Pefachrome® tPA5312 091-03

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

1.1 Product identifier

Trade name	Pefachrome® tPA5312
Article number	091-03

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

Application of the substance / the mixture	Chromogenic 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

3.1 Chemical characterization

Description

Chromogenic peptide substrate bound to p-nitroanilin group (pNA). Free pNA is classified as toxic. The toxic properties of pNA may be present also when bound to a peptide.

Chemical characterization

CH3SO2-D-Phe-Gly-Arg-pNA·AcOH

Name

amino(((S)-4-(2-((R)-2-(methylsulfonamido)-3-phenylpropanamido)acetamido)-5-((4-nitrophenyl)amino)-5-oxopentyl)amino)methaniminium acetate

Dangerous components		
CAS: 100-01-6	p-nitroaniline	0,1 - 1%
EINECS: 202-810-1	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 3, H412	

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 hazard which require special first aid measures.

After inhalation

Remove person to fresh air and keep 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 or 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 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

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	
CAS: 100-01-6	p-nitroaniline
MAK (Switzerland)	Long-term value: 3 mg/m³, 0,5 ppm H;

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

General Information	
Appearance	
Form	Powder
Colour	Off-white / pale yellow
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	
Decomposition temperature	Not determined.
Self-igniting	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
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.

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

p-Nitroanilin

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Non-classification of the product is based on the calculation method and the total concentration of paranitroanilin (free and bound to the peptide). The health hazards for para-nitroanilin bound to the peptide 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

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.

Repeated dose toxicity

Non-classification of the product is based on the calculation method and the total concentration of paranitroanilin (free and bound to the peptide). The health hazards for para-nitroanilin bound to the peptide have not been thoroughly investigated.

CMR effects (carcinogenity, 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.

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" — -

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

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

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

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, Schweis (Swiss Ordinance on volatile organic compounds)

VOC: Volatile Organic Compounds (USA, EU)

Acute Tox. 3: Acute toxicity, Hazard Category 3

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3