

Material Safety Data Sheet

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

1.1 Product identifier

Product Name: Fabrazyme/Agalsidase Alfa Biosimilar - Anti-Alpha-D-galactosidase A mAb - Research Grade

Product Reference: PX-TA1908

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

The product is intended for research and development use only. It is not intended for human use or injection.

1.3 Details of the supplier of the safety data sheet

Company Name: ProteoGenix SAS

Street Address: 19 rue de La Haye

City, Zip, Country: Schiltigheim, 67300, France

Phone: +33 (0) 390 205 470

Fax: +33 (0) 978 533 688

1.4 Emergency telephone number

Phone in case of emergency (Metropolitan France):

-SAMU: 15

-ORFILA: 01 45 42 59 59

Outside metropolitan France, contact your local poison center

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as dangerous according to Regulation (EC) No 1272/2008

2.2. Label elements

None

2.3. Other hazards

None

SECTION 3: Composition/information on ingredients

3.1. Substances

Fabrazyme/Agalsidase Alfa Biosimilar - Anti-Alpha-D-galactosidase A mAb - Research Grade

PBS buffer PH7.5

SECTION 4: First aid measures

4.1. Description of first aid measures

Dermal Exposure: Immediately wash skin with soap and copious amounts of water.

Eye Exposure: In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Oral Exposure: If swallowed, wash out mouth with water provided person is conscious. Call a physician.

Inhalation Exposure: If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

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

Inhalation: Possible irritation of airways, cough, headache.

Skin contact: Not expected.

Eye contact: Not expected.

Ingestion: Not expected.

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist

5.2. Special hazards arising from the substance or mixture

No specific fire or explosion hazard.

5.3. Advice for firefighters

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear rubber gloves when cleaning up any biological or chemical spill. Chemical safety goggles and other protective material are optional.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. Do not allow to enter drains.

6.3. Methods and material for containment and cleaning up

Spilled material can be cleaned up with ordinary cleaning procedures, i.e. soap and water, and flushed down drain or absorbed on sand or vermiculite and thrown away.

Wash and sanitize spill site after material pickup.

6.4. Reference to other sections

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Put on appropriate personal protective equipment (see section VIII). Eating and drinking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Do not ingest. Avoid contact with eyes, skin and clothing. 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.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with the datasheets recommendations in original container protected from direct sunlight in a dry, cool and well-ventilated area. Keep away from food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Proper storage temperature is indicated on original container and in the product datasheet.

7.3. Specific end use(s)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No limit value known

8.2. Exposure controls

Ventilation Data: Provide adequate local exhaust ventilation.
Respiratory Protection: None required if ventilation is adequate.
Protective Gloves: Wear chemical resistant gloves.
Other Protective Equipment : Eye protection, lab coat, apron or other protective clothing to minimize contact.
Eyewash stations and deluge showers should be available.
Work Practices: Observe appropriate laboratory hygiene practices. Avoid contact with skin or eyes.
Wash any exposed body area thoroughly with soap and water after completion of activities involving product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State: Frozen liquid or solid if lyophilized

Odor: Odorless

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal conditions of storage and manipulation.

10.2. Chemical stability

4°C for short term (1 week), -20°C or -80°C for long term.

Avoid freezing/thawing cycles; addition of 20-40% glycerol improves cryoprotection

10.3. Possibility of hazardous reactions

Not known

10.4. Conditions to avoid

Flames, heat

10.5. Incompatible materials

Strong acids, bases and oxidizing agents

10.6. Hazardous decomposition products

Not known

SECTION 11: Toxicological information

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

As far as toxicological properties have been investigated, classification data are not met.

11.2. Information on other hazards

May cause skin irritation.

May be harmful if absorbed through the skin.

May cause eye irritation.

May be Irritating to mucous membranes and upper respiratory tract.

May be harmful if inhaled.

May be harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

No known data

12.2. Persistence and degradability

No known data

12.3. Bioaccumulative potential

No known data

12.4. Mobility in soil

No known data

12.5. Results of PBT and vPvB assessment

No known data

12.6. Endocrine disrupting properties

No known data

12.7. Other adverse effects

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact a licensed professional waste disposal service to dispose of this material.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator with an afterburner and scrubber.

Observe all federal, state, and local environmental regulations.

SECTION 14: Transport information

14.1. UN number or ID number

Not available

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

Not available

14.6. Special precautions for user

Refer to section 8

14.7. Maritime transport in bulk according to IMO instruments

SECTION 15: Regulatory information

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

Not available

SECTION 16: Other information

Information given herein is offered in good faith as accurate, but without guarantee. All biological/biochemical material 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.

The product is intended for research and development use only. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user.