

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name

Rebiny® Coagulation Factor (Recombinant), GlycoPEGylated
All IU (Vials)

Product no.

-

REACH registration number

Not applicable

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

Relevant identified uses of the substance or mixture

Closed handling with occasional open handling, e.g. for sampling

Uses advised against

-

The full text of any mentioned and identified use categories are given in section 16

1.3. Details of the supplier of the safety data sheet

Company and address

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark
Tel:+45 44 44 88 88

Contact person

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E-mail

SDSsupport@novonordisk.com

SDS date

2018-02-09

SDS Version

2.0

1.4. Emergency telephone number

Contact The National Poisons Information Service. See section 4 "First aid measures".

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified according to Regulation (EC) No. 1272/2008 (CLP)

2.2. Label elements

Hazard pictogram(s)

-

Signal word

-

Hazard statement(s)

-

Safety statement(s)

General	-
Prevention	-
Response	-
Storage	-
Disposal	-

▼ Identity of the substances primarily responsible for the major health hazards

Not applicable

▼ 2.3. Other hazards

Consult the package insert

- Contains a pharmacologically active substance
- ▼ **Additional labelling**
Not applicable
- ▼ **Additional warnings**
Not applicable
- VOC**
Not applicable

SECTION 3: Composition/information on ingredients

▼ 3.1/3.2. Substances/Mixtures

NAME:	Lyophilized N9-GP and excipients
IDENTIFICATION NOS.:	CAS-no: 1175512-71-6
CONTENT:	100%
CLP CLASSIFICATION:	NA

NAME:	L-Histidin
IDENTIFICATION NOS.:	CAS-no: 71-00-1 EC-no: 200-745-3
CONTENT:	< 1%
CLP CLASSIFICATION:	NA

(*) See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

-

SECTION 4: First aid measures

4.1. Description of first aid measures

▼ General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

▼ Inhalation

Seek fresh air. Seek medical advice in case of persistent discomfort.

▼ Skin contact

Remove contaminated clothes immediately. Wash skin with soap and water. Seek medical advice in case of persistent discomfort.

▼ Eye contact

Flush immediately with water (preferably using eye wash equipment) for at least 5 minutes. Open eye wide. Remove any contact lenses. Seek medical advice if irritation continues.

▼ Ingestion

Rinse mouth thoroughly and then drink plenty of water. Do not induce vomiting. Seek medical advice in case of persistent discomfort.

Burns

Not applicable

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

Nothing special

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

Nothing special

Information to medics

Bring this safety data sheet.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Waterjets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

Nothing special

5.3. Advice for firefighters

No specific requirements.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No specific requirements.

6.2. Environmental precautions

No specific requirements.

6.3. Methods and material for containment and cleaning up

Collect spills carefully. Moist the material with water in order to prevent the formation and propagation of dust. To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section on "Disposal considerations" in regard of handling of waste. See section on 'Exposure controls/personal protection' for protective measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms. See section on 'Exposure controls/personal protection' for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Always store in containers of the same material as the original container. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

▼ Storage temperature

Refrigerator, 2 to 8°C

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

▼ OEL

Comply with any national regulations regarding occupational exposure limit if is any.

DNEL / PNEC

No data available

8.2. Exposure controls

Control is unnecessary if the product is used as intended.

General recommendations

Observe general occupational hygiene standards.

Exposure scenarios

In the event exposure scenarios are appended to the safety data sheet, the operational conditions and risk management measures in these shall be complied with.

▼ Exposure limits

Comply with any national regulations regarding occupational exposure limit if is any.

Appropriate technical measures

Apply standard precautions during use of the product. Avoid inhalation of gas or dust.

Hygiene measures

In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Always wash hands, forearms and face.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment



Generally

Use only CE marked protective equipment.

▼ Respiratory Equipment

Use suitable protective breathing equipment, if the ventilation is not sufficient. The choice depends on the

specific work situation. At oxygen deficient atmospheres or usage more than 3 hours (turbofilter excluded) self-contained respirator must be used: Using mask with filter, use filter type S/SL. P2 . White
Use respirator at dust producing work.

