

SAFETY DATA SHEET

Prolex™ Streptococcal Grouping Latex Kits

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

1.1 Product identifier

Product name : Prolex™ Streptococcal Grouping Latex Kits

Trade name		Code
	: Prolex™ <i>Streptococcal Grouping</i> Latex Kits:	PL.030 / PL.041
	Streptococcal Grouping Reagent Latex Suspension Group A	PL.031
	Streptococcal Grouping Reagent Latex Suspension Group B	PL.032
	Streptococcal Grouping Reagent Latex Suspension Group C	PL.033
	Streptococcal Grouping Reagent Latex Suspension Group D	PL.034
	Streptococcal Grouping Reagent Latex Suspension Group F	PL.035
	Streptococcal Grouping Reagent Latex Suspension Group G	PL.036
	Streptococcal Grouping Reagent Extraction Reagent 1	PL.037
	Streptococcal Grouping Reagent Extraction Reagent 2	PL.038
	Streptococcal Grouping Reagent Extraction Reagent 3	PL.039
	Streptococcal Grouping Reagent Positive Control	PL.040

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

Identified uses : Provides a rapid method for the serological identification of groups A, B, C, D, F and G of the Lancefield groups of streptococci grown on agar plates.

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

National advisory body/Poison Centre

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 Regulation (EC) No. 1272/2008 [CLP/GHS]

Streptococcal Grouping Reagent Extraction Reagent 1- PL.037

Acute Tox. 4, H302

Aquatic Acute 1, H400 (M=1)

Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038

Met. Corr. 1, H290

Skin Corr. 1, H314

Eye Dam. 1, H318

Streptococcal Grouping Reagent Extraction Reagent 3 - PL.039

Skin Irrit. 2, H315

Eye Irrit. 2, H319

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

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

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

2.2 Label elements

Hazard pictograms :



Signal word :

PL.031

No signal word.

PL.032

No signal word.

PL.033

No signal word.

PL.034

No signal word.

PL.035

No signal word.

PL.036

No signal word.

PL.037

Warning

PL.038

Danger

PL.039

Warning

PL.040

No signal word.

Hazard statements :

PL.031

No known significant effects or critical hazards.

PL.032

No known significant effects or critical hazards.

PL.033

No known significant effects or critical hazards.

PL.034

No known significant effects or critical hazards.

PL.035

No known significant effects or critical hazards.

PL.036

No known significant effects or critical hazards.

PL.037

H302 - Harmful if swallowed.

PL.038

H400 - Very toxic to aquatic life.

PL.039

H290 - May be corrosive to metals.

PL.040

H314 - Causes severe skin burns and eye damage.

PL.039

H319 - Causes serious eye irritation.

PL.040

H315 - Causes skin irritation.

PL.040

No known significant effects or critical hazards.

Precautionary statements

SECTION 2: Hazards identification

- Prevention** : P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing.
P234 - Keep only in original container.
P273 - Avoid release to the environment.
- Response** : P304 + P340 + P310 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or physician.
P301 + P310 + P331 - IF SWALLOWED: Immediately call a POISON CENTER or physician. Do NOT induce vomiting.
P303 + P361 + P353 + P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER or physician.
P305 + P310 - IF IN EYES: Immediately call a POISON CENTER or physician.
- Storage** : Not applicable.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazardous ingredients** : Sodium nitrite
- Supplemental label elements** : Not applicable.
- Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.
- Special packaging requirements**
- Containers to be fitted with child-resistant fastenings** : Not applicable.
- Tactile warning of danger** : Not applicable.

