SAFETY DATA SHEET
Proflow™ Rotavirus-Adenovirus Dual Test

According to Regulation (EC) No 1907/2006, Annex II, as amended.

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Product No.
Proflow™ Rotavirus-Adenovirus Dual Test	**PL.3033**
Proflow™ Rotavirus-Adenovirus Dual Test Test Device	PL.3340
Proflow™ Rotavirus-Adenovirus Dual Test Sample Preparation Device	PL.3350

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

Identified use:	Proflow™ Rotavirus-Adenovirus Dual Test is a single use chromatographic immunoassay for the qualitative detection of Rotavirus and Adenovirus antigens in human faecal samples. This test is intended as an aid in the diagnosis of Rotavirus and Adenovirus infections. As with other Rotavirus and Adenovirus tests, results should be considered in conjunction with clinical evaluation and medical history. For *In Vitro* Diagnostic Use.
Uses advised against:	No specific uses advised against are identified.

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer:

Pro-Lab Diagnostics
3 Bassendale Road
Bromborough,
Wirral, UK CH62 3QL
Tel: +44 (0) 151 353 1613
Fax: +44 (0) 151 353 1614
www.pro-lab.co.uk

1.4 Emergency telephone number

+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

2.1 Classification of the mixture

Classification (EC 1272/2008)

Physical hazards	Not classified
Health hazards	Not classified
Environmental hazards	Not classified

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.

2.2 Label elements

Hazard statements NC Not classified

2.3 Other hazards

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

3.1 Substances: No information available.

3.2 Mixtures

Mixture description: Sample Preparation Device contains buffer, salt, detergent and Sodium Azide (at a concentration <0.1%) as a preservative.

3.2.1 Hazardous components:

Description	CAS Number	EC Number	Concentration in the final product	Regulation (EC) no 1272/2008 (CLP)	Precautionary statements
Sodium azide	26628-22-8	247-852-1	PL.3340 <0.1% PL.3350 <0.1%	Acute Tox. 2: H300 Aquatic Acute 1: H400 Aquatic Chronic 1: H410	Due to concentration <0.1%, this preparation is not classified as dangerous on the basis of health and/or environmental effects.

Lowest generic cut-off value: ≥ 0.1.
Lowest specific concentration limits/M-factor: N/A (according to ATE Annex I section 3.1.3.6.1 and Table 3.1.2, classification ≥ 1.0%).
Additional information: For full text of Hazard statements: see Section 16.

The device consists of a strip composed of several layers: an absorbent material pre-dried with a coloured latex-antibody conjugate against the target antigens, a nitro-cellulose membrane with coated antibodies against the target antigens and cellulose absorbent. Contains Sodium Azide (at a concentration <0.1%) as a preservative.

The full text for all hazard statements is displayed in Section 16.

4. FIRST AID MEASURES

4.1 Description of 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 soap and 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 and then drink plenty of 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

5.1 Extinguishing media

Suitable extinguishing media	Water or CO_2. Use extinguishing media appropriate to the surrounding fire conditions.
Extinguishing measures to avoid	No specific measures.

5.2 Special hazards arising from substance or mixture

Thermal decomposition can lead to release of irritating gases and vapours.

5.3 Advice for firefighters

Special protective equipment for fire-fighting	Wear suitable respiratory equipment when necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothes. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Wear suitable personal protective equipment.

6.2 Environmental precautions

Given the nature of the product there is no possibilty of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Dispose of as special waste in compliance with local and national regulations.

7. HANDLING AND STORAGE

7.1 Precautons for safe handling

Wear appropriate personal protective equipment. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Specimens should be handled as potentially infectious materials.

7.2 Conditions for safe storage, including any incompatibilities

Store in dry conditions between 2°C and 30°C. Avoid storage near to heat sources. Keep container tightly closed. Store in correctly labelled containers.

7.3 Specific end use(s)

Only use provided diluent for sample dilution.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ensure adequate ventilation when in use.

8.2 Exposure controls

Sodium azide:
LTEL (8 hr) = 0.1 mg/m^3
STEL = 0.3 mg/m^3

Eye/face protection	Wear suitable eye protection.
Skin protection	Wear protective clothing. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Hygiene measures	No specific hygiene measures recommended but good personal hygiene practices should always be observed.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Proflow™ Rotavirus and Adenovirus Dual Test Test Device

Appearance	Plastic cassette inside a foil pouch
Colour	White
Odour	Odourless
pH	Not determined
Boiling point	n/a
Flash point	n/a
Vapour pressure	Not determined
Melting point	Not determined
Autoignition temperature	Not determined
Partition Coefficient	Not determined
Explosion limits	n/a
Vapour density	Not determined
Relative density	Not determined
Solubility	n/a
Flammability	n/a
Viscosity	Not determined
Explosive properties	None
Oxidizing properties	Not determined

Proflow™ Rotavirus and Adenovirus Dual Test Sample Preparation Device

Appearance	Liquid
Colour	Transparent, slightly yellowish
Odour	Odourless
pH	7.5-8.5
Boiling point	100^{o}C
Flash point	n/a
Vapour pressure	23hPa
Melting point	0^{o}C
Autoignition temperature	Not determined
Partition Coefficient	Not determined
Explosion limits	n/a
Vapour density	Not determined
Relative density	1g/cm^3
Solubility	Soluble
Flammability	n/a
Viscosity	Not determined
Explosive properties	None
Oxidizing properties	Not determined

9.2 Other safety information

No information required.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reactivity known.

10.2 Chemical stability

The product is stable under normal conditions.

10.3 Possibility of hazardous reactions

Thermal decomposition can lead to release of irritating gases and vapours.

10.4 Conditions to avoid

Heat/flame, temperatures outside the range of 2-30^{o}C. Avoid storing in places with high humidity.

10.5 Materials to avoid

The sample should only be treated with the reagent that is provided with the product before testing.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity Sodium Azide: Oral Rat LD_{50}: 27mg/kg Dermal Rabbit LD_{50}: 20mg/kg	Product does not present an acute toxicity hazard based on known or supplied information.
11.2 Skin corrosion/irritation	Based upon the available data the classification criteria are not met.
11.3 Serious eye damage/irritation	Based upon the available data the classification criteria are not met.
11.4 Respiratory or skin sensitisation	Based upon the available data the classification criteria are not met.
11.5 Germ cell mutagenicity	Based upon the available data the classification criteria are not met.
11.6 Carcinogenicity	A4 - Not classifiable as a human carcinogen.
11.7 Reproductive toxicity	Based upon the available data the classification criteria are not met.
11.8 Summary of evaluation of the CMR properties	Based upon the available data the classification criteria are not met.
11.9 STOT-single exposure	Based upon the available data the classification criteria are not met.
11.10 STOT-repeated exposure	Based upon the available data the classification criteria are not met.
11.11 Aspiration hazard	Based upon the available data the classification criteria are not met.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Based upon the available data the classification criteria are not met. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

12.2 Persistance and degradability

Based upon the available data the classification criteria are not met.

12.3 Bioaccumulative Potential

Based upon the available data the classification criteria are not met.

12.4 Mobility in soil

Based upon the available data the classification criteria are not met.

12.5 Results of PBT and vPvB assessment

No data available for assessment.

12.6 Other adverse effects

Based upon the available data the classification criteria are not met.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

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

National regulations EH40/2005 Workplace exposure limits.

EU legislation Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).
Regulaton (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and rEstriction of Chemicals (REACH) (as amended).

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out.

16. OTHER INFORMATION

16.1 Hazard Statements in full

H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

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Revision 3

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