Skin protection

No specific requirements.

▼ **Hand protection**

Use protective gloves. The choice of material depends on the specific work situation and the risk assessment of it.

Recommended material: Nitrile rubber. See the manufacturer's instructions.

▼ **Eye protection**

No specific requirements.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	Powder
Colour	No data available.
Odour	No data available.
Odour threshold (ppm)	No data available.
pH	No data available.
Viscosity (40°C)	No data available.
Density (g/cm ³)	No data available.

Phase changes

Melting point (°C)	No data available.
Boiling point (°C)	No data available.
Vapour pressure	No data available.
Decomposition temperature (°C)	No data available.
Evaporation rate (n-butylacetate = 100)	No data available.

Data on fire and explosion hazards

Flash point (°C)	No data available.
Ignition (°C)	No data available.
Auto flammability (°C)	No data available.
Explosion limits (% v/v)	No data available.
Explosive properties	No data available.

Solubility

Solubility in water	Soluble
n-octanol/water coefficient	No data available.

9.2. Other information

Solubility in fat (g/L)	No data available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

The product is stable under the conditions, noted in the section "Handling and storage".

10.3. Possibility of hazardous reactions

Nothing special

▼ **10.4. Conditions to avoid**

Frost.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

▼ **Acute toxicity**

Substance: Lyophilized N9-GP and excipients
Species: -

Test: -
Route of exposure: Dermal
Result: Not Classified

Substance: Lyophilized N9-GP and excipients
Species: -
Test: -
Route of exposure: Inhalation
Result: Not Classified

Substance: Lyophilized N9-GP and excipients
Species: -
Test: -
Route of exposure: Oral
Result: Not Classified

▼ **Skin corrosion/irritation**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Serious eye damage/irritation**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Respiratory or skin sensitisation**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Germ cell mutagenicity**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Carcinogenicity**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Reproductive toxicity**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **STOT-single exposure**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **STOT-repeated exposure**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

▼ **Aspiration hazard**

Data on substance: Lyophilized N9-GP and excipients
Result: Not Classified

Long term effects

Nothing special

SECTION 12: Ecological information

▼ **12.1. Toxicity**

No data available.

12.2. Persistence and degradability

Substance	Biodegradability	Test	Result
No data available.			

12.3. Bioaccumulative potential

Substance	Potential bioaccumulation	LogPow	BCF
No data available.			

12.4. Mobility in soil

No data available

▼ **12.5. Results of PBT and vPvB assessment**

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

▼ **12.6. Other adverse effects**

Nothing special

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose in accordance with local and national regulations

Waste

EWC code

-

Specific labelling

-

Contaminated packing

No specific requirements.

SECTION 14: Transport information

14.1 – 14.4

Not dangerous goods according to ADR, IATA and IMDG.

ADR/RID

14.1. UN number -

14.2. UN proper shipping name -

14.3. Transport hazard class(es) -

14.4. Packing group -

Notes -

Tunnel restriction code -

IMDG

UN-no. -

Proper Shipping Name -

Class -

PG* -

EmS -

MP** -

Hazardous constituent -

IATA/ICAO

UN-no. -

Proper Shipping Name -

Class -

PG* -

14.5. Environmental hazards

-

14.6. Special precautions for user

-

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

No data available

(*) Packing group

(**) Marine pollutant

SECTION 15: Regulatory information

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

Restrictions for application

-

Demands for specific education

-

Additional information

Not applicable

Seveso

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Sources

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 (CLP).

EC regulation 1907/2006 (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

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The full text of identified uses as mentioned in section 1

-

Additional label elements

Not applicable

Other

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The safety data sheet is validated by

JGOA

Date of last essential change (First cipher in SDS version)

2017-10-02

Date of last minor change (Last cipher in SDS version)

2017-10-02