

SAFETY DATA SHEET



In accordance with 1907/2006 annex II 2015/830 and 1272/2008
(All references to EU regulations and directives are abbreviated into only the numeric term)
Issued 2018-03-12
Version number 1.0

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

1.1. Product identifier

| | |
|------------|----------------------------|
| Trade name | 1199 Factor XIa Calibrator |
| | 1188 Factor XIa Control |
| | 9599 Factor IXa Calibrator |
| | 9588 Factor IXa Control |

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

| | |
|-----------------|-----------------------|
| Identified uses | Laboratory chemicals |
| | In Vitro Research Use |

1.3. Details of the supplier of the safety data sheet

| | |
|-----------|--------------------|
| Company | Rossix AB |
| | Taljegårdsgatan 3B |
| | 43153 Mölndal |
| | Sweden |
| Telephone | +46 (0)31 7068965 |
| E-mail | info@rossix.com |
| Website | www.rossix.com |

1.4. Emergency telephone number

Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

2.2. Label elements

| | |
|------------------|----------------|
| Hazard pictogram | Not applicable |
| Signal word | Not applicable |
| Hazard statement | Not applicable |

2.3. Other hazards

This product contains purified human coagulation factors isolated from human plasma. Each donor unit used in the preparation has tested negative (using FDA approved methods) for the presence of Hepatitis B surface antigen and antibodies against Hepatitis C, HIV 1 and 2.

This product contains bovine serum albumin (BSA). All donor animals are from BSE- and TSE-free livestock. Donor animals have been subjected to veterinary examination before and after donation, determining that the animals are indeed free of infectious materials.

Although this product has been thoroughly tested, biological materials should always be handled as potentially infectious as a precaution.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

The product contains no substances, nor concentration levels thereof, that require marking or that need to be declared.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

Upon skin contact

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Upon ingestion

Rinse mouth out thoroughly first with water, then SPIT OUT the rinse water. Drink at least half a litre of water and seek medical advice. DO NOT INDUCE VOMITING.

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

Upon eye contact

Splashes in eyes may cause burning pain.

Irritation may occur due to mechanical abrasion.

Upon skin contact

Prolonged contact may cause skin irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Upon contact with a doctor, make sure to have the label or this safety data sheet with you.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

5.2. Special hazards arising from the substance or mixture

Gases detrimental to health can be spread in case of fire.

5.3. Advice for fire-fighters

Protective measures should be taken regarding other material at the site of the fire.

In case of fire use a respirator mask.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid inhalation and exposure to skin and eyes.

Keep unauthorized and unprotected people at a safe distance.

Use recommended safety equipment, see section 8.

Ensure good ventilation.

6.2. Environmental precautions

Avoid release to drains, soil or watercourses.

6.3. Methods and material for containment and cleaning up

Carefully collect dry product without dust formation and dispose as waste.

Minor spills can be dried up or flushed away with water.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid spillage, inhalation and contact with eyes and skin.

Do not eat, drink or smoke in premises where this product is handled.

Use recommended safety equipment, see section 8.

7.2. Conditions for safe storage, including any incompatibilities

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.

Always use sealed and visibly labeled packages.

Store in a dry place at -20 C or colder.

The product is stable until the expiration date when stored under recommended conditions.

7.3. Specific end uses

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values

All ingredients (cf. Section 3) lack occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

To prevent occupational risks the health hazards for this product or any of the ingredients should be taken into account (see sections 2, 3 and 11), according to EU Directive 89/391 and 98/24 and national jurisdiction for occupational risks.

8.2.1. Appropriate engineering controls

Handle in premises which have modern ventilation standards.

Eye-rinsing facilities shall be available at the workplace.

Eye/face protection

Use dust protective glasses when handling may create dust.

Skin protection

Use suitable protective clothing.

During normal use hand protection is not necessary, but it is recommended during repeated/prolonged contact with the product. Recommended glove material: nitrile, butyl or rubber.

Respiratory protection

Dust filter (EN 143) may be necessary when performing dust forming work.

8.2.3. Environmental exposure controls

Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|------------------------------|
| a) Appearance | Form: lyophilised powder. |
| b) Odour | Not indicated |
| c) Odour threshold | Not indicated |
| d) pH | Not indicated |
| e) Melting point/freezing point | Not indicated |
| f) Initial boiling point and boiling range | Not indicated |
| g) Flash point | Not indicated |
| h) Evaporation rate | Not indicated |
| i) Flammability (solid, gas) | Not applicable |
| j) Upper/lower flammability or explosive limits | Not indicated |
| k) Vapour pressure | Not indicated |
| l) Vapour density | Not indicated |
| m) Relative density | Not indicated |
| n) Solubility | Solubility in water: Soluble |
| o) Partition coefficient: n-octanol/water | Not applicable |
| p) Auto-ignition temperature | Not indicated |
| q) Decomposition temperature | Not indicated |
| r) Viscosity | Not indicated |
| s) Explosive properties | Not applicable |
| t) Oxidising properties | Not applicable |

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Does not decompose to hazardous substances.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Not indicated.

Acute toxicity

The product is not classified as acute toxic.

Skin corrosion/irritation

Can cause skin irritation after repeated or prolonged contact.

Serious eye damage/irritation

Eye contact may cause burning pain or irritation.

Dust may cause mechanical abrasion of the cornea.

Respiratory or skin sensitisation

Hypersensitive reactions cannot be ruled out for persons who are overtly sensitive.

Germ cell mutagenicity

No mutagenic effects have been reported for the substance in this mixture.

Carcinogenicity

No carcinogenic effects have been reported for the substances in this product.

Reproductive toxicity

No toxic effects to reproduction have been reported for the substances in this mixture.

STOT-single exposure

No known hazards for occasional exposure.

STOT-repeated exposure

No known hazards for repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity

Avoid larger spills directly in soil, water and drains.

No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability

The product degrades easily in the natural environment.

12.3. Bioaccumulative potential

Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil

The product is miscible with water and is therefore variable in soil and water.

12.5. Results of PBT and vPvB assessment

The criteria for PBT and vPvB does not apply to inorganic substances.

12.6. Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste handling of the product

Avoid discharge of undiluted product into sewers.

The product is not classified as hazardous waste.

Observe local regulations.

See also national waste regulations.

Classification according to 2006/12

Recommended LoW-code: 18 01 07 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number

Not classified as dangerous goods

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information

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

Not indicated.

15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet

Revisions of this document

This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet

Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2018-03-12.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

- 1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- 2015/830 COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- 1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- 2006/12 DIRECTIVE 2006/12/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2006 on waste
- 1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

This product is not expected to cause severe harm to humans or the environment. The manufacturer, the distributor or the supplier are not responsible for adverse effects if the product is not handled in accordance with the directions for use.

Other relevant information

Editorial information



This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, www.kemrisk.se