Material Safety Data Sheet

ACTIVASE(R) Vials (50 & 100 mg) & CATHFLO ACTIVASE(R) Vials (2 mg)

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

1.1. Product identifier

Product name	ACTIVASE(R) Vials (50 & 100 mg) & CATHFLO ACTIVASE(R) Vials (2 mg)
Product code	SAP-10053301

1.3. Details of the supplier of the safety data sheet

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	Local representation:

1.4. Emergency telephone number

Emergency telephone number	US emergency phone: (800)-827-6243

SECTION 2: Hazards 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

Classification of the substance or mixture / Label elements

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 CAS: 105857-23-6	≤ 2.17 %

*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
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

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

7.2. 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) - ACGIH-TLV: 1 mg/m3	*2 *2

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	

*2 referring to: Phosphoric acid

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

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/m3	(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

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- moderately toxic for fish (fish, unspecified) LC_{50} 70 mg/l	*2

12.2. Persistence and degradability

Ready biodegradability	- readily biodegradable	*3

12.3. Bioaccumulative potential

Note	- no information available

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.

SECTION 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.