

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by UK REACH Regulation SI 2019/758

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

1.1 Product identifier

Product name **Thrombin, 500 units**

Catalogue Number **27084601**



EC number 232-648-7

CAS number 8002-04-4

Product description Not available.

Product type Solid.

Other means of identification Bovine thrombin; thrombin, bovine; Thrombase

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

Identified uses

☒ Analytical chemistry.
Laboratory chemicals
Scientific research and development

☒ Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier

Cytiva
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA United Kingdom
+44 1494 508000

Hours of operation

08.30 - 17.00

Person who prepared the SDS : sds_author@cytiva.com

1.4 Emergency telephone number

United Kingdom (UK)

Cytiva UK
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA
t: 0870 606 1921

Call INFOTRAC 24 Hour number:
001-352-323-3500 (Call Collect).

National advisory body/Poison Centre

United Kingdom (UK)

Health professionals should contact the National Poisons Information Service (NPIS) by telephone, or use TOXBASE www.toxbase.org.

NPIS <http://www.npis.org/> advise that others seeking specific information on poisons should contact:
In England and Wales: NHS Direct - 0845 4647 or 111
In Scotland: NHS 24 - 08454 24 24 24
In N Ireland: Contact your local GP or pharmacist during normal hours; click here (www.gpoutofhours.hscni.net/) for GP services Out-of-Hours.



SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mono-constituent substance

Classification according to UK CLP/GHS

☒ Skin Irrit. 2, H315
☒ Eye Irrit. 2, H319
☒ Resp. Sens. 1, H334
☒ STOT SE 3, H335

☒ The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms



Signal word ☒ Danger

Hazard statements ☒ Causes skin irritation.
☒ Causes serious eye irritation.
☒ May cause allergy or asthma symptoms or breathing difficulties if inhaled.
☒ May cause respiratory irritation.

Precautionary statements

General ☒ Not applicable.

Prevention ☒ Wear protective gloves. Wear eye or face protection. Wear respiratory protection. Avoid breathing dust. Wash thoroughly after handling.

Response ☒ IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. If experiencing respiratory symptoms: Call a POISON CENTER or doctor. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice or attention.

Storage ☒ Store in a well-ventilated place. Keep container tightly closed.

Disposal ☒ Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements ☒ Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles ☒ Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings ☒ Not applicable.

Tactile warning of danger ☒ Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

PBT	P	B	T	vPvB	vP	vB
<input checked="" type="checkbox"/> No	N/A	N/A	No	N/A	N/A	N/A

Other hazards which do not result in classification ☒ None known.

SECTION 3: Composition/information on ingredients

3.1 Substances		Mono-constituent substance		
Product/ingredient name	Identifiers	%	Classification	Type
Thrombin	EC: 232-648-7 CAS: 9002-04-4	100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335	[1]
See Section 16 for the full text of the H statements declared above.				

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type

[1] Constituent

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In the event of any complaints or symptoms, avoid further exposure.
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	Adverse symptoms may include the following: respiratory tract irritation coughing wheezing and breathing difficulties asthma
Skin contact	Adverse symptoms may include the following: irritation redness
Ingestion	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media ☒ Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media ☒ None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture ☒ No specific fire or explosion hazard.

Hazardous combustion products ☒ No specific data.

5.3 Advice for firefighters

Special precautions for fire-fighters ☒ Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters ☒ Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to British standard BS EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel ☒ No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders ☒ If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

☒ Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill ☒ Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill ☒ Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures ☒ Put on appropriate personal protective equipment (see Section 8). Persons with a history of asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene ☒ Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

☒ Do not store above the following temperature: -20°C (-4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.



7.3 Specific end use(s)

Recommendations	Analytical chemistry. Laboratory chemicals. Scientific research and development.
Industrial sector specific solutions	Not available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

No exposure limit value known.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures

Reference should be made to monitoring standards, such as the following: British Standard BS EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) British Standard BS EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) British Standard BS EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Not available.

PNECs

Not available.

