

# SAFETY DATA SHEET

## Prolex™ Streptococcal Xtra Select Kit

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

#### 1.1 Product identifier

<b>Product name</b>	: Prolex™ Streptococcal Xtra Select Kit	<b>Code</b>	
<b>Trade name</b>	: Prolex™ Streptococcal Xtra Select Kit: Group A Streptococcal Xtra Latex Reagent Group B Streptococcal Xtra Latex Reagent Streptococcal Xtra Extraction Reagent Polyvalent Positive Control	PL.1042 PL.1031 PL.1032 PL.1037 PL.1040	
<b>Material uses</b>	: Provides a rapid platform for serological identification of beta-haemolytic streptococci belonging to Lancefield groups A and B.		
<b>Other means of identification</b>	: Not available.		

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

Not applicable.

#### 1.3 Details of the supplier of the safety data sheet

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

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Product definition** : Mixture

#### Classification according to Directive 1999/45/EC [DPD]

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

<b>Classification</b>	: PL.1031	Not classified.
	PL.1032	Not classified.
	PL.1037	Not classified.
	PL.1040	Not classified.
<b>Physical/chemical hazards</b>	: PL.1031	Not applicable.
	PL.1032	Not applicable.
	PL.1037	Not applicable.
	PL.1040	Not applicable.

## SECTION 2: Hazards identification

<b>Human health hazards</b>	: PL.1031	Not applicable.
	PL.1032	Not applicable.
	PL.1037	Not applicable.
	PL.1040	Not applicable.
<b>Environmental hazards</b>	: PL.1031	Not applicable.
	PL.1032	Not applicable.
	PL.1037	Not applicable.
	PL.1040	Not applicable.

See Section 16 for the full text of the R phrases or H statements declared above.

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

### 2.2 Label elements

<b>Signal word</b>	: No signal word.
<b>Hazard statements</b>	: No known significant effects or critical hazards.
<b><u>Precautionary statements</u></b>	
<b>Prevention</b>	: Not applicable.
<b>Response</b>	: Not applicable.
<b>Storage</b>	: Not applicable.
<b>Disposal</b>	: Not applicable.
<b>Risk phrases</b>	: This product is not classified according to EU legislation.
<b>Safety phrases</b>	: Not applicable.
<b>Supplemental label elements</b>	: Not applicable.

### **Special packaging requirements**

<b>Containers to be fitted with child-resistant fastenings</b>	: Not applicable.
<b>Tactile warning of danger</b>	: Not applicable.

### 2.3 Other hazards

<b>Other hazards which do not result in classification</b>	: Not available.
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## SECTION 3: Composition/information on ingredients

<b>Substance/mixture</b>	: Mixture
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## SECTION 4: First aid measures

### 4.1 Description of first aid measures

<b>Eye contact</b>	: 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.
<b>Inhalation</b>	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
<b>Skin contact</b>	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	: 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.
<b>Protection of first-aiders</b>	: 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**

## SECTION 4: First aid measures

<b>Eye contact</b>	<b>:</b>	PL.1031	No known significant effects or critical hazards.
		PL.1032	No known significant effects or critical hazards.
		PL.1037	No known significant effects or critical hazards.
		PL.1040	No known significant effects or critical hazards.
<b>Inhalation</b>	<b>:</b>	PL.1031	No known significant effects or critical hazards.
		PL.1032	No known significant effects or critical hazards.
		PL.1037	No known significant effects or critical hazards.
		PL.1040	No known significant effects or critical hazards.
<b>Skin contact</b>	<b>:</b>	PL.1031	No known significant effects or critical hazards.
		PL.1032	No known significant effects or critical hazards.
		PL.1037	No known significant effects or critical hazards.
		PL.1040	No known significant effects or critical hazards.
<b>Ingestion</b>	<b>:</b>	PL.1031	No known significant effects or critical hazards.
		PL.1032	No known significant effects or critical hazards.
		PL.1037	No known significant effects or critical hazards.
		PL.1040	No known significant effects or critical hazards.

### Over-exposure signs/symptoms

<b>Eye contact</b>	<b>:</b>	No specific data.
<b>Inhalation</b>	<b>:</b>	No specific data.
<b>Skin contact</b>	<b>:</b>	No specific data.
<b>Ingestion</b>	<b>:</b>	No specific data.

### 4.3 Indication of any immediate medical attention and special treatment needed

<b>Notes to physician</b>	<b>:</b>	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
<b>Specific treatments</b>	<b>:</b>	No specific treatment.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	<b>:</b>	Use an extinguishing agent suitable for the surrounding fire.
<b>Unsuitable extinguishing media</b>	<b>:</b>	None known.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	<b>:</b>	No specific fire or explosion hazard.
<b>Hazardous thermal decomposition products</b>	<b>:</b>	No specific data.

### 5.3 Advice for firefighters

<b>Special protective actions for fire-fighters</b>	<b>:</b>	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.
<b>Special protective equipment for fire-fighters</b>	<b>:</b>	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 Section 8 for additional information on hygiene 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 materials 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 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. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- 7.2 Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

### 7.3 Specific end use(s)

- Recommendations** : Store in the original containers at 2°C to 8°C.
- Industrial sector specific solutions** : Not available.