2.3 Other hazards

- Other hazards which do not result in classification** : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
Streptococcal Grouping Reagent Extraction Reagent 1 - PL.037 Sodium nitrite	EC: 231-555-9 CAS: 7632-00-0 Index: 007-010-00-4	≥5 - ≤10	Ox. Sol. 3, H272 Acute Tox. 3, H301 Aquatic Acute 1, H400 (M=10)	[1]
Methanol	EC: 200-659-6 CAS: 67-56-1 Index: 603-001-00-X	≤0.3	Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370	[1] [2]
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	EC: 200-580-7	<25	Flam. Liq. 3, H226	[1] [2]



SECTION 3: Composition/information on ingredients

	CAS: 64-19-7 Index: 607-002-00-6		Skin Corr. 1A, H314 Eye Dam. 1, H318	
--	-------------------------------------	--	---	--

There are no additional 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.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Get medical attention immediately. Call a poison centre or physician. Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Chemical burns must be treated promptly by a physician.
- Inhalation** : Get medical attention immediately. Call a poison centre or physician. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Get medical attention immediately. Call a poison centre or physician. Flush contaminated skin with plenty of water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Chemical burns must be treated promptly by a physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Get medical attention immediately. Call a poison centre or physician. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Chemical burns must be treated promptly by a physician. Never give anything by mouth to an unconscious person.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects



SECTION 4: First aid measures

Eye contact	:	PL.031	No known significant effects or critical hazards.
		PL.032	No known significant effects or critical hazards.
		PL.033	No known significant effects or critical hazards.
		PL.034	No known significant effects or critical hazards.
		PL.035	No known significant effects or critical hazards.
		PL.036	No known significant effects or critical hazards.
		PL.037	No known significant effects or critical hazards.
		PL.038	Causes serious eye damage.
		PL.039	Causes serious eye irritation.
		PL.040	No known significant effects or critical hazards.
Inhalation	:	PL.031	No known significant effects or critical hazards.
		PL.032	No known significant effects or critical hazards.
		PL.033	No known significant effects or critical hazards.
		PL.034	No known significant effects or critical hazards.
		PL.035	No known significant effects or critical hazards.
		PL.036	No known significant effects or critical hazards.
		PL.037	No known significant effects or critical hazards.
		PL.038	No known significant effects or critical hazards.
		PL.039	No known significant effects or critical hazards.
		PL.040	No known significant effects or critical hazards.
Skin contact	:	PL.031	No known significant effects or critical hazards.
		PL.032	No known significant effects or critical hazards.
		PL.033	No known significant effects or critical hazards.
		PL.034	No known significant effects or critical hazards.
		PL.035	No known significant effects or critical hazards.
		PL.036	No known significant effects or critical hazards.
		PL.037	No known significant effects or critical hazards.
		PL.038	Causes severe burns.
		PL.039	Causes skin irritation.
		PL.040	No known significant effects or critical hazards.
Ingestion	:	PL.031	No known significant effects or critical hazards.
		PL.032	No known significant effects or critical hazards.
		PL.033	No known significant effects or critical hazards.
		PL.034	No known significant effects or critical hazards.
		PL.035	No known significant effects or critical hazards.
		PL.036	No known significant effects or critical hazards.
		PL.037	Harmful if swallowed.
		PL.038	No known significant effects or critical hazards.
		PL.039	No known significant effects or critical hazards.
		PL.040	No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	:	Adverse symptoms may include the following: pain watering redness
Inhalation	:	No known significant effects or critical hazards.
Skin contact	:	Adverse symptoms may include the following: pain or irritation redness blistering may occur
Ingestion	:	Adverse symptoms may include the following: stomach pains

SECTION 4: First aid measures

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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** : This material is very toxic to aquatic life. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides

5.3 Advice for firefighters

- Special protective actions for fire-fighters** : No special measures are required.
- 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. Do not breathe vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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".

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). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

6.3 Methods and material for containment and cleaning up

SECTION 6: Accidental release measures

Spill : Stop leak if without risk. Move containers from spill area. Absorb spillage to prevent material damage. Approach the release from upwind. 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. Contaminated absorbent material may pose the same hazard as the spilt product.

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). Do not get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container. Absorb spillage to prevent material damage.

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

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. Store in corrosive resistant container with a resistant inner liner. Store locked up. 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. Store between the following temperatures: 2°C to 8°C.

Seveso Directive - Reporting thresholds (in tonnes)

Named substances

Name	Notification and MAPP threshold	Safety report threshold
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 Methanol	500	5000

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1 9i: Very toxic for the environment	100 100	200 200

7.3 Specific end use(s)

SECTION 7: Handling and storage

- Recommendations** : Not available.
Industrial sector specific solutions : Not available.

