

SAFETY DATA SHEET

According to 1907/2006/EC, Article 31



RVV Factor X Activator 5U

121-06

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

1.1 Product identifier

Trade name RVV Factor X Activator 5U
Article number 121-06

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

Application of the substance / the mixture Diagnostic reagent

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier DSM Nutritional Products Ltd Branch Pentapharm
Dornacherstrasse 112
CH- 4147 Aesch / Switzerland
Phone +41 61 706 48 48
Fax +41 61 706 48 00
Further information obtainable from pentapharm@pentapharm.com

1.4 Emergency telephone number

Tox Info Suisse : +41 44 251 51 51 (24h; 7 days a week)

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



Health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Skins Sens. 1 H317 May cause an allergic skin reaction

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS08

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Signal word

Danger

Hazard-determining components of labelling

Factor X activator from Russell's viper venom Dimeric protein endopeptidase (MW 120'000 daltons)

Hazard statements

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

Precautionary statements

P284 In case of inadequate ventilation wear respiratory protection.

P261 Avoid breathing dust.

P280 Wear protective gloves / protective clothing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Additional information

2% of the mixture consists of component(s) of unknown toxicity extracted from snake venom. Classification of the product is derived from the starting material (snake venom) and general knowledge of enzyme properties. This product itself has not been tested.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.



vPvB: According to current knowledge, the product contains no vPvB substance.

3 Composition/information on ingredients

3.2 Chemical characterization

Description

This product is a lyophilized cake to be reconstituted with deionized water. The active compound is a Factor X activator purified from Russell's viper venom (endopeptidase, MW 120'000). It is stabilized by a collagen peptide fraction with a concentration of approx. 98%.

Dangerous components		
79393-92-3	Factor X activator from Russell's viper venom Dimeric protein, endopeptidase (MW 120'000 daltons)  Resp. Sens. 1, H334;  Skin Sens. 1, H317	1 - 2.5%

SVHC

According to current knowledge no SVHC contained.

Additional information

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For the wording of the listed risk phrases refer to section 16.

4 First aid measures

4.1 Description of first aid measures

General information

No special measures required

After inhalation

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

After skin contact

Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

After eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

After swallowing

Immediately call a POISON CENTRE/doctor.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction

May cause allergy or asthma symptoms or breathing difficulties if inhaled

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

CO₂, foam, dry powder, or water.

5.2 Specific hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment

Wear self-contained respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact and particle inhalation.

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6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Collect in suitable containers.

Clean the affected area carefully and ensure adequate ventilation.

Avoid dust formation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

7.1 Precautions for safe handling

Avoid skin and eye contact and particle inhalation.

Information about fire - and explosion protection

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles

No special requirements.

Information about storage in one common storage facility

Not required.

Further information about storage conditions

Store the product in a dry place protected from light at a temperature between 2 to 8°C.

7.3 Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

A limit value has not been defined.

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Additional information

The lists valid during the making were used as basis.

The professional use of this product by young people is restricted or prohibited altogether. The corresponding legal bases and precise regulations are set out in section 15.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Do not breath dust.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Respiratory protection

In case of inadequate ventilation war respiratory protection.

Respiratory protection must be compliant with the specifications of Directive 89/686/EEC and be in accordance with the EN standards resulting thereof.

Protection of hands



Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications of EU Directive 89/686/EEC and be in accordance with the standard EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Eye protection



Safety glasses

Protective goggles must be compliant with the specifications of Directive 89/686 / EEC and be in accordance with the standard EN166.

Limitation and supervision of exposure into the environment

Do not allow to enter sewers/ surface or ground water.

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9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information	
Appearance	
Form	Lyophilizate
Colour	White to off white
Odour	Odourless
Odour threshold	Not determined.
pH-value	Not determined.
Change in condition	
Melting point/Melting range	Not determined.
Boiling point/Boiling range	Not determined.
Flash point	Not applicable.
Flammability (solid, gaseous)	Not determined.
Ignition temperature	Not determined.
Decomposition temperature	Not determined.
Self-igniting	Product is not self-igniting.
Danger of explosion	Not determined
Explosion limits	
Lower	Not determined.
Upper	Not determined.
Oxidising properties	Not determined.
Vapour pressure	Not applicable.
Density	
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water	Soluble.
Partition coefficient (n-octanol/water)	Not determined.
Viscosity	
Dynamic	Not applicable.
Kinematic	Not applicable.
Solvent content	
VOC (EC)	Not determined.
VOCV (CH)	Not determined.

9.2 Other information

No further relevant information available.

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10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

No information available

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Heat may cause this product to decompose.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Nature of decomposition products not known.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

2% of the mixture consists of component(s) of unknown toxicity extracted from snake venom.

The toxicological properties have not been thoroughly investigated.

May be harmful by inhalation, ingestion, or skin absorption

Primary irritant effect

Skin corrosion/irritation

No data available.

Serious eye damage/irritation

No data available.

Respiratory or skin sensitisation

Classification of the product is derived from the starting material (snake venom extract) and general knowledge of enzyme properties. This product itself has not been tested.

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Other information

The toxicological properties of this product have not been thoroughly investigated. Use appropriate precautions.

Repeated dose toxicity

No data available.

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CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

No CMR effects known.

12 Ecological information

12.1 Toxicity

Aquatic toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT

According to current knowledge, the product contains no PBT substance.

vPvB

According to current knowledge, the product contains no vPvB substance.

12.6 Other adverse effects

No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

European waste catalogue (The Swiss waste code is identical)	
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

* = hazardous waste

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

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14.1 UN-number

ADR, ADN, IMDG, IATA

Void

ADR, ADN, IMDG, IATA

Void

ADR, ADN, IMDG, IATA

Class

Void

ADR, IMDG, IATA

Void

Marine pollutant

No

Not applicable.

Not applicable.

Transport/Additional information

ADR

Remarks

Not classified.

IMDG

Remarks

Not classified.

IATA

Remarks

Not classified.

UN "Model Regulation"

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I

None of the ingredients is listed.

National regulations

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Information about limitation of use:

Article 4 para. 4 of the Ordinance on the protection of young people in the workplace (SR 822.115) and Article 1lit. f of the EAER regulation on hazardous work and young people (SR 822.115.2) Young people undergoing basic vocational training may only work with this product if the relevant training ordinance makes provision for them to do so with a view to enabling them to achieve their training objectives and if the preconditions for the training plan have been met and the applicable age restrictions have been complied with. Young people who are not completing any basic vocational training are not permitted to work with this product. Employees of either sex who are under 18 years old are classed as young people.

Waterhazard class

Water hazard class 1 (Self-assessment): slightly hazardous to water.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16 Other information

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. DSM Nutritional Products Ltd Branch Pentapharm shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

Relevant phrases

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Abbreviations and acronyms

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of

Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

VOC: Volatile Organic Compounds (USA, EU)

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1