Safety Data Sheet

TNKase(R) Lyophilized Powder (50 mg)

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

1.1. Product identifier

Product name	TNKase(R) Lyophilized Powder (50 mg)
Product code	CSE-3071

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

Use - enzyme used as a thrombolytic drug *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:

1.4. Emergency telephone number

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

*1 referring to: Tenecteplase

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.
- P280 Wear protective gloves/ protective clothing / eye protection / face protection.

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.
527 amino acid glycoprotein (enzyme) *1
tissue plasminogen activator (tPA) *1

Ingredients	**Concentration**
Tenecteplase	6.8 %

*1 referring to: Tenecteplase

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 - summon a physician 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	- corrodes metals with formation of hydrogen, which may form explosive mixtures with air - heating containers will cause pressure to rise (risk of bursting or explosion) - 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 - chemical incident emergency response unit with full protective equipment
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	- below 30 °C - protected from light	
Validity	- 8 hours, 2 to 8 °C - 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	*2
Packaging materials	- vials	

*2 referring to: TNKase reconstituted solution

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	*3 *3
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.06 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: Tenecteplase
*3 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		sterile, lyophilized powder	
Odor		odourless	
Molecular mass		~ 65 kDa	*1
Solubility		148’700 mg/l, water (20 °C)	*4
Partition coefficient		log P_{ow} -4.20 (octanol/water°C)	*4
pH value	(20 °C)	< 0.5 (100 g/l)	*3
	(20 °C)	11.4 (100 g/l)	*4
		7.3	*2

9.2. Other information

Note - no information available

*1 referring to: Tenecteplase
*2 referring to: TNKase reconstituted solution
*3 referring to: Phosphoric acid
*4 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)	*3

10.6. Hazardous decomposition products

Note	- not combustible	*3
	- very hygroscopic	*3

*3 referring to: Phosphoric acid

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration				*1
	- LD_{50}	1’530	mg/kg	(oral, rat)	*3
	- LC_{50}	> 850	mg/m3	(inhal., rat, 1 h)	*3
	- LD_{50}	2’740	mg/kg	(dermal, rabbit)	*3
	- LD_{50}	> 5’110	mg/kg	(oral, rat)	*4
Local effects	- skin: corrosive				*3
Sensitization	- anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described				*1
Reproductive toxicity	- NOEL (maternal or developmental toxicity) = 5 mg/kg (approx. 8-10 times the human dose) (i.v., rabbit)				*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact				
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA				

*1 referring to: Tenecteplase
*3 referring to: Phosphoric acid
*4 referring to: L-Arginine

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- moderately toxic for fish (fish, unspecified) LC_{50} 70 mg/l	*3

12.2. Persistence and degradability

Ready biodegradability	- readily biodegradable	*4

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	-	harmful effect due to change of pH	*3

*3	referring to:	Phosphoric acid
*4	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	-	changes from previous version in sections 2

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.