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

Product/ingredient name	Exposure limit values
Streptococcal Grouping Reagent Extraction Reagent 1 - PL.037 Methanol	EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin. STEL: 333 mg/m ³ 15 minutes. STEL: 250 ppm 15 minutes. TWA: 266 mg/m ³ 8 hours. TWA: 200 ppm 8 hours.
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	EU OEL (Europe, 12/2009). TWA: 10 ppm 8 hours. TWA: 25 mg/m ³ 8 hours.

- 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 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** : If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants 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.

SECTION 8: Exposure controls/personal protection

- 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: chemical splash goggles and/or face shield. If inhalation hazards exist, a full-face respirator may be required instead.
- 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- 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** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Environmental exposure 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**
- | | |
|--------|-----------------------|
| PL.031 | Liquid. [Suspension.] |
| PL.032 | Liquid. [Suspension.] |
| PL.033 | Liquid. [Suspension.] |
| PL.034 | Liquid. [Suspension.] |
| PL.035 | Liquid. [Suspension.] |
| PL.036 | Liquid. [Suspension.] |
| PL.037 | Liquid. [Solution.] |
| PL.038 | Liquid. [Solution.] |
| PL.039 | Liquid. [Solution.] |
| PL.040 | Liquid. [Solution.] |
- Colour**
- | | |
|--------|----------------------|
| PL.031 | Blue. |
| PL.032 | Blue. |
| PL.033 | Blue. |
| PL.034 | Blue. |
| PL.035 | Blue. |
| PL.036 | Blue. |
| PL.037 | Yellow, transparant. |
| PL.038 | Red, transparant. |
| PL.039 | Blue, transparant. |
| PL.040 | Colourless, clear. |
- Odour** : Not available.

SECTION 9: Physical and chemical properties

Odour threshold	: Not available.
pH	: PL.031 8
	PL.032 8
	PL.033 8
	PL.034 8
	PL.035 8
	PL.036 8
	PL.037 7.5
	PL.038 2
	PL.039 7.8
	PL.040 6 to 7
Melting point/freezing point	: Not available.
Initial boiling point and boiling range	: 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)	: Miscible in water.
Partition coefficient: n-octanol/ water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
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.



SECTION 10: Stability and reactivity

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

Product/ingredient name	Result	Species	Dose	Exposure
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	LD50 Oral	Rat	3310 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Streptococcal Grouping Reagent Latex Suspension Group A to G - PL.031 to PL.036 Boric acid	Skin - Mild irritant	Human	-	72 hours 15 mg Intermittent	-
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 Sodium nitrite	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
	Skin - Mild irritant	Human	-	24 hours 50 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 50 mg	-
	Skin - Severe irritant	Rabbit	-	525 mg	-
Streptococcal Grouping Reagent Extraction Reagent 3 - PL.039 Trometamol	Skin - Moderate irritant	Rabbit	-	25%	-
	Skin - Severe irritant	Rabbit	-	500 mg	-
	Skin - Moderate irritant	Woman	-	1%	-
Polyethylene Glycol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Mild irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	500 mg	-

Sensitisation

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)

Name	Category	Route of exposure	Target organs
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 Methanol	Category 1	Not determined	Not determined



