

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Praxbind® solution for injection (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	12.04.2017	000000040209	Date of first issue: 12.04.2017

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

#### 1.1 Product identifier

Trade name : Praxbind® solution for injection (finished product)

Synonyms : Praxbind® solution for injection 50 mg/mL  
with active ingredient: Idarucizumab (BI 655075)

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

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Safety Data Sheet only for the professional user.

#### 1.3 Details of the supplier of the safety data sheet

Company : Boehringer Ing. Pharma GmbH & Co.KG  
Binger Str. 173  
55216 Ingelheim am Rhein

E-mail address of person  
responsible for the SDS : EHS-Services@Boehringer-Ingelheim.com

#### 1.4 Emergency telephone number

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008)**  
The product is not subject to classification (medicinal product)

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**  
The product does not need to be labelled (medicinal product).

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.  
The pharmacological effect of the medicament has to be considered (see package leaflet).

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

Chemical nature : organic

#### Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Idarucizumab	1362509-93-0		5

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).  
First Aid responders should pay attention to self-protection and use the recommended protective clothing  
Remove from exposure, lie down.  
Take off immediately all contaminated clothing.  
Victim to lie down in the recovery position, cover and keep him warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.  
Keep eye wide open while rinsing.

If swallowed : Rinse mouth.  
Drink plenty of water.

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

Risks : No information available.

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

Treatment : Observe the summary of product characteristics of proprietary medicinal products  
Symptomatic treatment (decontamination, vital functions).

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Water  
Dry chemical  
Foam  
Carbon dioxide (CO<sub>2</sub>)

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.  
Can be released in case of fire:  
Carbon oxides  
Product itself is non-combustible.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. complete suit protecting against chemicals

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Wear personal protective equipment.  
Ensure adequate ventilation.  
High risk of slipping due to leakage/spillage of product.

#### 6.2 Environmental precautions

Environmental precautions : Do not flush into surface water or sanitary sewer system.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and transfer to properly labelled containers.

#### 6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

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- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Advice on protection against fire and explosion : No special protective measures against fire required. The product is not flammable.
- Hygiene measures : General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

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

- Requirements for storage areas and containers : No special storage conditions required.
- Advice on common storage : Keep away from food, drink and animal feedingstuffs. Advice on Segregation
- Storage class (TRGS 510) : 12, Non Combustible Liquids

### 7.3 Specific end use(s)

- Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Components	Basis	Category	Values	Remark
Idarucizumab, Peptide sequence 1362509-93-0	BIEL	3A	< 100 µg/m <sup>3</sup>	
	BIPC	2		

**Abbreviations:**  
BIEL = Boehringer Ingelheim Exposure Limit  
BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)  
BIPC = Boehringer Ingelheim Pregnancy Category  
BIPC 2: There is no data available to classify the compound according to its reproductive risk.

### 8.2 Exposure controls

#### Engineering measures

- Local exhaust
- Emergency sprinkling nozzle

#### Personal protective equipment

- Eye protection : Safety glasses with side-shields

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Hand protection	
Material	: Nitrile rubber
Break through time	: 480 min
Glove thickness	: 0,43 mm
Directive	: Protective gloves against chemicals and micro-organisms
Protective index	: Class 6
Skin and body protection	: Laboratory: laboratory coat; factory: disposable Overall.
Respiratory protection	: No personal respiratory protective equipment normally required. Breathing apparatus needed only when aerosol or mist is formed. Respiratory protection ABEK2
Protective measures	: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: Not applicable
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: No data available

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Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Bulk density	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Explosive properties	:	Not tested
Oxidizing properties	:	No data available

### 9.2 Other information

Self-ignition	:	No data available
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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

No decomposition if stored and applied as directed.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	No dangerous reaction known under conditions of normal use.
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### 10.4 Conditions to avoid

Conditions to avoid	:	Extremes of temperature and direct sunlight.
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### 10.5 Incompatible materials

Materials to avoid	:	No data available
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### 10.6 Hazardous decomposition products

No data available

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

##### Components:

##### **Idarucizumab:**

Acute oral toxicity : Remarks: The active ingredient is a peptide sequence, after oral administration proteolysis/degradation and hence no bio-availability is expected.  
Expert judgement

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

##### Components:

##### **Idarucizumab:**

Remarks: No data available

#### Serious eye damage/eye irritation

##### Components:

##### **Idarucizumab:**

Remarks: No data available

#### Respiratory or skin sensitisation

##### Components:

##### **Idarucizumab:**

Remarks: No data available

#### Germ cell mutagenicity

##### Components:

##### **Idarucizumab:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

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### Carcinogenicity

#### Components:

##### Idarucizumab:

Remarks: No data available

### Reproductive toxicity

#### Components:

##### Idarucizumab:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

### STOT - single exposure

#### Components:

##### Idarucizumab:

Remarks: No data available

### STOT - repeated exposure

#### Components:

##### Idarucizumab:

Remarks: No data available

### Aspiration toxicity

#### Components:

##### Idarucizumab:

No data available

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Idarucizumab:

Toxicity to fish : Remarks: No data available



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Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to microorganisms :  
Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

### 12.2 Persistence and degradability

#### Components:

##### **Idarucizumab:**

Biodegradability : Remarks: No data available

### 12.3 Bioaccumulative potential

#### Components:

##### **Idarucizumab:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

### 12.4 Mobility in soil

#### Components:

##### **Idarucizumab:**

Distribution among environmental compartments : Remarks: No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

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### 12.6 Other adverse effects

#### Components:

##### **Idarucizumab:**

Additional ecological information : No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.  
Uncontaminated packaging can be recycled.

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## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

Water contaminating class (Germany) : WGK 1 slightly water endangering  
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : Total dust:  
Not applicable  
Inorganic substances in powdered form:  
Not applicable  
Inorganic substances in vapour or gaseous form:  
Not applicable  
Organic Substances:  
Not applicable  
Carcinogenic substances:  
Not applicable  
Mutagenic:  
Not applicable  
Toxic to reproduction:  
Not applicable

### The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
Idarucizumab  
Non-hazardous galenic excipients

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

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IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

### 15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

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## SECTION 16: Other information

### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Training advice : Provide adequate information, instruction and training for operators.

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Other information : Vertical lines in the left hand margin indicate an amendment from the previous version.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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