

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

### **1.1 Product identifier**

Trade name RVV-Factor V Activator  
Article number 121-03

### **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 BL / 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.

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According to 1907/2006/EC, Article 31



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### Hazard pictograms



GHS08

### Signal word

Danger

### Hazard-determining components of labelling:

Factor V activator from Russell's viper venom serine proteinase (MW 28'000 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/fume/gas/mist/vapours/spray

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

0.1-1% 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 extract) 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.

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

## 3 Composition/information on ingredients

### 3.2 Chemical characterization

#### Description

Mixture of substances listed below with nonhazardous additions.

Dangerous components	
Factor V activator from Russell's viper serine proteinase (MW 28'000 daltons)	0.1 - 1%
 Resp. Sens. 1, H334;  Skin Sens. 1, H317	

### SVHC

According to current knowledge no SVHC contained.

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### Additional information

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/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 agents

CO<sub>2</sub>, 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.

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### 6 Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact and particle inhalation.

#### 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

RVV-Factor V Activator may be adsorbed on glass, cellulose and numerous synthetic polymers. Contaminated materials may be freed from RVV-Factor V Activator either by heating for 1 h at 180 °C or by treatment with formaldehyde.

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.

### 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.

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 wear 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

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

0.1-1% 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.

##### **Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

##### **Serious eye damage/irritation**

Based on available data, the classification criteria are not met.

##### **Respiratory or skin sensitization**

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 allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

##### **Germ cell mutagenicity**

Based on available data, the classification criteria are not met.

##### **Carcinogenicity**

Based on available data, the classification criteria are not met.

##### **Reproductive toxicity**

Based on available data, the classification criteria are not met.

##### **STOT-single exposure**

Based on available data, the classification criteria are not met.

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### STOT-repeated exposure

Based on available data, the classification criteria are not met.

### Aspiration hazard

Based on available data, the classification criteria are not met.

## 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.

#### vPvB

According to current knowledge, the product contains no vPvB.

### 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). In Switzerland codes for hazardous waste are marked with an „S“ (“Sonderabfall”) instead of an asterisk.

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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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)

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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

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