## SECTION 8: Exposure controls/personal protection

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).

### 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 European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

#### Derived effect levels

No DELs available.

#### Predicted effect concentrations

No PECs available.

### 8.2 Exposure controls

**Appropriate engineering controls** : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

#### 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 or dusts.

#### 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.

**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** : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

**Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	: PL.1031	Liquid. [Suspension.]
	PL.1032	Liquid. [Suspension.]
	PL.1037	Liquid. [Transparant.]
	PL.1040	Liquid. [Transparant.]
<b>Colour</b>	: PL.1031	Blue.
	PL.1032	Blue.
	PL.1037	White.
	PL.1040	White.
<b>Odour</b>	: Not available.	
<b>Odour threshold</b>	: Not available.	
<b>pH</b>	: PL.1031	7.35
	PL.1032	7.35
	PL.1037	8.5
	PL.1040	7.4
<b>Melting point/freezing point</b>	: Not available.	
<b>Boiling point</b>	: Not available.	
<b>Flash point</b>	: PL.1031	Not available.
	PL.1032	Not available.
	PL.1037	Not available.
	PL.1040	Not available.
<b>Evaporation rate</b>	: Not available.	
<b>Flammability</b>	: Not available.	
<b>Burning time</b>	: Not applicable.	
<b>Burning rate</b>	: Not applicable.	
<b>Upper/lower flammability or explosive limits</b>	: Not available.	
<b>Vapour pressure</b>	: Not available.	
<b>Vapour density</b>	: Not available.	
<b>Relative density</b>	: PL.1031	Not available.
	PL.1032	Not available.
	PL.1037	Not available.
	PL.1040	Not available.
<b>Solubility(ies)</b>	: PL.1031	Not available.
	PL.1032	Not available.
	PL.1037	Not available.
	PL.1040	Not available.
<b>Partition coefficient: n-octanol/water</b>	: Not available.	
<b>Auto-ignition temperature</b>	: Not available.	
<b>Decomposition temperature</b>	: Not available.	
<b>Viscosity</b>	: Not available.	
<b>Explosive properties</b>	: Not available.	
<b>Oxidising properties</b>	: 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** : No specific data.
- 10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

There is no data available.

#### Irritation/Corrosion

- Skin** : There is no data available.
- Eyes** : There is no data available.
- Respiratory** : There is no data available.

#### Sensitisation

- Skin** : There is no data available.
- Respiratory** : 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** : 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** : No specific data.

## SECTION 11: Toxicological information

<b>Inhalation</b>	: No specific data.
<b>Skin contact</b>	: No specific data.
<b>Ingestion</b>	: No specific data.

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

<b>Potential immediate effects</b>	: Not available.
<b>Potential delayed effects</b>	: Not available.

#### Long term exposure

<b>Potential immediate effects</b>	: Not available.
<b>Potential delayed effects</b>	: Not available.

#### Potential chronic health effects

<b>General</b>	: No known significant effects or critical hazards.
<b>Carcinogenicity</b>	: No known significant effects or critical hazards.
<b>Mutagenicity</b>	: No known significant effects or critical hazards.
<b>Teratogenicity</b>	: No known significant effects or critical hazards.
<b>Developmental effects</b>	: No known significant effects or critical hazards.
<b>Fertility effects</b>	: 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

<b>Soil/water partition coefficient (<math>K_{oc}</math>)</b>	: No data available.
<b>Mobility</b>	: Not available.

### 12.5 Results of PBT and vPvB assessment

<b>PBT</b>	: Not applicable.
<b>vPvB</b>	: 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. 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.

**Hazardous waste** : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

#### 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

	<b>ADR/RID</b>	<b>ADN/ADNR</b>	<b>IMDG</b>	<b>IATA</b>
<b>14.1 UN number</b>	Not regulated.	Not regulated.	Not regulated.	Not regulated.
<b>14.2 UN proper shipping name</b>	-	-	-	-
<b>14.3 Transport hazard class(es)</b>	-	-	-	-
<b>14.4 Packing group</b>	-	-	-	-
<b>14.5 Environmental hazards</b>	No.	No.	No.	No.
<b>14.6 Special precautions for user</b>	Not available.	Not available.	Not available.	Not available.
<b>Additional information</b>	-	-	-	-

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** : Not available.

## 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

#### Substances of very high concern

None of the components are listed.

## SECTION 15: Regulatory information

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

### Other EU regulations

**Europe inventory** : Not determined.

**Black List Chemicals** : Not listed

**Priority List Chemicals** : Not listed

**Integrated pollution prevention and control list (IPPC) - Air** : Not listed

**Integrated pollution prevention and control list (IPPC) - Water** : Not listed

**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]  
 DNEL = Derived No Effect Level  
 EUH statement = CLP-specific Hazard statement  
 PNEC = Predicted No Effect Concentration  
 RRN = REACH Registration Number

### Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

### 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.

**Full text of abbreviated R phrases** : Not applicable.

**Full text of classifications [DSD/DPD]** : Not applicable.

### History

**Date of issue (dd/mm/yyyy)** : 15/02/2012

**Version** : 1

**Revised Section(s)** : Not applicable.

### 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.