SECTION 11: Toxicological information

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	PL.031	No known significant effects or critical hazards.
	PL.032	No known significant effects or critical hazards.
	PL.033	No known significant effects or critical hazards.
	PL.034	No known significant effects or critical hazards.
	PL.035	No known significant effects or critical hazards.
	PL.036	No known significant effects or critical hazards.
	PL.037	No known significant effects or critical hazards.
	PL.038	Causes serious eye damage.
	PL.039	Causes serious eye irritation.
Inhalation	PL.040	No known significant effects or critical hazards.
	PL.031	No known significant effects or critical hazards.
	PL.032	No known significant effects or critical hazards.
	PL.033	No known significant effects or critical hazards.
	PL.034	No known significant effects or critical hazards.
	PL.035	No known significant effects or critical hazards.
	PL.036	No known significant effects or critical hazards.
	PL.037	No known significant effects or critical hazards.
	PL.038	No known significant effects or critical hazards.
Skin contact	PL.039	No known significant effects or critical hazards.
	PL.040	No known significant effects or critical hazards.
	PL.031	No known significant effects or critical hazards.
	PL.032	No known significant effects or critical hazards.
	PL.033	No known significant effects or critical hazards.
	PL.034	No known significant effects or critical hazards.
	PL.035	No known significant effects or critical hazards.
	PL.036	No known significant effects or critical hazards.
	PL.037	No known significant effects or critical hazards.
Ingestion	PL.038	Causes severe burns.
	PL.039	Causes skin irritation.
	PL.040	No known significant effects or critical hazards.
	PL.031	No known significant effects or critical hazards.
	PL.032	No known significant effects or critical hazards.
	PL.033	No known significant effects or critical hazards.
	PL.034	No known significant effects or critical hazards.
	PL.035	No known significant effects or critical hazards.
	PL.036	No known significant effects or critical hazards.
PL.037	Harmful if swallowed.	
PL.038	No known significant effects or critical hazards.	
PL.039	No known significant effects or critical hazards.	
PL.040	No known significant effects or critical hazards.	

Symptoms related to the physical, chemical and toxicological characteristics

SECTION 11: Toxicological information

- Eye contact** : Adverse symptoms may include the following:
pain
watering
redness
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur
- Ingestion** : Adverse symptoms may include the following:
stomach pains

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

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

Long term exposure

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

Product/ingredient name	Result	Species	Exposure
Streptococcal Grouping Reagent Latex Suspension Group A to G - PL.031 to PL.036 Boric acid	Acute LC50 45.5 mg/L Fresh water Acute LC50 133000 µg/L Fresh water Acute LC50 75 mg/L Marine water Chronic NOEC 6000 µg/L Fresh water Chronic NOEC 2100 µg/L Fresh water	Crustaceans - Ceriodaphnia dubia Daphnia - Daphnia magna - Neonate Fish - Pagrus major Daphnia - Daphnia magna Fish - Oncorhynchus mykiss	48 hours 48 hours 96 hours 21 days 87 days
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 Sodium nitrite	Acute EC50 159000 µg/L Marine water Acute EC50 1600000 µg/L Marine water Acute LC50 1100 µg/L Fresh water Acute LC50 48 µg/L Fresh water Chronic NOEC 0.912 mg/L Marine water	Algae - Tetraselmis chuii Algae - Tetraselmis chuii Crustaceans - Cherax quadricarinatus Fish - Ictalurus punctatus - Fingerling Fish - Hippocampus abdominalis - Juvenile (Fledgling, Hatchling, Weanling)	72 hours 96 hours 48 hours 96 hours 35 days

SECTION 12: Ecological information

Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	Acute EC50 73400 µg/L Fresh water Acute EC50 65000 µg/L Fresh water Acute LC50 50.1 ul/L Marine water Acute LC50 75000 µg/L Fresh water	Algae - Navicula seminulum Daphnia - Daphnia magna - Neonate Crustaceans - Artemia sp. Fish - Lepomis macrochirus	96 hours 48 hours 48 hours 96 hours
Streptococcal Grouping Reagent Extraction Reagent 3 - PL.039 Polyethylene Glycol	Acute LC50 >1000000 µg/L Fresh water	Fish - Salmo salar - Parr	96 hours

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Streptococcal Grouping Reagent Latex Suspension Group A to G - PL.031 to PL.036 Boric acid	-1.09	-	low
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037 Sodium nitrite	-3.7	-	low
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Acetic acid	-0.17	3.16	low
Streptococcal Grouping Reagent Extraction Reagent 3 - PL.039 Polyethylene Glycol	-	3.2	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : There is no data available.

Mobility : There is no data 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).

