

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

1.1 Product identifiers

Product Code:	abx831279
Product Name:	Idarucizumab
CAS number:	None
Commodity Code (Harmonized Code):	3822.90.00
REACH No.:	A registration number is not available for this kit as its substances or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline

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

Recommended uses:	For research use only.
Uses advised against:	Not for diagnostic or therapeutic use.

1.3 Details of the supplier of the safety data sheet

Company:	Abbexa Ltd. 181 Cambridge Science Park Cambridge, CB4 0GJ United Kingdom
Telephone:	+44 (0)1223 755950
Fax:	+44 (0)1223 755951
E-mail address:	info@abbexa.com

1.4 Emergency telephone number

Territory	Service	Telephone number
Great Britain (GB)	National Health Service (NHS)	111
Northern Ireland (NI)	General Practitioner services	Check with local providers
United States of America (USA)	Emergency Services	911
European Union (EU)	Emergency Services	112
Rest of World (RoW)	Refer to local services	N/A

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC. According to the OSHA Hazard Communication Standard 29CFR 1910:1200, these products are not considered hazardous.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws as it is not dangerous. Precautionary statements (EU) No. 28 1272/2008, wear protective gloves/protective clothing.

2.3 Other hazards

Physical/chemical hazards:	Not applicable.
Human health hazards:	No specific hazard.

Safety Datasheet

Version: 1.0.0

Revision date: 09 Oct 2024



Substances with endocrine disrupting properties: None.

For Reference Only

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The mixture is not classified as hazardous in compliance with Directive 67/548/EEC and Regulation (EC) No 1272/2008.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice:

Show this safety data sheet to the physician in **attendance**.

Ingestion:

Never give anything by mouth to an **unconscious** person. Rinse mouth with water. Loosen tight clothing such as **ties, belts or waistbands**. Do **NOT** induce vomiting unless directed to do so by medical personnel. Seek medical attention immediately.

Inhalation:

Move person into fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention immediately.

Skin contact:

Wash off with soap and plenty of water. Remove contaminated clothing and shoes. Wash any contaminated clothing or shoes before reuse. Seek medical attention immediately.

Eye contact:

Rinse thoroughly with plenty of water for at least 15 minutes and seek medical attention immediately.

Aggravating conditions:

Repeated or prolonged exposure is not known to aggravate medical conditions.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Absorb liquid with an absorbent material. Transfer contaminated absorbent to a chemical waste container for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Wash hands after handling. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Remarks

Store according to product and label instructions.

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Suitable personal protective equipment (PPE) should be worn prior to use. Wash hands before breaks and at the end of work day.

Eye and face protection

Avoid contact with eyes. Always use protective safety glasses with side-shields conforming to EN 166 (EU).

Skin protection

Avoid contact with skin and mucous membranes. Avoid prolonged or repeated contact with skin. Always use disposable chemical-resistant gloves conforming to EN 374 (EU) to handle the product. Gloves must be inspected prior to use and should consist of materials such as latex, butyl rubber, ethyl vinyl alcohol laminate (EVAL), neoprene, nitrile/butadiene rubber ("nitrile"/NBR) or polyvinyl chloride ("vinyl"/PVC). When prolonged or frequently repeated contact is expected, gloves with protection class 6 (breakthrough time > 480 min according to EN 374) are recommended. When only brief contact is expected, gloves with protection class 1 (breakthrough time > 10 min according to EN 374) are recommended. The selection of a specific glove type should also take into account all relevant factors, such as but not limited to: other chemicals that may be handled; physical requirements such as puncture protection, dexterity and thermal protection; potential allergic reactions to glove material; and additional instructions and specifications from the glove manufacturer. If gloves are damaged during use, immediately remove and replace. Use proper glove removal technique, ensuring that the outside of the glove does not come into contact with bare skin. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands after use.

Body Protection

The type of protective equipment must be selected according to the concentration and quantity of dangerous substances present at the specific workplace. Impervious clothing, such as laboratory coats, are recommended.

Respiratory protection

A respirator is not expected to be required under normal conditions of use. Where risk assessment shows air-purifying respirators are appropriate, use a full-face respirator with multi-purpose combination US or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH US or CEN EU.

Control of environmental exposure

Comply with applicable environmental regulations. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical State:	Liquid at room temperature.
Colour:	No data available.
Odour:	No data available.
Melting point/freezing point:	Essentially that of water.
Initial boiling point and boiling range:	Essentially that of water.
Flammability:	No data available.
Lower and upper explosion limit:	No data available.
Flash point:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
pH:	No data available.
Kinematic viscosity:	No data available.
Solubility:	Soluble.
Partition coefficient (n-octanol/water):	No data available.
Vapour pressure:	No data available.
Relative density:	No data available.
Relative vapour density:	No data available.
Particle characteristics:	No data available.

9.2.1 Information with regard to physical hazard classes

None applicable.

9.2.2 Other safety information

None applicable.

SECTION 10: Stability and reactivity

10.1 Reactivity

No known reactions when used as described.

10.2 Chemical stability

Product is stable under normal operating conditions and when used as described in the product technical data sheet.

10.3 Possibility of hazardous reactions

No known hazardous reactions when used as described in the product technical data sheet.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Routes of exposure may include inhalation, skin absorption, ingestion, and eye and skin contact.

Toxicological data:	No data available.
Skin corrosion /irritation:	May cause skin irritation.
Serious eye damage/eye irritation:	May cause eye irritation.
Respiratory or skin sensitization:	No data available.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	No data available.
Specific target organ toxicity - single exposure:	No data available.
Specific target organ toxicity - repeated exposure:	No data available.
Aspiration hazard:	No data available.
Additional Information:	RTECS: Not available The product is not subject to OSHA classification according to internally approved calculation methods for preparations. When used and handled according to specifications, this product does not have any harmful effects according to our experience and the information provided to us.

11.2 Information on other hazard classes which relates to endocrine disrupting properties

No data available.

SECTION 12: Ecological information

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with all applicable local and national regulations. Must adhere to state and federal regulations. Smaller quantities can be disposed of with solid waste. Disposal must be made according to the regulations found in 40 CFR 261. This product is not considered a RCRA hazardous waste.

Contaminated packaging: Dispose of as unused product.

SECTION 14: Transport information

14.1-5 UN number, groups, classes

DOT: Not Regulated.

ADR/RID: This substance is considered non-hazardous for land transport.

IMDG: This substance is considered non-hazardous for sea transport.

IATA: This substance is considered non-hazardous for air transport.

IATA-DGR: This substance is considered non-hazardous for air transport.

14.6 Special precautions for user

No data available.

SECTION 15: Regulatory information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

To the best of our knowledge, the information contained herein is accurate. However, neither Abbexa Ltd 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.

This product is intended for research use only.