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

1.1 Product identifier

Trade name: Pefafluor® FIXa
Article number: 095-03

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

Application of the substance / the mixture: Fluorogenic peptide substrate
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
The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: Void
Hazard pictograms: Void
Signal word: Void
Hazard statements: Void
Additional information: The health hazards for this substance have not been thoroughly investigated.

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
Fluorogenic peptide substrate bound to 7-Amino-4-methylcoumarin group (AMC). Free AMC is classified as irritating. The irritating properties of AMC may be present also when bound to a peptide.

Chemical characterization
CH₃SO₂-D-CHG-Gly-Arg-AMC x AcOH

Name
amino(((S)-4-(2-((R)-2-cyclohexyl-2-(methylsulfonamido)acetamido)acetamido)-5-((4-methyl-2-oxo-2H-chromen-7-yl)amino)-5-oxopentyl)(amino)methaniminium acetate

Dangerous components

<table>
<thead>
<tr>
<th>CAS: 26093-31-2</th>
<th>7-amino-4-methylcoumarin</th>
<th>0,1 - 1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 247-454-8</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td></td>
</tr>
</tbody>
</table>

SVHC
According to current knowledge no SVHC contained.

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
Remove person to fresh air and keep 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 importance symptoms and effects, both acute and delayed
No further relevant information available.

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
CO₂, dry chemical powder, or appropriate foam.

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 aerosol 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
Pick up mechanically.
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
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Additional information
The lists valid during the making were used as basis.

8.2 Exposure controls
Personal protective equipment
General protective and hygienic measures
The usual precautionary measures are to be adhered to when handling chemicals.
Ensure good ventilation/exhaustion at the workplace.
Wash hands before breaks and at the end of work.
Respiratory protection
Use suitable respiratory protective device in case of insufficient ventilation.
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 cannot 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.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>General Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Powder.</td>
</tr>
<tr>
<td>Colour</td>
<td>White to slightly beige.</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless.</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

| pH-value            | Not determined. |

<table>
<thead>
<tr>
<th>Change in condition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/Melting range</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

| Flash point         | Not applicable. |

| Flammability (solid, gaseous) | Not determined. |

<table>
<thead>
<tr>
<th>Ignition temperature</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Decomposition temperature</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

| Self-igniting        | Product is not self-igniting. |

| Danger of explosion  | Product does not present an explosion hazard. |

<table>
<thead>
<tr>
<th>Explosion limits</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

| Vapour pressure      | Not applicable. |

<table>
<thead>
<tr>
<th>Density</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

| 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.

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
No further relevant information available.

10.6 Hazardous decomposition products
7-Amino-4-methylcumarin

11 Toxicological information

11.1 Information on toxicological effects

  Acute toxicity
No data available.

  Primary irritant effect

  Skin corrosion/irritation
Non-classification of the product is based on the calculation method and the total concentration of 7-Amino-4-methylcumarin (free and bound to the peptide). The health hazards for 7-Amino-4-methylcumarin bound to the peptide have not been thoroughly investigated.
Serious eye damage/irritation
Non-classification of the product is based on the calculation method and the total concentration of 7-Amino-4-methylcumarin (free and bound to the peptide). The health hazards for 7-Amino-4-methylcumarin bound to the peptide have not been thoroughly investigated.

Respiratory or skin sensitisation
Sensitisation possible through inhalation.
Sensitisation possible through skin contact.

Other information
The toxicological properties of this product have not been thoroughly investigated. Use appropriate precautions. May be harmful by inhalation, ingestion, or skin absorption.

Repeated dose toxicity
No data available.

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.
SAFETY DATA SHEET  
According to 1907/2006/EC, Article 31

**Pefafluor® FIXa**  
095-03

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### European waste catalogue (The Swiss code is identical)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 00 00</td>
<td>WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)</td>
</tr>
<tr>
<td>18 01 00</td>
<td>wastes from natal care, diagnosis, treatment or prevention of disease in humans</td>
</tr>
<tr>
<td>18 01 06*</td>
<td>chemicals consisting of or containing dangerous substances</td>
</tr>
</tbody>
</table>

* = hazardous waste

---

**Uncleaned packaging**

Recommendation: Disposal must be made according to official regulations.

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### 14 Transport information

#### 14.1 UN-number

ADR, ADN, IMDG, IATA  
Void

#### 14.2 UN Proper shipping name

ADR, ADN, IMDG, IATA  
Void

#### 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA  
Class  
Void

#### 14.4 Packing group

ADR, IMDG, IATA  
Void

#### 14.5 Environmental hazards

Marine pollutant  
No

#### 14.6 Special precautions for user

Not applicable.

#### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

Transport/Additional information

ADR  
Not classified.

IMDG  
Not classified.

IATA  
Not classified.

UN “Model Regulation”  
-  

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### 15 Regulatory information

#### 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

Waterhazard 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
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Abbreviations and acronyms
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)
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3