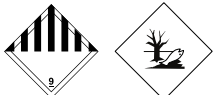
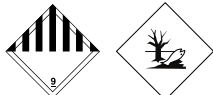
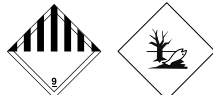

13.1 Waste treatment methods

Product

SECTION 13: Disposal considerations

- 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** : The classification of the product may meet the criteria for a hazardous waste.
- 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. Care should be taken when handling empty containers that have not been cleaned or rinsed out. 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	UN3316	UN3316	UN3316	UN3316
14.2 UN proper shipping name	CHEMICAL KIT	CHEMICAL KIT	CHEMICAL KIT. Marine pollutant (Sodium nitrite)	CHEMICAL KIT
14.3 Transport hazard class(es)	9 	9 	9 	9 
14.4 Packing group	II	II	II	II
14.5 Environmental hazards	Yes.	Yes.	Yes.	Yes. The environmentally hazardous substance mark is not required.
Additional information	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg. Remarks Limited Quantity Exemption	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg. Remarks Limited Quantity Exemption	The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg. Emergency schedules (EmS) F-A, S-P Remarks Limited Quantity Exemption	The environmentally hazardous substance mark may appear if required by other transportation regulations. Remarks Limited Quantity Exemption

- 14.6 Special precautions for user** : **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 : All components are listed or exempted.

Ozone depleting substances (1005/2009/EU)

Not listed.

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

Not listed.

Seveso Directive

This product is controlled under the Seveso Directive.

Named substances

Name
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037
Methanol

Danger criteria

Category
Streptococcal Grouping Reagent Extraction Reagent 1- PL.037
E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1
9i: Very toxic for the environment

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

Key literature references and sources for data : Streptococcal Grouping Reagent Latex Suspension: Group A – PL.031; Group B – PL.032; Group C – PL.033; Group D – PL.034; Group F – PL.035; Group G – PL.036

SECTION 16: Other information

[Procedure used to derive the classification according to Regulation \(EC\) No. 1272/2008 \[CLP/GHS\]](#)

Classification	Justification
Streptococcal Grouping Reagent Extraction Reagent 1 - PL.037 Acute Tox. 4, H302 Aquatic Acute 1, H400 (M=1)	Expert judgment Expert judgment
Streptococcal Grouping Reagent Extraction Reagent 2 - PL.038 Met. Corr. 1, H290 Skin Corr. 1, H314 Eye Dam. 1, H318	Expert judgment Expert judgment Expert judgment
Streptococcal Grouping Reagent Extraction Reagent 3 - PL.039 Skin Irrit. 2, H315 Eye Irrit. 2, H319	Expert judgment Expert judgment

Full text of abbreviated H statements

PL.037 H225 H272 H301 H302 H311 H331 H370 H400 PL.038 H226 H290 H314 H318 PL.039 H315 H319 H335	Highly flammable liquid and vapour. May intensify fire; oxidiser. Toxic if swallowed. Harmful if swallowed. Toxic in contact with skin. Toxic if inhaled. Causes damage to organs. Very toxic to aquatic life. Flammable liquid and vapour. May be corrosive to metals. Causes severe skin burns and eye damage. Causes serious eye damage. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.
---	--

Full text of classifications [CLP/GHS]

PL.037 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Acute Tox. 4, H302 Aquatic Acute 1, H400 Flam. Liq. 2, H225 Ox. Sol. 3, H272 STOT SE 1, H370 PL.038 Eye Dam. 1, H318 Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1, H314 Skin Corr. 1A, H314 PL.039 Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335	ACUTE TOXICITY: ORAL - Category 3 ACUTE TOXICITY: SKIN - Category 3 ACUTE TOXICITY: INHALATION - Category 3 ACUTE TOXICITY: ORAL - Category 4 AQUATIC TOXICITY (ACUTE) - Category 1 FLAMMABLE LIQUIDS - Category 2 OXIDISING SOLIDS - Category 3 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1 FLAMMABLE LIQUIDS - Category 3 CORROSIVE TO METALS - Category 1 SKIN CORROSION/IRRITATION - Category 1 SKIN CORROSION/IRRITATION - Category 1A SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 SKIN CORROSION/IRRITATION - Category 2 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE [Respiratory tract irritation] - Category 3
--	--



SECTION 16: Other information

History

Date of issue (dd/mm/yyyy) : 15/02/2017
Date of previous issue : 15/04/2016
Version : 7
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.

