

Safety Data Sheet

CATHFLO ACTIVASE(R) Vials (2 mg)

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

1.1. Product identifier

Product name CATHFLO ACTIVASE(R) Vials (2 mg)
Product code SAP-10146313
Synonyms - ACTIVASE 2mg

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

Use - pharmaceutical active substance *1

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Alteplase

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SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.2 Skin corrosion/irritation (Category 2)

H315 Causes skin irritation.

3.3 Serious eye damage/eye irritation (Category 2A)

H319 Causes serious eye irritation.

Signalword: Warning

Label:



Precautionary statements:

- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P309 IF exposed or if you feel unwell: Get medical advice/attention.

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization

0.5 M arginine phosphate buffer is used as a buffering agent to maintain pH at 7.3.

Ingredients

Concentration

Alteplase

< 2.17 %

CAS: 105857-23-6

*1 referring to:

Alteplase

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact

- rinse immediately with tap water for 10 minutes - open eyelids forcibly
- always consult ophthalmologist

Skin contact

- remove immediately contaminated clothes, wash affected skin with plenty of water
- get medical treatment

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- Inhalation
- remove the casualty to fresh air and keep him/her calm
 - get medical treatment immediately

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

- Note
- no information available

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

- Note to physician
- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media
- adapt extinguishing media to surrounding fire conditions
- Flash point (liquid)
- not applicable
- Unsuitable extinguishing media
- full water jet

5.2. Special hazards arising from the substance or mixture

- Specific hazards
- may attack metals and produce hydrogen gas which may form explosive mixture with air
 - it develops corrosive and irritating vapours, also in case of fire
 - formation of toxic and corrosive combustion gases (phosphorus oxides (eg, phosphorus pentoxide)) possible

5.3. Advice for firefighters

- Protection of fire-fighters
- precipitate gases/vapours/mists with water spray
 - use self-contained breathing apparatus
- Special method of fire-fighting
- if possible precipitate fire gases with a water jet

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Personal precautions
- if this is not endangering the action force or other people, ventilate sewers and cellars

6.2. Environmental precautions

- Environmental protection
- if possible close leaks
 - collect the leaked product by all means available
 - if the substance reaches waters or the sewer system, inform the competent authority

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6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from light

Validity - see "best use before" date stated on the label, after opening the content should be used within a short period, any remaining reconstituted solution should be discarded

Packaging materials - vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air - STEL: 3 mg/m³ (4 x 15 min) *2
- ACGIH-TLV: 1 mg/m³ *2

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.2 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- in case of open handling or accidental release:
particle mask or respirator with independent air supply

Hand protection - protective gloves (neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Alteplase

*2 referring to: Phosphoric acid

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to off-white	
Form	lyophilized powder	
Molecular mass	~ 65 kDa	*1
Solubility	148'700 mg/l, water (20 °C)	*3
Partition coefficient	log P _{ow} -4.20 (octanol/water°C)	*3
pH value	7.3 (reconstituted solution)	

9.2. Other information

Note - no information available

*1 referring to: Alteplase

*3 referring to: L-Arginine

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared reconstituted solution
- do not freeze the reconstituted solution

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - temperatures above 30 °C
- light

10.5. Incompatible materials

Materials to avoid - alkalis (strong exothermic reaction), metals (danger of ignition), metallic oxides (danger of ignition), nitromethane (risk of explosion)*2

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10.6. Hazardous decomposition products

Note	- not combustible	*2
	- very hygroscopic	*2

*2 referring to: Phosphoric acid

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀	> 5'110	mg/kg	(oral, rat)	*3
	- LD ₅₀	1'530	mg/kg	(oral, rat)	*2
	- LC ₅₀	> 850	mg/m ³	(inhal., rat, 1 h)	*2
	- LD ₅₀	2'740	mg/kg	(dermal, rabbit)	*2

Local effects - skin: corrosive *2

Sensitization - anaphylactic reactions may occur following the intravenous application of proteins *1

Mutagenicity - negative (Ames test) *1
- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) *1

Reproductive toxicity - Activase® has been shown to have an embryocidal effect in rabbits when intravenously administered in doses of approximately two times (3 mg/kg) the human dose. *1

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Alteplase

*2 referring to: Phosphoric acid

*3 referring to: L-Arginine

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - moderately toxic for fish (fish, unspecified)
LC₅₀ 70 mg/l *2

12.2. Persistence and degradability

Ready biodegradability - readily biodegradable *3

12.3. Bioaccumulative potential

Note - no information available

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12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*2 referring to: Phosphoric acid

*3 referring to: L-Arginine

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

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SECTION 16: Other information

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| Note | - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user. |
| Edition documentation | - first edition |

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.