



SAFETY DATA SHEET

Proflow™ *Giardia*

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

Identification of the substance or mixture

Product name	: Proflow™ <i>Giardia</i>	Code
Trade name	: Proflow™ <i>Giardia</i>	PL.3021
	Proflow™ <i>Giardia</i> Cassette	PL.3121
	Proflow™ <i>Giardia</i> Sample Prep Device	PL.3221

Identified uses : ProFlow™ *Giardia* is a single use immunochromatographic assay for the qualitative detection of *Giardia lamblia* in human stool specimens. This test is intended as an aid in the diagnosis of *Giardia lamblia* infections. As with other *Giardia lamblia* tests, results should be considered in conjunction with clinical evaluation and medical history. For In Vitro Diagnostic Use.

Company identification

Supplier/Manufacturer : Pro-Lab Diagnostics
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Bromborough,
Wirral, UK CH62 3QL
Tel: +44 (0) 151 353 1613
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www.pro-lab.com

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

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

2. HAZARDS IDENTIFICATION

Classification of the mixture

The product contains Sodium azide, at a concentration ≤ 0.1 %. So according to the classification rules related in Regulation (EC) No 1272/2008, this product is non-hazardous. Information about Sodium azide being present in the product is referred to in Other hazards (related to Sodium azide) and in Section 3. The product also contains some substances from human origin. It is therefore recommended to handle it according to the convenient procedures relative to infectious material.

Label elements

Regarding Regulation (EC) No 1272/2008, no particular statement is required since the product is not considered as hazardous.



Other hazards (related to Sodium azide)

Even in small amounts, Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Sodium azide is also rapidly absorbed through skin.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Cassette:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
5-Chloro-2-methyl-2H-isothiazol-3-one	26172-55-4	247-500-7	Chemical	<1%	T; R23 C; R34 Xn; R21/22-42/43
2-Methyl-2H-isothiazol-3-one	2682-20-4	220-239-6	Chemical	<1%	C; R34 Xi; R43 N; R50
Sodium azide	26628-22-8	247-852-1	Chemical	<0.1%	T : R28, R32 N : R50/53 Acute toxicity 2, Acute aquatic toxicity 1, Chronic aquatic toxicity 1 H300, H410

Sample Prep Device Diluent:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product (%w/w)	Hazard classification and risk phrase*
Tween 20	9005-64-5	500-018-3	Chemical	0.5 -1 %	Not classified
Sodium chloride	7647-14-5	231-598-3	Chemical	0.5-1%	Not classified
Glycine 005-221	56-40-6	200-272-2	Chemical	0-0.5%	Not classified
Sodium azide	26628-22-8	247-852-1	Chemical	0.095%	T : R28, R32 N : R50/53 Acute toxicity 2, Acute aquatic toxicity 1, Chronic aquatic toxicity 1 H300, H410

*For the full text of H-statements and R-Phrases mentioned in this section, see Section 16

Non-Hazardous components:

Description	CAS Number	Einecs Number
CASEIN	9000-71-9	232-555-1
MES FREE ACID	4432-31-9	224-632-3
SODIUM CHLORIDE	7647-14-5	231-598-3
SUCROSE 005-265 (Sucrose) 200-334-9	57-50-1	200-334-9

Confidential components:

n/a



4. FIRST AID MEASURES

General information	: Consult a physician if necessary. Show this SDS to the doctor in attendance.
Eye contact	: Contact lenses should be removed. Immediately flush eyes with plenty of water for 15 minutes, occasionally lifting the upper and lower eyelids. Seek medical attention if irritation or symptoms persist.
Skin contact	: Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist.
Inhalation	: Move exposed person to fresh air. If breathing is difficult give oxygen. Seek medical attention if symptoms persist.
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.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing media appropriate to the surrounding fire conditions.
Extinguishing measures to avoid	: No specific measures.
Special risk	: Burning produces irritating, toxic and obnoxious fumes. Carbon dioxide (CO ₂).
Special protective equipment for fire-fighting	: Wear suitable respiratory equipment when necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	: Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Wear suitable personal protective equipment.
Environmental precautions	: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Prevent further spillage if safe.
Cleaning and waste collection	: Dispose of as special waste in compliance with local and national regulations.



7. HANDLING AND STORAGE

- Handling** : Wear appropriate personal protective equipment. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Avoid contact with eyes and skin.
- Storage** : Store at room temperatures between 2°C and 30°C. Keep container tightly closed. Store in correctly labelled containers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Exposition cut off** : Sodium azide: VLE = 0.3 mg/m³
Sodium azide: VME = 0.1 mg/m³
Sucrose: VLE = 20 mg/m³
Sucrose: VME = 10 mg/m³
- Individual exposure control** : Wash hands after handling the product. Wear suitable personal protective equipment.
- Environmental exposure control** : Collect dipstick and buffer in containers according to official regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Cassette	
Aspect	Solid
Colour	White
Odour	No data available

Sample Prep Device Diluent	
Aspect	Liquid
Colour	Colourless
Odour	Odourless

Other information

N/A

10. STABILITY AND REACTIVITY

- Chemical stability** : The product is stable under normal conditions.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : Heat/flame and moisture.
- Materials to avoid** : n/a
- Hazardous decomposition Products** : n/a



11. TOXICOLOGICAL INFORMATION

Sodium Azide:

Oral Rat LD50: 27mg/kg

Dermal Rabbit LD50: 20mg/kg

12. ECOLOGICAL INFORMATION

Sodium Azide:

Daphnia EC50/48h: 4.2mg/l

Lepomis macrochirus LC50/96h: 0.68

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 2008/98/EC.

14. TRANSPORT INFORMATION

Maritime Transport IMDG

: The product is not classified as dangerous for carriage.

Transport by road ADR

: The product is not classified as dangerous for carriage.

Transport by train OACI/IATA

: The product is not classified as dangerous for carriage.

Air Transport RID

: The product is not classified as dangerous for carriage.

15. REGULATORY INFORMATION

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

Product labelling complies with the 98/79/EC IVD Medical Device directive. No specific warning labelling is required. This SDS is prepared according to Hazard Communication Standard 29 CFR 1910.1200, and Regulation (EC) No 1272/2008 – classification, labelling and packaging of substances and mixtures (CLP) of the European Parliament and of the Council of the 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.



Chemical Safety Assessment

No symbol is necessary based on our current knowledge.

16. OTHER INFORMATION

Risk Phrases in full

R21/22: Harmful in contact with skin and if swallowed.

R23: Toxic by inhalation.

R28: Very toxic if swallowed.

R32: Contact with acids liberates very toxic gas.

R34: Causes burns.

R42/43: May cause sensitisation by inhalation and skin contact.

R43: May cause sensitisation by skin contact.

R50: Very toxic to aquatic organisms.

R50/53: Very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

Hazard Statements in full

H300: Fatal if swallowed.

H410: Very toxic to aquatic life with long lasting effects.

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Notice to reader

The product is intended for in vitro diagnostic use by health professionals. Proflow™ *Giardia* does not contain any hazardous substances beyond the limits set by the HSE (Sodium azide TWA 0.1 mg/m³ STEL 0.3 mg/m³). The toxic risk is then considerably reduced and acceptable. The information in this document is based on the state of our current knowledge of the product. This document is composed in accordance with the rules and regulations of Regulation (EC) No 1272/2008.

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.