

Safety Data Sheet

# ACTIVASE® Vials (100 mg)

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

### 1.1. Product identifier

Product name                      ACTIVASE® Vials (100 mg)  
 Product code                      SAP-10053301  
 Synonyms                          - ACTIVASE 100mg

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

Use                                      - pharmaceutical active substance (thrombolytic)                      \*1

### 1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: 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	Local representation:
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### 1.4. Emergency telephone number

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

\*1 referring to:                      Alteplase

## SECTION 2: Hazards identification

### Classification of the substance or mixture / Label elements

GHS Classification                      no classification and labelling according to GHS

### Other hazards

Note                                      - no information available

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### 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	GHS-Classification (pure ingredient)
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Alteplase 105857-23-6	2.17 %	
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\*1 referring to: Alteplase

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly

Skin contact - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation - remove the casualty to fresh air and keep him/her calm  
- in the event of symptoms get medical treatment

#### 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 - no particular hazards known



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### 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

## 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 ~ 64 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

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### 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

Note - no information available

### 10.6. Hazardous decomposition products

Note - no information available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
	- TD <sub>10</sub> > 10 mg/kg (i.v., rat)	*1
	- LD <sub>50</sub> 1'530 mg/kg (oral, rat)	*2
	- LC <sub>50</sub> > 850 mg/m <sup>3</sup> (inhal., rat, 1 h)	*2
	- LD <sub>50</sub> 2'740 mg/kg (dermal, rabbit)	*2
	- LD <sub>50</sub> > 5'110 mg/kg (oral, rat)	*3
Subacute toxicity	- LD <sub>0</sub> 10 mg/kg/d (i.v., several species, 14 d)	*1
Local effects	- skin: non-irritant (rabbit; OECD No. 404)	*3
	- eye: not severe irritant or corrosive	*3
	- skin: corrosive	*2
Sensitization	anaphylactic reactions may occur following the intravenous application of proteins	*1
Mutagenicity	- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test))	*1
	- negative (Ames test)	*1
	- negative, both with and without metabolic activation (in vitro test system; OECD No. 473 (Mammalian Cytogenic Test))	*3
Carcinogenicity	- no information available	
Reproductive toxicity	- Alteplase has been shown to have an embryocidal effect in rabbits when intravenously administered at a dose of 3 mg/kg, which is roughly twice the human dose for acute myocardial infarction	*1
STOT-single exposure	- no information available	

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STOT-repeated exposure	- no information available
Aspiration hazard	- no information available
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	- barely toxic for fish (zebrafish) LC <sub>50</sub> (96 h) 2800 mg/l NOEC (96 h) 1000 mg/l (OECD No. 203, semistatic)	*3
	- barely toxic for planktonic crustaceans (Daphnia magna) NOEC (24 h) 1000 mg/l (OECD No. 202)	*3
	- barely toxic for microorganisms (Pseudomonas putida) EC <sub>10</sub> (16 h) > 10000 mg/kg (DIN 38'412, part 8)	*3
	- no information available	*1
	- moderately toxic for fish (fish, unspecified) LC <sub>50</sub> 70 mg/l	*2

#### 12.2. Persistence and degradability

Ready biodegradability	- globular proteins are generally well biodegradable	*1
	- readily biodegradable	*3

#### 12.3. Bioaccumulative potential

Note	- no information available
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#### 12.4. Mobility in soil

Note	- no information available
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#### 12.5. Results of PBT and vPvB assessment

Note	- no information available
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### 12.6. Other adverse effects

Note - no information available

\*1 referring to: Alteplase  
\*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 as Dangerous Good according to the Dangerous Goods 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 and to local officials.  
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

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 - changes from previous version in sections 7

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.