

## TNKase(R) Lyophilized Powder (50 mg)

### 1.1. Product identifier

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

Use	- enzyme used as a thrombolytic drug	*1
-----	--------------------------------------	----

Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone        001-973/235 50 00 E-Mail       info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

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

\*1 referring to: Tenecteplase

## Emergency Overview

Form	sterile, lyophilized powder
Color	white to off-white
Odor	odourless

## TNKase(R) Lyophilized Powder (50 mg)

### 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., 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.	
	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	<ul style="list-style-type: none"> <li>- rinse immediately with tap water for 10 minutes - open eyelids forcibly</li> <li>- always consult ophthalmologist</li> </ul>
Skin contact	<ul style="list-style-type: none"> <li>- remove immediately contaminated clothes, wash affected skin with plenty of water</li> <li>- get medical treatment</li> </ul>
Inhalation	<ul style="list-style-type: none"> <li>- remove the casualty to fresh air and keep him/her calm</li> <li>- summon a physician immediately</li> </ul>

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

Note - no information available

## **TNKase(R) Lyophilized Powder (50 mg)**

### **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

## TNKase(R) Lyophilized Powder (50 mg)

### SECTION 7: Handling and storage

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	<ul style="list-style-type: none"> <li>- below 30 °C</li> <li>- protected from light</li> </ul>	
Validity	<ul style="list-style-type: none"> <li>- 8 hours, 2 to 8 °C</li> <li>- 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</li> </ul>	*2
Packaging materials	<ul style="list-style-type: none"> <li>- vials</li> </ul>	
*2 referring to:	TNKase reconstituted solution	

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Threshold value (USA) air	<ul style="list-style-type: none"> <li>- STEL: 3 mg/m<sup>3</sup> (4 x 15 min)</li> <li>- ACGIH-TLV: 1 mg/m<sup>3</sup></li> </ul>	*3 *3
---------------------------	--	----------

#### 8.2. Exposure controls

Respiratory protection	<ul style="list-style-type: none"> <li>- 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.</li> <li>- in case of open handling or accidental release: particle mask or respirator with independent air supply</li> </ul>	
Hand protection	<ul style="list-style-type: none"> <li>- protective gloves (neoprene, nitrile or butyl rubber)</li> </ul>	
Eye protection	<ul style="list-style-type: none"> <li>- safety glasses</li> </ul>	

\*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 <sub>ow</sub> -4.20 (octanol/water°C)	*4

## TNKase(R) Lyophilized Powder (50 mg)

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

## TNKase(R) Lyophilized Powder (50 mg)

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
	- LD <sub>50</sub> 1'530 mg/kg (oral, rat)	*3
	- LC <sub>50</sub> > 850 mg/m <sup>3</sup> (inhal., rat, 1 h)	*3
	- LD <sub>50</sub> 2'740 mg/kg (dermal, rabbit)	*3
	- LD <sub>50</sub> > 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
*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 <sub>50</sub> 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	
------	----------------------------	--

## **TNKase(R) Lyophilized Powder (50 mg)**

### **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 - 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.