

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 28-Jan-2021

Revision Date 27-Feb-2023

Revision Number 2

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

1.1. Product identifier

Product Code(s) PN002630
Product Name PyroSmart NextGen™ Recombinant LAL Reagent
Synonyms Pyrosmart NextGen™ Recombinant LAL Reagent

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

Recommended use Laboratory reagent
For professional use only
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

<u>Importer</u>	<u>Manufacturer</u>
Associates of Cape Cod International Deacon Park, Moorgate Road Knowsley, Liverpool, UK, L33 7RX TEL: (+44) 151 547 7444	Associates of Cape Cod, Inc. 124 Bernard E. Saint Jean Drive East Falmouth, MA 02536-4445 508 540 3444

For further information, please contact

E-mail address mbedford@acciusa.com

1.4. Emergency telephone number

Emergency telephone CHEMTEL: +1-360-256-7365 (INTERNATIONAL)
+1-800-704-9215 (NORTH AMERICA)

Emergency telephone - §45 - (EC)1272/2008

Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

Hazard statements

Not classified

2.3. Other hazards

May be harmful if swallowed.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if symptoms occur.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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

Symptoms	None.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	None known based on information supplied.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	None known based on information supplied.
Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). Sulphur oxides. Sodium oxides.

5.3. Advice for firefighters

Specific/special fire-fighting	Fires need to be assessed to determine appropriate protocols and safety measures for
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measures	firefighting, including establishing safe zones, extinguishing media to be used, firefighter protection, and actions to control or extinguish the fire.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with eyes.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labelled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep container tightly closed.
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7.3. Specific end use(s)

Specific use(s).	No information available
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Engineering controls	Showers Eyewash stations Ventilation systems.
Personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No special environmental measures are necessary.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Appearance	White to yellow lyophilized powder
Physical state	Solid
Colour	White to yellow
Odour	None
Odour threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Soluble	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon monoxide. Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Sulphur oxides. Sodium oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known.

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

ATEmix (oral) 3,000.40 mg/kg

Unknown acute toxicity

24.99 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Waste codes / waste designations according to EWC / AVV According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information**IMDG**

14.1 UN number or ID number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards Not applicable
 Marine pollutant Not applicable
 14.6 Special Precautions for Users
 Special Provisions None
 14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special Precautions for Users
 Special Provisions None

ADR

14.1 UN number or ID number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special Precautions for Users
 Special Provisions None

IATA

14.1 UN number or ID number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated

14.5 Environmental hazards Not applicable

14.6 Special Precautions for Users

Special Provisions None

Note: None

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) obviously hazardous to water (WGK 2)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV). This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 Environmental Protection Agency (EPA)
 Acute Exposure Guideline Level(s) (AEGl(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 Japan GHS Classification
 Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
 Organisation for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

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Revision Note 2

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet