

SAFETY DATA SHEET

Proflow™ *C. difficile* GDH

Section 1. Identification

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

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

Identified uses

The Proflow™ *C. difficile* GDH is a qualitative lateral flow test for the 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. The test detects GDH and will not differentiate between toxigenic and non-toxigenic strains of *C. difficile*. The results should be considered in conjunction with patient history and additional laboratory investigations. This test is intended for laboratory use only.

Supplier's details : Pro-Lab Diagnostics
20 Mural Street, Unit 4
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Canada L4B 1K3
Tel: +1-905-731-0300
Fax: +1-905-731-0206
www.pro-lab.com

Emergency telephone number (with hours of operation) : 905-731-0300 –Monday to Friday 8:00 am to 4:30 pm Eastern Standard Time.
416-230-0692 –Outside the above hours.

Section 2. Hazard identification

Classification of the substance or mixture : SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms :



Section 2. Hazard identification

Signal word	: PL.3101	No signal word.
	PL.3102	No signal word.
	PL.3103	Warning
Hazard statements	: PL.3101	No known significant effects or critical hazards.
	PL.3102	No known significant effects or critical hazards.
	PL.3103	H317 - May cause an allergic skin reaction.
Precautionary statements		
Prevention	: P280 - Wear protective gloves.	
	P261 - Avoid breathing vapor.	
	P272 - Contaminated work clothing should not be allowed out of the workplace.	
Response	: P362 + P364 - Take off contaminated clothing and wash it before reuse.	
	P302 + P352 - IF ON SKIN: Wash with plenty of water.	
	P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention.	
Storage	: Not applicable.	
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.	

Section 3. Composition/information on ingredients

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

Ingredient name	%(w/v)	CAS number
Proflow™ C. difficile GDH Cassette Glass, oxide, chemicals Cellulose	1 - 5 0.1 - 1	65997-17-3 9004-34-6
Proflow™ C. difficile GDH Positive Control Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	0.05	55965-84-9

Ranges if listed above for hazardous ingredient(s) are prescribed ranges. The actual concentration(s) or actual concentration range(s) are being withheld as a trade secret.

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. 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.

Section 4. First-aid measures

- 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.
- 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.

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** : 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.

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. 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.

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** : No specific fire or explosion hazard.



Section 5. Fire-fighting measures

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
metal oxide/oxides
- 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. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach 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 (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. 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). 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 vapor 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 8. Exposure controls/personal protection

CA Alberta Provincial (Canada, 6/2018).
8 hrs OEL: 10 mg/m³ 8 hours.
CA Ontario Provincial (Canada, 1/2018).
TWA: 10 mg/m³ 8 hours.

- 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. 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.

Section 9. Physical and chemical properties

Appearance

- Physical state** : **PL.3101** Solid. [Test Cassette in an aluminum foil pouch with a desiccant.]
PL.3102 Liquid.
PL.3103 Liquid. [Clear.]
- Color** : **PL.3101** Not available.
PL.3102 Pale yellow.
PL.3103 Colorless.

Section 9. Physical and chemical properties

Odor	: Not available.
Odor threshold	: Not available.
pH	: PL.3101 Not available. PL.3102 7.4 PL.3103 6.5
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	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: 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
Proflow™ <i>C. difficile</i> GDH Cassette Cellulose	LD50 Oral	Rat	>5 g/kg	-
Proflow™ <i>C. difficile</i> GDH Positive Control 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

There is no data available.

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)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

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.

Section 11. Toxicological information

- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

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** : 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.
- Reproductive toxicity** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Proflow™ <i>C. difficile</i> GDH Positive Control Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	53	300	N/A	3	N/A

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Section 12. Ecological information

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. 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 spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

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

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.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

Canadian lists

Canadian NPRI : None of the components are listed.

CEPA Toxic substances : None of the components are listed.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.

Canada : At least one component is not listed in DSL but all such components are listed in NDSL.

China : Not determined.

Europe : Not determined.

Japan : **Japan inventory (ENCS)**: Not determined.
Japan inventory (ISHL): Not determined.

New Zealand : Not determined.

Philippines : Not determined.

Republic of Korea : Not determined.

Taiwan : Not determined.

Thailand : Not determined.

Turkey : Not determined.

United States : All components are active or exempted.

Viet Nam : Not determined.

Section 16. Other information

History

Date of issue/Date of revision : 07/15/2020

Date of previous issue : 09/30/2018

Version : 2

Prepared by : KMK Regulatory Services Inc.

Section 16. Other information

Key to abbreviations

- : ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- HPR = Hazardous Products Regulations
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- N/A = Not available
- SGG = Segregation Group
- UN = United Nations

Procedure used to derive the classification

Classification	Justification
Proflow™ <i>C. difficile</i> GDH Positive Control SKIN SENSITIZATION - Category 1	Calculation method

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.