

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier

Product name: PreTect X LYSIS BUFFER

Part number:

Name	Product codes
PreTect X LYSIS BUFFER	111003

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

Product for In Vitro diagnostic use.

1.3 Details of the supplier of the safety data sheet

Manufacturer: PreTect AS

Ustadhagan 8 N-3490 Klokkarstua

NORWAY

Telephone: + 47 32 79 88 00

E-mail address: pretect@pretect.no

1.4 Emergency telephone number

Giftinformasjonssentralen + 47 22 59 13 00 or Call a POISON CENTRE or doctor/physician

Section 2: Hazards Identification

2.1 Classification of substance or mixture

Product description: In vitro diagnostic reagent, Clear; Liquid;

Classification according to EC 1272/2008 (CLP/GHS):

Health hazards

Acute toxicity, oral Category 4 H302 - Harmful if swallowed.

Acute toxicity, dermal Category 4 H312 - Harmful in contact with skin.

Acute toxicity, inhalation Category 4 H332 - Harmful if inhaled.

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard Category 3 H412 - Harmful to aquatic life with long lasting effects.

Hazard summary

Physical hazards Not classified for physical hazards.

Health hazards Harmful by inhalation, in contact with skin and if swallowed.

Environmental hazards Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Specific hazards Harmful by inhalation, in contact with skin and if swallowed. Do not breathe dust/fume/gas/mist/vapors/spray. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Main symptoms Skin irritation. Irritation of eyes and mucous membranes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

2.2 Label Elements According to EC 1272/2008 (CLP/GHS) US-OSHA and UN GHS

Hazardous Ingredients: Guanidinium thiocyanate,

Triton X-100 Surfactant

Pictogram:
Signal Word: Warning

Hazard Statements: H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H332 Harmful if inhaled.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements: Prevention

P261 Avoid breathing mist or vapour. P273 Avoid release to the environment.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and

water.

Supplemental label information EUH031 - Contact with acids liberates toxic gas.

2.3 Other Hazards

Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

See 'Section 11: Toxicological Information' for more detailed health information.

SDS PreTect X Lysis buffer Revision date: 2020-08-28

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Section 3: Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients	CAS no.	% by weight	Hazard Classification of
		in <i>End</i>	Pure Ingredients EU
		Product	1272/2008 CLP/GHS
Guanidinium thiocyanate	593-84-0 209-812-1	20 - < 40	Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Corr. 1C;H314, Eye Dam. 1;H318, Acute Tox. 4;H332, Aquatic Chronic 3;H412
Triton X-100 Surfactant	9002-93-1	1 - < 3	Acute Tox. 4;H302, Eye Dam. 1;H318, Aquatic Chronic 2;H411
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	< 0.1	Eye irritation (Category 2), H319

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation: Get medical attention immediately. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Call a physician if symptoms develop or persist.

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control centre immediately.

Skin Contact: Take off immediately all contaminated clothing. Immediately flush skin with plenty of water. For minor skin contact, avoid spreading material on unaffected skin. Get medical attention if irritation develops and persists.

Ingestion: Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

4.2 Most important symptoms and effects, both acute and delayed

Skin irritation. Irritation of eyes and mucous membranes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Refer to Section 3 for composition and Section 11 for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment neededNo specific medical attention or treatment required. Symptoms may be delayed.

Section 5: Fire Fighting Measures

Flammable Properties: Non-flammable aqueous solution. No unusual fire or explosion hazards noted.

5.1 Extinguishing Media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

5.2 Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed

5.3 Advice for fire fighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Move containers from fire area if you can do so without risk. Use standard firefighting procedures and consider the hazards of other involved materials

5.4 Additional information

No further relevant information applicable.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained.

For personal protection, see section 8.

6.2 Environmental Precautions

Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

As a precautionary measure dilute with water and absorb with an inert dry material and place in an appropriate waste disposal container.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7: Handling and Storage

7.1 Precautions for safe handling

Universal precautions should be followed when using this product. Wash hands thoroughly after handling. Avoid release to the environment.

7.2 Conditions for safe storage, including any incompatibilities

Store in a well-ventilated area between 4-30°C. Do not use past expiration date stated on the label. Store away from incompatible materials (see Section 10 of the SDS).