8.2 Exposure controls**Appropriate engineering controls**

Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures**Hygiene measures**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection**Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties**Appearance**

Physical state	Solid.
Colour	White.
Odour	Odourless.
Odour threshold	Not available.



pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flammability (solid, gas)	Not considered to be flammable .
Upper/lower flammability or explosive limits	Not applicable.
Flash point	[Product does not sustain combustion.]
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	<input checked="" type="checkbox"/> Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C): Not available.
Solubility(ies)	
Media	Result
<input checked="" type="checkbox"/> Cold water	Easily soluble
hot water	Easily soluble
Solubility in water	Not available.
Miscible with water	Yes.
Partition coefficient: n-octanol/water	Not available.
Vapour pressure	Not available.
Evaporation rate	Not available.
Relative density	Not available.
Vapour density	Not applicable.
Explosive properties	Not considered to be a product presenting a risk of explosion.
Oxidising properties	Not available.
<u>Particle characteristics</u>	
Median particle size	Not available.

9.2 Other information

Not available.

Burning time	Not available.
Burning rate	Not available.
Solubility in water	Not available.

SECTION 10: Stability and reactivity

10.1 Reactivity	<input checked="" type="checkbox"/> No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	<input checked="" type="checkbox"/> The product is stable.
10.3 Possibility of hazardous reactions	<input checked="" type="checkbox"/> Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	<input checked="" type="checkbox"/> No specific data.
10.5 Incompatible materials	<input checked="" type="checkbox"/> No specific data.
10.6 Hazardous decomposition products	<input checked="" type="checkbox"/> Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not available.

Conclusion/Summary [Product] Not available.

Acute toxicity estimates

N/A

Skin corrosion/irritation

Not available.



Conclusion/Summary [Product] Not available.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] Not available.

Respiratory

Conclusion/Summary [Product] Not available.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] Not available.

Carcinogenicity

Not available.

Conclusion/Summary [Product] To the best of our knowledge, the toxicological properties of this substance have not been thoroughly investigated. May be fatal if the substance enters bloodstream.

Reproductive toxicity

Not available.

Conclusion/Summary [Product] Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name

Thrombin

Result

STOT SE 3, H335 (Respiratory tract irritation)

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

- Inhalation

Causes serious eye irritation.
- Ingestion

No known significant effects or critical hazards.
- Skin contact

Causes skin irritation.
- Eye contact

Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	Adverse symptoms may include the following: respiratory tract irritation coughing wheezing and breathing difficulties asthma
Ingestion	No specific data.
Skin contact	Adverse symptoms may include the following: irritation redness
Eye contact	Adverse symptoms may include the following: pain or irritation watering redness
Delayed and immediate effects as well as chronic effects from short and long-term exposure	
Short term exposure	
Potential immediate effects	Not available.
Potential delayed effects	Not available.
Long term exposure	
Potential immediate effects	Not available.
Potential delayed effects	Not available.
Potential chronic health effects	
Not available.	
Conclusion/Summary [Product]	Not available.
General	Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Reproductive toxicity	No known significant effects or critical hazards.
Other information	Not available.

SECTION 12: Ecological information

12.1 Toxicity

Not available.

Conclusion/Summary [Product] Not available.

12.2 Persistence and degradability

Not available.

Conclusion/Summary [Product] Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient Not available.

Mobility Not available.

12.5 Results of PBT and vPvB assessment

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB
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According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Other adverse effects No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste

The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions

This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments

Not available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

UK (GB)/REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.



Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

No listed substance

Seveso Directive

❑ This product is not controlled under the Seveso Directive.

EU regulations

**Industrial emissions
(integrated pollution
prevention and control) - Air** Not listed

**Industrial emissions
(integrated pollution
prevention and control) -
Water** Not listed

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

United States	This material is active or exempted.
Canada inventory	This material is not listed in DSL but is listed in NDSL.
China	This material is listed or exempted.
Japan	Japan inventory (CSCL): Not determined. Japan inventory (ISHL): Not determined.

**15.2 Chemical safety
assessment** ❑ Not available.

SECTION 16: Other information

❑ Indicates information that has changed from previously issued version.

Abbreviations and acronyms

ATE = Acute Toxicity Estimate
GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = GB CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
❑ Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335	According to package According to package According to package According to package
Full text of abbreviated H statements	❑ H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation.
Full text of classifications	❑ Eye Irrit. 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 Resp. Sens. 1 RESPIRATORY SENSITISATION - Category 1 Skin Irrit. 2 SKIN CORROSION/IRRITATION - Category 2 STOT SE 3 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3
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Version

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Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

