

SAFETY DATA SHEET

according to ChemO 2015 - SR 813.11



PEFABLOC® TH (α NAPAP)

381-01

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

1.1 Product identifier

Trade name	Pefabloc® TH (α NAPAP)
Article number	381-01
CAS number	402751-13-7

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

Product category Protease inhibitor

Application of the substance / the mixture

Pefabloc® TH can be used in diagnostic systems, analytical applications, research and industrial purification processes to exclude undesired thrombin activity. It can also be used as a potent anticoagulant in in-vitro test systems.

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



Acute Tox. 4 H302 Harmful if swallowed.

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



GHS07

PEFABLOC® TH (α NAPAP)

381-01

Signal word

Warning

Hazard-determining components of labelling

N α -(2-Naphthylsulfonylglycyl)-4-amidino-(D,L)-phenylalanine piperidide x AcOH

Hazard statements

H302 Harmful if swallowed.

Precautionary statements

P264 Wash hands thoroughly after handling.

2.3 Other hazards

To our knowledge the health hazards for the intact compound have not been thoroughly investigated. The compound is a synthetic low molecular weight competitive inhibitor selective for serine proteases and should not come in contact with skin, eye, and should not be inhaled.

Results of PBT and vPvB assessment

PBT: No further relevant information available.

vPvB: No further relevant information available.

3 Composition/information on ingredients

3.2 Chemical characterization: Substances

CAS No.

402751-13-7

Chemical name

N α -(2-Naphthylsulfonylglycyl)-4-amidino-(D,L)-phenylalanine piperidide x AcOH (NAPAP)

Chemical formula

C₂₇H₃₁N₅O₄S × AcOH

Molecular weight

581.7 g/mol

SVHC

According to current knowledge no SVHC contained.

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.

PEFABLOC® TH (α NAPAP)

381-01

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

The compound is a synthetic low molecular weight competitive inhibitor selective for serine proteases and should not come in contact with skin, eye, and should not be inhaled.

Harmful if swallowed.

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 to enter sewers / surface or ground water.

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.

PEFABLOC® TH (αNAPAP)

381-01

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.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

PEFABLOC® TH (α NAPAP)

381-01

Respiratory protection

Use suitable respiratory protective device in case of insufficient ventilation.

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 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	White to off-white
Odour	Not detected.
Odour threshold	Not determined.
pH-value	Not applicable.
Change in condition	
Melting point/freezing point	222 - 225 °C
Initial boiling point and boiling range	Not determined.

SAFETY DATA SHEET

according to ChemO 2015 - SR 813.11



PEFABLOC® TH (αNAPAP)

381-01

Flash point	Not determined.
Flammability (solid, gas)	Not determined.
Ignition temperature	
Decomposition temperature	Not determined.
Auto-ignition temperature	Not applicable.
Explosive properties	Not determined.
Explosion limits	
Lower	Not determined.
Upper	Not determined.
Oxidising properties	Not applicable.
Vapour pressure	Not applicable.
Density	
Relative density	Not applicable.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with water at 20 °C	1.5 mg/ml
Partition coefficient (n-octanol/water)	Not applicable.
Viscosity	
Dynamic	Not applicable.
Kinematic	Not applicable.

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 decomposition if used according to specifications.

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

Avoid moisture, exposure to light, enzymes and strong acids and bases.

10.5 Incompatible materials

None known.

PEFABLOC® TH (αNAPAP)
381-01
10.6 Hazardous decomposition products

Sulphur oxides (SO_x)
 Carbon monoxide and carbon dioxide
 Nitrogen oxides

11 Toxicological information
11.1 Information on toxicological effects
Acute toxicity

Harmful if swallowed.

LD/LC50 values relevant for classification:
402751-13-7 Na-(2-Naphthylsulfonylglycyl)-4-amidino-(D,L)-phenylalanine piperidide x AcOH

Oral	LD50	>800 mg/kg (mouse)
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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 sensitisation

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

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.

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

Based on the ingredients not classified as harmful for the environment.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No further relevant information available.

PEFABLOC® TH (αNAPAP)

381-01

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

Transport additional information

ADR/ADN

Remarks Not classified.

IMGD

Remarks Not classified.

IATA

Remarks Not classified.

UN "Model Regulation" Void

15 Regulatory information

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

National regulations

Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012)
Annex 1: Volume threshold according to MAO in kg: 20'000 kg (Source: FOEN - List 2015 - Volume thresholds in accordance with the Major Accidents Ordinance / Volume Threshold Calculator)

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The product contains no substances subject to authorization according to Annex 1.17 in concentrations $\geq 0.1\%$ w/w or above specific concentration limits (if $< 0.1\%$ w/w).

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The preparation or substances contained therein are not subject to any prohibition or restriction in accordance with Annexes 1 and 2.

Chemicals Ordinance (ChemO; SR 813.11):

The product contains no substances of very high concern according to Annex 3 in concentrations $\geq 0.1\%$ w/w.

Waterhazard class: Water hazard class: class B (self-classification).

OVOC (CH) 0.00 %

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.

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)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - Category 4