7.3 Specific end uses

No further relevant information available.

Section 8: Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

Hazardous Ingredients	CAS no.	Occupational exposure limits EU directive 2000/39/EC
Guanidinium thiocyanate	593-84-0	No exposure limits noted for ingredient(s).
Triton X-100 Surfactant	9002-93-1	No exposure limits noted for ingredient(s).
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	No exposure limits noted for ingredient(s).

8.2 Exposure controls

Engineering Controls: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Refer European Standard EN166 or appropriate government standards.

Skin Protection: Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer European Standard EN374 or appropriate government standards.

Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance Form: Liquid

Colour: Clear colourless or nearly colourless

Odour: No data available
Odour Threshold: No data available

pH: 8

Melting point/freezing point: No data available Initial boiling point and boiling range: No data available No data available Flash point: Evaporation rate: No data available Flammability (solid, gas): Not applicable Upper/lower flammability or explosive limits: Not determined Vapour pressure: No data available No data available Vapour density: Relative density: No data available Water solubility: Not determined Partition coefficient noctanol/water: Not determined Auto-ignition temperature: No data available Not determined Decomposition temperature: Not determined Viscosity: Explosive properties: Not determined Oxidizing properties: Not determined

9.2 Other Information

No further relevant information available.

Section 10: Stability and Reactivity

10.1 Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

10.2 Chemical stability

The product is stable in accordance with recommended storage conditions as stated on product labelling.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Avoid contact with incompatible materials.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11: Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Ingredient	CAS no.	Information for pure ingredient
Guanidinium thiocyanate	593-84-0	LD50 Oral-Rat-593 mg/kg
		LD50Intraperitoneal-Mouse-300 mg/kg
Triton X-100 Surfactant	9002-93-1	
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	LD50 Oral-Rat-male and female-4.500 mg/kg

General information Occupational exposure to the substance or mixture may cause adverse effects.

Primary Routes of Exposure: Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Inhalation: Harmful if inhaled.

Skin corrosion/irritation: Causes severe skin burns. Harmful in contact with skin.

Serious eye damage/eye irritation: Causes serious eye damage. **Ingestion:** Causes digestive tract burns. Harmful if swallowed.

Symptoms: Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity: No data available.

Reproductive Toxicity: No component of this product present at levels greater than or equal to 0.1% is identified as contributing to reproductive toxicity.

Specific target organ toxicity (single exposure): Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity (repeated exposure): No data available.

Aspiration hazard: No data available.

Other Information: Not available.

Section 12: Ecological Information

12.1 Ecotoxicity

Ingredient	CAS no.	Information for pure ingredient
Guanidinium thiocyanate	593-84-0 209-812-1	EC50-Daphnia (water flea)-42,4 mg/l-48 h
Triton X-100 Surfactant	9002-93-1	Fish LC50 Bluegill (Lepomis macrochirus) 2.8 - 3.2 mg/l, 96 hours
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	LC50-Lepomis macrochirus (Bluegill sunfish)-41 mg/l-96 h EC50-Daphnia magna (Water flea)-625 mg/l-48 h

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product.

PBT: Not applicable

vPvB: Not applicable.

12.6 Other Adverse Effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This material and its container must be disposed of as hazardous waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14: Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

14.1 UN number

ADR/RID: 1759 IMDG: 1759 IATA: 1759

14.2 UN proper shipping name

ADR/RID: CORROSIVE SOLID, N.O.S.(Guanidinium thiocyanate) IMDG: CORROSIVE SOLID, N.O.S.(Guanidinium thiocyanate) IATA: Corrosive solid, N.O.S (Guanidinium thiocyanate)

14.3 Transport hazard class(es)

ADR/RID: 8 IMDG: 8 IATA: 8

14.4 Packaging group

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

Section 15: Regulatory Information

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

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization: No ingredients listed.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Section 16: Other Information

Hazard Class, hazard statements and risk phrase description from section 3

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CLP - Classification, Labeling and Packaging

EC50 - Environmental Lethal Concentration, 50%

GHS - Globally Harmonized System

IARC - Internal Agency for Research on Cancer

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

LC50 – Lethal Concentration, 50%

LD50 – Lethal Dose, 50%

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

vPvB - Very persistent and very bioaccumulative substances

Disclaimer: PreTect AS cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.