

Revision date 06-May-2023

Version 9

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

1.1. Product identifier

Product No P8010
Product name Factor Xa Protease
Pure substance/mixture Mixture

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

Recommended use This product is for research and development only
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier Address
New England BioLabs
240 County Road
Ipswich, MA 01938
USA

For further information, please contact

Company Phone Number 978-927-5054, 800-632-5227 (toll free)
Telefax 978-921-1350
E-mail address info@neb.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number Chemtrec +44 20 3885 0382

Europe	+1 978-380-2125
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

EUH210 - Safety data sheet available on request

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.**2.3. Other hazards**

No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium Chloride 7647-14-5	1 - 5	No data available	231-598-3	No data available	-	-	-

Full text of H- and EUH-phrases: see section 16**Acute Toxicity Estimate**

No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium Chloride 7647-14-5	3000	10000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)**SECTION 4: First aid measures****4.1. Description of first aid measures****Inhalation** Remove to fresh air.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth.

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

Symptoms	No information available.
Effects of Exposure	No information available.

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

Note to physicians	Treat symptomatically.
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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.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Personal precautions	Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510) Storage class 10.

7.3. Specific end use(s)

Risk management methods [RMM] The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Sodium Chloride 7647-14-5	-	-	-	TWA: 5 mg/m ³	TWA: 5 mg/m ³

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Glycerol 56-81-5	-	-	56 mg/m ³ [5] [6]
Sodium Chloride 7647-14-5	-	295.52 mg/kg bw/day [4] [6] 295.52 mg/kg bw/day [4] [7]	2068.62 mg/m ³ [4] [6] 2068.62 mg/m ³ [4] [7]
Hepes 7365-45-9	-	3.33 mg/kg bw/day [4] [6]	23.5 mg/m ³ [4] [6]

Notes

- [4] Systemic health effects.
 [5] Local health effects.
 [6] Long term.
 [7] Short term.

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Glycerol 56-81-5	229 mg/kg bw/day [4] [6]	-	33 mg/m ³ [5] [6]
Sodium Chloride 7647-14-5	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	443.28 mg/m ³ [4] [6] 443.28 mg/m ³ [4] [7]
Hepes 7365-45-9	1.67 mg/kg bw/day [4] [6]	-	5.8 mg/m ³ [4] [6]

Notes

[4]	Systemic health effects.
[5]	Local health effects.
[6]	Long term.
[7]	Short term.

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Glycerol 56-81-5	0.885 mg/L	8.85 mg/L	0.0885 mg/L	-	-
Sodium Chloride 7647-14-5	5 mg/L	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Glycerol 56-81-5	3.3 mg/kg sediment dw	0.33 mg/kg sediment dw	1000 mg/L	0.141 mg/kg soil dw	-
Sodium Chloride 7647-14-5	-	-	500 mg/L	4.86 mg/kg soil dw	-

8.2. Exposure controls

Engineering controls	No information available.
Individual protection measures, such as personal protective equipment	
Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Colorless
Color	No information available
Odor	Mild.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	392.78 °C	
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	20,233.70 mg/kg
ATEmix (dermal)	18,895.70 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-vapor)	99,999.00 mg/l
ATEmix (inhalation-dust/mist)	99,999.00 mg/l

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Chloride	-	LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i>) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i>) LC50: 6020 - 7070mg/L (96h, <i>Pimephales promelas</i>) LC50: =7050mg/L (96h, <i>Pimephales promelas</i>) LC50: 6420 - 6700mg/L (96h, <i>Pimephales promelas</i>) LC50: 4747 - 7824mg/L (96h, <i>Oncorhynchus mykiss</i>)	-	EC50: =1000mg/L (48h, <i>Daphnia magna</i>) EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i>)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Sodium Chloride	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

- 14.1 UN number or ID number Not regulated
- 14.2 Extended Proper Shipping Name Not regulated
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing group Not regulated
- 14.5 Environmental hazard Not applicable
- 14.6 Special precautions for user Special Provisions None

IMDG

- 14.1 UN number or ID number Not regulated
- 14.2 Extended Proper Shipping Name Not regulated
- 14.3 Transport hazard class(es) Not regulated

14.4 Packing group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special precautions for user	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN/ID No	Not regulated
14.2 Extended Proper Shipping Name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special precautions for user	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special precautions for user	
Special Provisions	None

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Chemical name	French RG number
Sodium Chloride - 7647-14-5	RG 78

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sodium Chloride - 7647-14-5	Plant protection agent
Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sodium Chloride - 7647-14-5	Product-type 1: Human hygiene

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status

KECL Contact supplier for inventory compliance status
PICCS Contact supplier for inventory compliance status
AIC Contact supplier for inventory compliance status
NZIoC Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
+	Sensitizers		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGl(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 National Institute of Technology and Evaluation (NITE)
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program
 Organization for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

Prepared by Environmental, Health and Safety

Revision note SDS is valid 3 years from revision date. Contact info@neb.com for latest revision.

Revision date

06-May-2023

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

Disclaimer

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End of Safety Data Sheet