1 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 spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised 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".

6.2 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).

6.3 Methods and material for containment and cleaning up

- Spill** : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. 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. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

SECTION 7: Handling and storage

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.

7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 2 to 30°C (35.6 to 86°F). 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. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

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. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

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

Individual protection measures



SECTION 8: Exposure controls/personal protection

- 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. Contaminated work clothing should not be allowed out of the workplace. 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- 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.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : **PL.3101** Solid. [Test strip in a plastic cassette packaged in a aluminum foil pouch with a desiccant.]
: **PL.3102** Liquid.
: **PL.3103** Liquid.
- Colour** : **PL.3101** Not available.
: **PL.3102** Colourless.
: **PL.3103** Colourless.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : **PL.3101** Not available.
: **PL.3102** Not available.
: **PL.3103** Not available.
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.

SECTION 9: Physical and chemical properties

Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Upper/lower flammability or explosive limits	: Not available.
Vapour pressure	: Not available.
Vapour density	: Not available.
Relative density	: Not available.
Solubility(ies)	: Not available.
Partition coefficient: n-octanol/ water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
C. difficile GDH Sample Diluent Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one	LD50 Oral	Rat	53 mg/kg	-

Irritation/Corrosion

There is no data available.

Sensitisation

There is no data available.

SECTION 11: Toxicological information

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)

There is no data available.

Aspiration hazard

There is no data available.

Information on 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** : May cause an allergic skin reaction.
- 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** : Adverse symptoms may include the following:
 - irritation
 - redness
- Ingestion** : No known significant effects or critical hazards.

Delayed and immediate effects as well as 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** : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.

SECTION 11: Toxicological information

- 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.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

There is no data available.

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

There is no data available.

12.4 Mobility in soil

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

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

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

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised 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.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

SECTION 13: Disposal considerations

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 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

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.
on the manufacture,
placing on the market
and use of certain
dangerous substances,
mixtures and articles

Other EU regulations

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

SECTION 15: Regulatory information

Seveso Directive

This product is not controlled under the Seveso Directive.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
C. difficile GDH Sample Diluent Skin Sens. 1, H317	Calculation method

Full text of abbreviated H statements

C. difficile GDH Sample Diluent H301 H311 H314 H317 H318 H331 H400 H410	Toxic if swallowed. Toxic in contact with skin. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Causes serious eye damage. Toxic if inhaled. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
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Full text of classifications [CLP/GHS]

C. difficile GDH Sample Diluent Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1, H317	ACUTE TOXICITY (oral) - Category 3 ACUTE TOXICITY (dermal) - Category 3 ACUTE TOXICITY (inhalation) - Category 3 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1 SKIN CORROSION/IRRITATION - Category 1B SKIN SENSITISATION - Category 1
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History

Date of issue (dd/mm/yyyy) : 30/09/2018
Date of previous issue : Not applicable
Version : 1
Prepared by : KMK Regulatory Services Inc.



SECTION 16: Other information

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.

