



Material Safety Data Sheet

ACTIVASE(R) Lyophilized Powder (100 mg)

1. Product and Company Identification

Product name ACTIVASE(R) Lyophilized Powder (100 mg)

Product code SAP-10053301

Company information Enquiries:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone 001-973/235 50 00
E-Mail info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

2. Hazard identification

Emergency Overview

Form lyophilized powder

Color white to off-white

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: Hematopoietic/blood system, Immune System

 - Acute Effects: May cause allergic reactions., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause "flu-like" symptoms such as fever, fatigue, chills, headache, nausea and muscular pain., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight., May cause blood system effects.

 - Chronic Effects: No adverse effects known

 - Carcinogenicity: formulation not listed by NTP, IARC or OSHA

3. Composition/Information on ingredients

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

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Ingredients	Concentration
Alteplase CAS: 105857-23-6	2.17 %
*1 referring to:	Alteplase
4. First-aid measures	
Eye contact	<ul style="list-style-type: none">- rinse immediately with tap water for 10 minutes - open eyelids forcibly- always consult ophthalmologist
Skin contact	<ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with plenty of water- get medical treatment
Inhalation	<ul style="list-style-type: none">- remove the casualty to fresh air and keep him/her calm- get medical treatment immediately
Note to physician	<ul style="list-style-type: none">- treat symptomatically
5. Fire-fighting measures	
Suitable extinguishing media	<ul style="list-style-type: none">- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable
Unsuitable extinguishing media	<ul style="list-style-type: none">- full water jet
Specific hazards	<ul style="list-style-type: none">- 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
Protection of fire-fighters	<ul style="list-style-type: none">- precipitate gases/vapours/mists with water spray- use self-contained breathing apparatus
Special method of fire-fighting	<ul style="list-style-type: none">- if possible precipitate fire gases with a water jet
6. Accidental release measures	
Personal precautions	<ul style="list-style-type: none">- if this is not endangering the action force or other people, ventilate sewers and cellars
Environmental protection	<ul style="list-style-type: none">- 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
Methods for cleaning up	<ul style="list-style-type: none">- collect solids (avoid dust formation) and hand over to waste removal

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7. Handling and storage

Storage

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

8. Exposure controls/Personal protection

Engineering Measures - see 7.

Monitoring

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

Personal protective equipment

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

*2 referring to: Phosphoric acid

9. 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)	

*1 referring to: Alteplase

*3 referring to: L-Arginine

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10. Stability and reactivity

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	
Conditions to avoid	- temperatures above 30 °C - light	
Materials to avoid	- alkalis (strong exothermic reaction), metals (danger of ignition), metallic oxides (danger of ignition), nitromethane (risk of explosion) ²	
Note	- not combustible - very hygroscopic	*2 *2

*2 referring to: Phosphoric acid

11. Toxicological information

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

*1 referring to: Alteplase

*2 referring to: Phosphoric acid

*3 referring to: L-Arginine

12. Ecological information

Ready biodegradability	- readily biodegradable	*3
Ecotoxicity	- moderately toxic for fish (fish, unspecified) LC ₅₀ 70 mg/l	*2
*2 referring to:	Phosphoric acid	
*3 referring to:	L-Arginine	

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13. Disposal considerations

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

14. Transport information

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

15. Regulatory information

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.

16. Other information

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.