# SAFETY DATA SHEET
# Proflow™ Legionella Urinary Antigen
**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™ Legionella Urinary Antigen** | **PL.3007** |
| Proflow™ Legionella Urinary Antigen Test Device | PL.3701 |
| Proflow™ Legionella Urinary Antigen Reagent A | PL.3702 |
| Proflow™ Legionella Positive Control Swab | PL.3703 |
| Proflow™ Legionella Positive Control Reagent | PL.3704 |
| Proflow™ Legionella Negative Control Swab | PL.3705 |
| Proflow™ Legionella Negative Control Reagent | PL.3706 |

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

Identified use: Proflow™ Legionella Urinary Antigen is a single use chromatographic immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 soluble antigens in human urine samples. This test is intended as an aid in the diagnosis of *L.pneumophila* infections. As with other *L.pneumophila* 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:** Reagent A, Positive Control Reagent and Negative Control Reagent contain buffer, salt, 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.3701 <0.1%<br>PL.3702 <0.1%<br>PL.3703 <0.1%<br>PL.3704 <0.1%<br>PL.3705 <0.1%<br>PL.3706 <0.1% | Acute Tox. 2: H300<br>Aquatic Acute 1: H400<br>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 Positive Control is an inactivated *L.pneumophila* serogroup 1 antigen extract dried on a swab which contains Sodium Azide (at a concentration <0.1%) as a preservative.

The Negative Control is a non-specific antigen extract dried on a swab which 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™ Legionella Urinary Antigen 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™ Legionella Urinary Antigen Reagent A**

| | |
|---|---|
| Appearance | Liquid |
| Colour | Transparent, slightly yellowish |
| Odour | Odourless |
| pH | 8.7-9.7 |
| Boiling point | 100°C |
| Flash point | n/a |

| | |
|---|---|
| Vapour pressure | 23hPa |
| Melting point | 0°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 |

**Proflow™ Legionella Urinary Antigen Positive Control Swab**

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

**Proflow™ Legionella Urinary Antigen Positive Control Reagent**

| | |
|---|---|
| Appearance | Liquid |
| Colour | Transparent, slightly yellowish |
| Odour | Odourless |
| pH | 8.7-9.7 |
| Boiling point | 100°C |
| Flash point | n/a |
| Vapour pressure | 23hPa |
| Melting point | 0°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 |

**Proflow™ Legionella Urinary Antigen Negative Control Swab**

| | |
|---|---|
| Appearance | Swab inside a foil pouch |
| Colour | White |
| Odour | Odourless |
| pH | Not determined |
| Boiling point | n/a |
| Flash point | n/a |
| Vapour pressure | n/a |

| | |
|---|---|
| Melting point | n/a |
| Autoignition temperature | Not determined |
| Partition Coefficient | Not determined |
| Explosion limits | n/a |
| Vapour density | Not determined |
| Relative density | n/a |
| Solubility | Non-soluble |
| Flammability | Not determined |
| Viscosity | Not determined |
| Explosive properties | None |
| Oxidizing properties | Not determined |

**Proflow™ Legionella Urinary Antigen Negative Control Reagent**

| | |
|---|---|
| Appearance | Liquid |
| Colour | Transparent, slightly yellowish |
| Odour | Odourless |
| pH | 8.7-9.7 |
| Boiling point | 100°C |
| Flash point | n/a |
| Vapour pressure | 23hPa |
| Melting point | 0°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°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** Product does not present an acute toxicity hazard based on known or supplied information.

Sodium Azide:

Oral Rat $LD_{50}$: 27mg/kg
Dermal Rabbit $LD_{50}$: 20mg/kg

**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.

**Revision date** 2021 01

**Revision** 3

**Supersedes date** 2020 05

**SDS number** PF005

**Disclaimer**

**The information in the safety data sheet was obtained from current and reliable sources. However, the data is provided without warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal of the product are beyond Pro-Lab Diagnostics' control, it is the user's responsibilty to perform thorough testing of this product when used in combination with any other product. It is suggested that users familiarise themselves with this safety data sheet before handling the product.**