

Safety Data Sheet

Factor VIII INH Kit



SDS No. 0F00.01
p 1/7 EN

Temp.: TFD366.01
Art. 01 to D00068

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name/Reference No.	Factor VIII INH Kit native	~ 2 – 4 tests	REF 5152005
	Factor VIII INH Kit	~ 2 – 4 tests	REF 5152009

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

Identified Use(s)	For professional users only
Component 1	Factor VIII Normal Plasma
Component 2	Factor VIII Inhibitor Plasma
Component 3	FVIII Inhibitor Free Plasma
Component 4	Imidazole buffer
Uses Advised Against	Not known.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Company Identification	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Address of Manufacturer	Brunner Strasse 67 1230 Vienna Austria
Postal code	1230
Telephone:	+43 1 86373-0
Fax	+43 1 86373-44
E-mail	products@technoclone.com
Office hours	8:00 – 16:00

1.4 Emergency telephone number

Emergency Phone No.	+43 1 86373-0
Contact	products@technoclone.com
National response center	
Address	NHS Direct
Emergency Phone No.	+44 111

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	
Factor VIII Normal Plasma	Not classified as dangerous for supply/use
Factor VIII Inhibitor Plasma	Not classified as dangerous for supply/use
FVIII Inhibitor Free Plasma	Not classified as dangerous for supply/use
Imidazole buffer	Classified as Repr. 1A: May damage the unborn child

2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) Imidazole buffer
Hazard Pictogram(s)	 GHS08
Signal Word(s)	Danger
Hazard Statement(s)	H360D: May damage the unborn child.
Precautionary Statement(s)	None

2.3 Other hazards

None known.

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2.4 Additional Information

Imidazole buffer The usual precautions for handling chemicals should be observed..
Factor VIII Normal Plasma Contains human derived material - potentially biohazardous
Factor VIII Inhibitor Plasma
FVIII Inhibitor Free Plasma
For full text of H/P Statements see section 16.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Imidazole	288-32-4	EC No. 206-019-2	< 0.4%	acute oral tox. cat 4, H302, skin corrosion cat 1C, H314, repr. Tox. Cat 1B, H360d	GHS05 GHS08 GHS07

Contains no non-classified vPvB substances or substances with a Union workplace exposure limit.
For full text of H/P Statements see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation IF exposed or concerned: Get medical advice/attention.
Skin Contact IF exposed or concerned: Get medical advice/attention.
Eye Contact IF exposed or concerned: Get medical advice/attention.
Ingestion IF exposed or concerned: Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

IF exposed or concerned: Get medical advice/attention. Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media As appropriate for surrounding fire.
Unsuitable extinguishing media None.

5.2 Special hazards arising from the substance or mixture

Heating may cause decomposition.

5.3 Advice for firefighters

Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Ensure full personal protection (including respiratory protection) during removal of spillages.

6.2 Environmental precautions

Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

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6.3 Methods and material for containment and cleaning up

Adsorb spillages onto sand, earth or any suitable adsorbent material.
Transfer to a container for disposal.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature	+2°C to +8°C
Storage life	Stable under normal conditions.
Incompatible materials	None known.

7.3 Specific end use(s)

In vitro diagnostic use

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits No Occupational Exposure Limit assigned.

8.2 Exposure controls

8.2.1. Appropriate engineering controls Use with ventilation, local exhaust ventilation or breathing protection.

8.2.2. Personal protection equipment

Eye Protection	Wear eye protection with side protection (EN166).
Skin protection	Wear protective clothing and gloves: Impervious gloves (EN 374).
Respiratory protection	A suitable mask with filter type A (EN14387 or EN405) may be appropriate.
Thermal hazards	None known.

8.2.3. Environmental Exposure Controls Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state

Factor VIII Normal Plasma	solid
Factor VIII Inhibitor Plasma	solid
FVIII Inhibitor Free Plasma	solid
Imidazole buffer	liquid

Colour

Factor VIII Normal Plasma	white-yellowish
Factor VIII Inhibitor Plasma	white-yellowish
FVIII Inhibitor Free Plasma	white-yellowish
Imidazole buffer	Without colour

Odour

odourless

Melting point/freezing point Not known.

Boiling point or initial boiling point and boiling range Not applicable.

Flammability Not known.

Lower and upper explosion limit Not known.

Flash Point Not applicable.

Auto-ignition temperature Not known.

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Decomposition Temperature	Not known.
pH	6-8
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : readily miscible. Solubility (Other) : Not known
Partition coefficient n-octanol/water (log value)	Not known.
Vapour pressure	Not known.
Density and/or relative density	Not known.
Relative vapour density	Not known.
Particle characteristics	Not known.

9.2 Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None anticipated.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

None anticipated.

10.5 Incompatible materials

Not known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity - Ingestion	Calculation method : Calculated acute toxicity estimate (ATE) Calc ATE - 147058.81000
Acute toxicity - Skin Contact	Calculation method : Not classified.
Acute toxicity - Inhalation	Calculation method : Not classified.
Skin corrosion/irritation	Calculation method : Not classified.
Serious eye damage/irritation	Calculation method : Not classified.
Skin sensitization data	Calculation method : Not classified.
Respiratory sensitization data	Calculation method : Not classified.
Germ cell mutagenicity	Calculation method : Not classified.
Carcinogenicity	Calculation method : Not classified.
Reproductive toxicity	Self classification: May damage the unborn child.
Lactation	Calculation method : Not classified.
STOT - single exposure	Calculation method : Not classified.
STOT - repeated exposure	Calculation method : Not classified.
Aspiration hazard	Calculation method : Not classified.

11.2 Information on other hazards

Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity - Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity - Fish	Low toxicity to fish.

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Toxicity - Algae Low toxicity to algae.
Toxicity - Sediment Compartment Not classified.
Toxicity - Terrestrial Compartment Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

Not known.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of contents in accordance with local, state or national legislation.
Dispose of this material and its container to hazardous or special waste collection point. Dispose at suitable refuse site.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: TRANSPORT INFORMATION

Not classified as hazardous for transport.

14.1 UN number or ID number

Not applicable

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 classified as a Marine Pollutant.

14.6 Special precautions for user

Not known

14.7 Maritime transport in bulk according to IMO instruments

Not known

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SECTION 15: REGULATORY INFORMATION

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

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation Not listed
REACH: ANNEX XIV list of substances subject to authorisation Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Imidazole (288-32-4)
Community Rolling Action Plan (CoRAP) Imidazole (288-32-4)
Regulation (EC) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals Not listed

National regulations

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Date of Issue 07.03.2019 (0F00E.01_SDB)
Date of Revision 24.05.2023

LEGEND

Hazard Pictogram(s)



GHS08

Hazard classification

Repr. 1A : Reproductive toxicity, Category 1A

Hazard Statement(s)

H360D: May damage the unborn child.

Precautionary Statement(s)

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P405: Store locked up.
P501: Dispose of contents in accordance with local, state or national legislation.

Acronyms

ATE : Acute Toxicity Estimate
CAS : Chemical Abstracts Service
CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL : Derived No Effect Level
EC : European Community
EINECS : European Inventory of Existing Commercial Chemical Substances
LTEL : Long term exposure limit
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No Effect Concentration
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL : Short term exposure limit

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STOT : Specific Target Organ Toxicity
vPvB : very Persistent and very Bioaccumulative

Key literature references and sources for data used to compile the SDS Regulation (EC) No. 1272/2008 (CLP)

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