SAFETY DATA SHEET

Praxbind® solution for injection

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	10/20/2015	000000033890	Date of first issue: 10/20/2015

SECTION 1. IDENTIFICATION

Product name : Praxbind® solution for injection

Synonyms : Idarucizumab® solution,
Dabigatran reversal agent

Product code : 000000033890

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

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SECTION 2. HAZARDS IDENTIFICATION

GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

Other hazards

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 5 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Idarucizumab	1362509-93-0	5
Non-hazardous galenic excipients	Not Assigned	95

SECTION 4. FIRST AID MEASURES

General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection

and use the recommended protective clothing

If inhaled	:	Move to fresh air. Call a physician immediately.
In case of skin contact	:	Wash off immediately with plenty of water. Call a physician immediately.
In case of eye contact	:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
If swallowed	:	Rinse mouth. Drink plenty of water. Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	Symptomatic treatment (decontamination, vital functions). Observe the summary of product characteristics of proprietary medicinal products

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Dry chemical Foam Carbon dioxide (CO2)
Specific hazards during firefighting	:	In case of fire and/or explosion do not breathe fumes. Can be released in case of fire: Carbon oxides Nitrogen oxides (NOx) Product itself is non-combustible.
Further information	:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Special protective equipment for firefighters	:	Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Suppress vapours with waterspray.

Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Wear personal protective equipment. Large spills should be collected mechanically (remove by pumping) for disposal. Clean-up methods - small spillage Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	The product is not flammable.
Advice on safe handling	:	Provide sufficient air exchange and/or exhaust in work rooms. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.
Conditions for safe storage	:	Keep tightly closed in a dry and cool place. Keep in a well-ventilated place. Protect from heat and direct sunlight. Jointless smooth floor
Materials to avoid	:	Keep away from food, drink and animal feedingstuffs. Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Factor	Catergory	Values	Remark
Idarucizumab, Peptide sequence 1362509-93-0	ECL		3A	< 100 µg/m3	
ECL (BIPI Exposure Control Limit)					

Engineering measures	:	Local exhaust Emergency sprinkling nozzle Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required. Breathing apparatus needed only when aerosol or mist is formed. Protecting mask (EN 136)

multirange filter ABEK (EN 141)

Use NIOSH approved respiratory protection.

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

Eye protection	:	Tightly fitting safety goggles
Skin and body protection	:	Laboratory: laboratory coat; factory: disposable Overall.
Protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not breathe vapour. 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.
Hygiene measures	:	General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	light yellow, clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	5.3 - 5.7
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	does not ignite
Upper explosion limit	:	Not applicable

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute toxicity (other routes of administration)	:	LD0 (Rat): = 50 mg/l Application Route: intravenous LD0 (Rat): = 175 mg/l Application Route: intravenous

Components:

Idarucizumab:

Acute oral toxicity : Remarks: The active ingredient is an antibody, after oral administration proteolysis/degradation and hence no bioavailability 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

Carcinogenicity

Components:

Idarucizumab:

Remarks: No data available

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.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

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

Repeated dose toxicity

Product:

Species: Rat
NOAEL: 500 mg/kg
Application Route: intravenous
Exposure time: 28-day

Species: Monkey
NOAEL: 500 mg/kg
Application Route: intravenous

Aspiration toxicity

Components:

Idarucizumab:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Idarucizumab:

Toxicity to fish : Remarks: No data available

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

Toxicity to algae : 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

Toxicity to bacteria : Remarks: No data available

Persistence and degradability

Components:

Idarucizumab:
Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Idarucizumab:
Bioaccumulation : Remarks: No data available

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

Mobility in soil

Components:

Idarucizumab:
Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

Idarucizumab:
Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

TSCA list : Not relevant

WHMIS Classification : Not Rated

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Idarucizumab	1362509-93-0	5 - 10 %

New Jersey Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Idarucizumab	1362509-93-0	5 - 10 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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

REACH : Not in compliance with the inventory

: Idarucizumab

: Non-hazardous galenic excipients

CH INV : Not in compliance with the inventory

: Idarucizumab

: Non-hazardous galenic excipients

TSCA : Not On TSCA Inventory

: Idarucizumab

: Non-hazardous galenic excipients

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

: Idarucizumab

: Non-hazardous galenic excipients

CEPA : Not in compliance with the inventory

: Idarucizumab

: Non-hazardous galenic excipients

AICS : Not in compliance with the inventory

	:	Idarucizumab
	:	Non-hazardous galenic excipients
NZIoC	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients
ENCS	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients
ISHL	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients
KECI	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients
PICCS	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients
IECSC	:	Not in compliance with the inventory
	:	Idarucizumab
	:	Non-hazardous galenic excipients

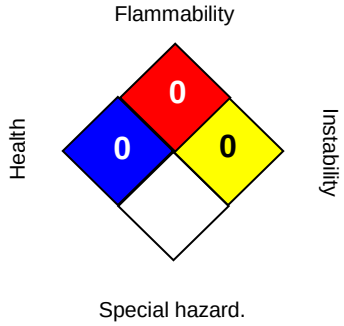
Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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.
Revision Date	:	10/20/2015

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.