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Revision Number 4

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 None

Pure substance/mixture Mixture

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

Supplier

Associates of Cape Cod, Intl, Inc.
Unit 1 F/G/H Academy Business Park,
Lees Road, Knowsley,
Liverpool L33 7SA
(T) 44-151-547-7444

For further information, please contact

E-mail address custservice@acciusa.com

1.4. Emergency telephone number

Emergency telephone Chemtel
(International) +1-360-256-7365
(North America) +1-800-704-9215

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified

2.2. Label elements

Not classified

Hazard statements

Not classified.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

The product does not contain any substance(s) classified as PBT or vPvB.

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

| Chemical name | Weight-% | EC No (EU Index No) | UK REACH registration number | Classification according to GB CLP (SI 2020/1567 as amended) | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|-------------------|----------|---------------------|------------------------------|--|------------------------------------|----------|----------------------|
| Glutamine 56-85-9 | 0.063 | 200-292-1 | - | - | - | - | - |

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

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (UK 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.

Skin contact Wash skin with soap and water.

Ingestion Clean mouth with water and afterwards drink plenty of water.

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

Symptoms No information available.

Effects of Exposure No information available.

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

Note to doctors Treat symptomatically.

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 No information available.

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

5.3. Advice for firefighters

Special protective equipment and precautions 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 Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent product from entering drains.

Methods for cleaning up Ventilate the area. Wash contaminated area with soap and water.

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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Avoid breathing dust.

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.

7.3. Specific end use(s)

Specific use(s) No information available.

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

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.

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

| Chemical name | Oral | Dermal | Inhalation |
|----------------------|------|----------------------------|---------------------------------|
| Glutamine 56-85-9 | | 196.6 mg/kg bw/day [4] [6] | 138.6 mg/m ³ [4] [6] |

Notes

[4] Systemic health effects.
[6] Long term.

Derived No Effect Level (DNEL) - General Public

| Chemical name | Oral | Dermal | Inhalation |
|----------------------|--------------------------|--------|--------------------------------|
| Glutamine 56-85-9 | 9.8 mg/kg bw/day [4] [6] | | 34.2 mg/m ³ [4] [6] |

Notes

[4] Systemic health effects.
[6] Long term.

Predicted No Effect Concentration (PNEC)

| Chemical name | Freshwater | Freshwater (intermittent release) | Marine water | Marine water (intermittent release) | Air |
|----------------------|------------|---|--------------|---|-----|
| Glutamine 56-85-9 | 0.95 mg/L | 9.5 mg/L | 0.095 mg/L | | |

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). Eye protection must conform to standard EN 166.

| | |
|--|--|
| 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. |
| 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 |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|--|---------------|-------------------------|
| Melting point / freezing point | | No data available |
| Initial boiling point and boiling range | | No data available |
| Flammability | | No data available |
| Flammability Limit in Air | | |
| Upper flammability or explosive limits | | No data available |
| Lower flammability or explosive limits | | No data available |
| Flash point | | No data available |
| Autoignition temperature | | No data available |
| Decomposition temperature | | No data available |
| pH | | No data available |
| pH (as aqueous solution) | | No data available |
| Kinematic viscosity | | No data available |
| Dynamic viscosity | | No data available |
| Water solubility | Soluble | No data available |
| Solubility(ies) | | No data available |
| Partition coefficient | | No data available |
| Vapour pressure | | No data available |
| Relative density | | No data available |
| Bulk density | | No data available |
| Liquid Density | | No data available |
| Vapour density | | No data available |
| Particle characteristics | | |
| Particle Size | | No data available |
| Particle Size Distribution | | No data available |

| | |
|-----------------------------|---------------------------|
| Explosive properties | No information available. |
| Oxidising properties | No information available. |

9.2. Other information

| | |
|------------|--------------------------|
| VOC | No information available |
|------------|--------------------------|

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

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 None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition can lead to release of irritating and toxic gases and vapours, Carbon monoxide, Carbon dioxide (CO₂), Nitrogen oxides (NO_x), PIB monomers/oligomers, Silicon oxides.

SECTION 11: Toxicological information**11.1. Toxicological information****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.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity**

Based on available data, the classification criteria are not met.

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|----------------------|-------------|-----------------|
| Glutamine | = 7500 mg/kg (Rat) | - | - |

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

| | |
|--|---|
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. |
| Respiratory or skin sensitisation | Based on available data, the classification criteria are not met. |
| Germ cell mutagenicity | Based on available data, the classification criteria are not met. |
| Carcinogenicity | Based on available data, the classification criteria are not met. |
| Reproductive toxicity | Based on available data, the classification criteria are not met. |
| STOT - single exposure | Based on available data, the classification criteria are not met. |
| STOT - repeated exposure | Based on available data, the classification criteria are not met. |
| Aspiration hazard | Based on available data, the classification criteria are not met. |
| 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. |
| Unknown aquatic toxicity | Contains 0 % of components with unknown hazards to the aquatic environment. |

12.2. Persistence and degradability

| | |
|--------------------------------------|---------------------------|
| Persistence and degradability | No information available. |
|--------------------------------------|---------------------------|

12.3. Bioaccumulative potential

| | |
|------------------------|------------------------------------|
| Bioaccumulation | There is no data for this product. |
|------------------------|------------------------------------|

| Chemical name | Partition coefficient |
|---------------|-----------------------|
|---------------|-----------------------|

| | |
|-----------|-------|
| Glutamine | -3.15 |
|-----------|-------|

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

| Chemical name | PBT and vPvB assessment |
|---------------|---------------------------------|
| Glutamine | The substance is not PBT / vPvB |

12.6. Other adverse effects

No information available.

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.

SECTION 14: Transport information

IMDG Not regulated
 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 applicable
 14.5 Environmental hazards 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 Not regulated
 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 applicable
 14.5 Environmental hazards Not applicable
 14.6 Special Precautions for Users
 Special Provisions None

ADR Not regulated
 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 applicable
 14.5 Environmental hazards Not applicable
 14.6 Special Precautions for Users
 Special Provisions None

IATA Not regulated
 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 applicable |
| 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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report

Chemical safety assessments for substances in this mixture were not carried out

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 |

+ Sensitisers SCBA Self-contained breathing apparatus

| 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

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
EPA (Environmental Protection Agency)
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)
National Institute of Technology and Evaluation (NITE)
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 Library of Medicine's PubMed database (NLM PUBMED)
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

Issuing Date 27-Apr-2023**Revision Date** 20-Aug-2024**Revision Note** Address update**This material safety data sheet complies with the requirements of UK REACH****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**

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