

Date : 15/08/2017

Version : 2

## SAFETY DATA SHEET

#### E. coli O157 Antiserum

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

1.1 Product identifier

Product name : E. coli O157 Antiserum

Trade name : E. coli 0157 Antiserum PL.6250

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

Identified uses : Pro-Lab E. coli O157 Antiserum is for use in the slide agglutination test for the

presumptive identification of Escherichia coli serotype O157 antigen on laboratory

culture media.

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

**Emergency telephone** : +44 (0)151 353 1613 -Monday to Friday 8:30 am to 5:00 pm.

number (with hours of +44 (0)7714 429 646 -Outside the above hours.

operation)

#### **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]

Not classified.

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

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

2.2 Label elements

Signal word : No signal word.

**Hazard statements** : No known significant effects or critical hazards.





#### **SECTION 2: Hazards identification**

#### **Precautionary statements**

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label : Not applicable.

elements

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and

: Not applicable.

**Special packaging requirements** 

Containers to be fitted with child-resistant

: Not applicable.

fastenings

articles

Tactile warning of danger : Not applicable.

2.3 Other hazards

Inhalation

Ingestion

Skin contact

Other hazards which do not result in classification

: None known.

## SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

There are no 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.

#### **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. Get medical attention if irritation occurs.

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

: Flush contaminated skin with plenty of water. Get medical attention if symptoms

: Wash out mouth with water. 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. Do not induce vomiting unless

directed to do so by medical personnel. Get medical attention if symptoms occur.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training.

## 4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contactInhalationNo known significant effects or critical hazards.No known significant effects or critical hazards.



#### **SECTION 4: First aid measures**

Skin contactIngestionNo known significant effects or critical hazards.No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

Eye contact
 Inhalation
 Skin contact
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 Indestion
 No known significant effects or critical hazards.
 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

: In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous combustion products

: No specific data.

#### 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. 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".





#### SECTION 6: Accidental release measures

## **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. 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.

## 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).

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

Keep container tightly closed. Store at 2°C to 8°C.

#### 7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific : Not available.

solutions

## **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





### **SECTION 8: Exposure controls/personal protection**

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**

**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. 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.

Recommended: Disposable vinyl gloves.

**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 Environmental exposure : Not applicable.

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 : Liquid. [Antiserum vial / 3.0 ml fill.]

**Colour** : Clear brownish solution.

Odour : Not available.
Odour threshold : Not available.
pH : Not available.





### **SECTION 9: Physical and chemical properties**

Melting point/freezing point Initial boiling point and boiling

range

: Not available.

: Not available.

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/: Not available.

water

**Auto-ignition temperature** : Not available. **Decomposition temperature** : Not available. : Not available. **Viscosity** 

**Explosive properties**  Not available. **Oxidising properties** : Not available.

#### 9.2 Other information

No additional information.

## **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 : Under normal conditions of storage and use, hazardous decomposition products should not be produced. decomposition products

## SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

#### **Acute toxicity**

There is no data available.

#### Irritation/Corrosion

There is no data available.

#### **Sensitisation**



## SECTION 11: Toxicological information

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 likely routes

of exposure

: Dermal contact. Eye contact. Inhalation. Ingestion.

#### Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

#### Symptoms related to the physical, chemical and toxicological characteristics

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 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** : No known significant effects or critical hazards.

effects

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

**Potential immediate** : No known significant effects or critical hazards.

effects

Potential delayed effects : No known significant effects or critical hazards.

#### Potential chronic health effects

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.



## Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - United Kingdom (UK)



E. coli O157 Antiserum

### SECTION 11: Toxicological information

**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

: Not available.

 $\textbf{coefficient} \; (\textbf{K}_{\text{oc}})$ 

**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** 

: Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

#### **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.

#### **Special precautions**

: This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt 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<br>hazard class(es) | -              | -              | -              | -              |
| 14.4 Packing group                 | -              | -              | -              | -              |
| 14.5<br>Environmental<br>hazards   | No.            | No.            | No.            | No.            |
| Additional information             | -              | -              | -              | -              |

user

14.6 Special precautions for : 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

**Europe inventory** : Not determined. Ozone depleting substances (1005/2009/EU)

Not listed.

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

Not listed.

**Seveso Directive** 

This product is not controlled under the Seveso Directive.

**National regulations** 



## Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - United Kingdom (UK)



E. coli O157 Antiserum

## **SECTION 15: Regulatory information**

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 |
|-----------------|---------------|
| Not classified. |               |

#### Full text of abbreviated H statements

Not applicable.

#### Full text of classifications [CLP/GHS]

Not applicable.

#### **History**

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Prepared by : KMK Regulatory Services Inc.

#### 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.

