Cryopep
La cryogénie au service de l'hémostase

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SAFETY DATA SHEET

*N° **601** – Version **2026/10***

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identifier

Product form: Mixture (lyophilized powder). Chromogenic peptide substrates labeled with p-nitroaniline (pNAPEP range).

Part code	Trade name	Packaging
61010216	pNAPEP-0216	25 mg
61010238	pNAPEP-0238	25 mg
61011022	pNAPEP-1022	25 mg
61011032	pNAPEP-1032	25 mg
61011065	pNAPEP-1065	25 mg
61011266	pNAPEP-1266	25 mg
61011344	pNAPEP-1344	25 mg
61011566	pNAPEP-1566	25 mg
61011566-50	pNAPEP-1566	50 mg
61011588	pNAPEP-1588	25 mg
61011703	pNAPEP-1703	25 mg
6101-1751	pNAPEP-1751	25 mg
61011902	pNAPEP-1902	25 mg
61030779	pNAPEP-0779	25 mg
61030968	pNAPEP-0968	25 mg
61031025	pNAPEP-1025	25 mg
61038109	pNAPEP-8109	25 mg
61038111	pNAPEP-8111	25 mg
61038111-6	pNAPEP-8111-6	10 µmol
61038117	pNAPEP-8117	100 mg
61038305	pNAPEP-8305	25 mg
61038401	pNAPEP-8401	25 mg
61038503	pNAPEP-8503	25 mg
61038506	pNAPEP-8506	25 mg
61038703	pNAPEP-8703	25 mg
61038731	pNAPEP-8731	10 µmol
61038902	pNAPEP-8902	25 mg
61039035	pNAPEP-9035	25 mg
61039041	pNAPEP-9041	1 g
61039101	pNAPEP-9101	25 mg
61039502	pNAPEP-9502	100 mg
61039502-25	pNAPEP-9502	25 mg

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

Recommanded use : Laboratory reagent; chromogenic substrate for the measurement of enzymatic activities. For professional use only.

Use advised against : Consumer use; food, cosmetic, therapeutic or veterinary applications; any use other than the identified use.

1.3. Company identification

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1.4. Emergency phone number

France : ORFILA (INRS) : +33 (0)1 45 42 59 59 (24 h/day, 7 days/week)
Poison centres : www.centres-antipoison.net

Belgium : Poison Centre : +32 70 245 245

Netherlands : NVIC: +31 30 274 88 88 (for healthcare professionals only)

Other countries : National poison centre of the country of use

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2. HAZARDS IDENTIFICATION

2.1. Product classification

Not classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP), including hazard classes introduced by Delegated Regulation (EU) 2023/707 (endocrine disruption, PBT/vPvB, PMT/vPvM).

Not classified as hazardous according to the US OSHA Hazard Communication Standard (29 CFR 1910.1200).

2.2. Labelling Elements

No hazard pictogram, signal word, hazard statement or precautionary statement required.

2.3. Other hazards

- The product contains residual free p-nitroaniline (pNA), guaranteed to be below 0.5% (w/w). This concentration is below all classification thresholds.
- During use, enzymatic hydrolysis of the substrate releases pNA (yellow coloration measured at 405 nm). Reaction solutions therefore contain more free pNA than the product as supplied; under normal assay conditions concentrations remain low.
- pNA is a methemoglobin-forming agent and may be absorbed through the skin. Avoid skin contact and inhalation of dust.
- The mixture contains no substance assessed as PBT or vPvB, nor identified as having endocrine-disrupting properties, at concentrations ≥ 0.1%.

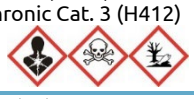
3. COMPONENT / INFORMATIONS ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Chromogenic peptide (proprietary, non-classified substance) covalently bound to p-nitroaniline, supplied as a lyophilized powder. The following component is listed for voluntary informational purposes:

Name	Identification	Concentration	Classification according to 1272/2008/EC	Specific Concentration Limits / M-factor
Para-nitroanilin (pNA)	CAS : 100-01-6 EC : 202-810-1 Index : 612-012-00-09	< 0.5 % (w/w)	Acute Tox. Cat. 3 (H301, H311, H331) STOT RE Cat. 2 (H373) Aquatic Chronic Cat. 3 (H412) 	None

Minimum classification (CLP, Annex VI, harmonized entry). For the full text of H-statements, see Section 16.1 (p. 7).

4. FIRST AID MEASURES

4.1. Description of first aid measures

Remove the affected person from exposure.
Remove contaminated clothing.
Symptoms may be delayed. As a general rule, whenever in doubt or if symptoms persist, always seek medical advice and provide the physician with this Safety Data Sheet.
NEVER induce swallowing or administer anything by mouth to an unconscious person.

Inhalation : Move the affected person to fresh air and keep at rest. In case of respiratory discomfort or cyanosis, administer oxygen (trained personnel only) and seek medical attention.

Skin contact : Remove contaminated clothing. Wash immediately and thoroughly with soap and water. Seek medical attention if symptoms occur.

Eye contact : Rinse immediately and thoroughly with water for at least 15 minutes, keeping the eyelids open. Remove contact lenses if present and easy to do. Seek medical attention or consult an ophthalmologist.

Ingestion : Rinse the mouth if the person is conscious. Do not induce vomiting. Never give anything by mouth to an unconscious person. Immediately contact a poison center or a physician.

4.2. Most important symptoms and effects, both acute and delayed

No adverse effects are expected from the small quantities normally handled. Following significant exposure to p-nitroaniline (pNA), methemoglobinemia may occur, characterized by cyanosis (bluish discoloration of the lips and fingernails), headache, dizziness, fatigue, increased heart rate, nausea, and respiratory distress. Effects may be delayed. Repeated exposure to pNA may affect the blood (anemia), liver, and spleen.

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4.3. Indication of any immediate attention and special treatment needed

Provide symptomatic treatment.
Determine blood methemoglobin levels in cases of cyanosis.
Intravenous methylene blue is the antidote for methemoglobinemia; it should only be administered upon medical assessment and decision.

5. Fire Fighting Measures

5.1. Suitable extinguishing media

Suitable extinguishing media : Water spray, foam, dry chemical powder, or carbon dioxide, depending on the surrounding fire
Unsuitable extinguishing media : Direct water jet (risk of product dispersion)

5.2. Special hazards arising from the product

The product is not flammable under normal conditions. Combustion may generate toxic carbon oxides (CO, CO_2) and nitrogen oxides (NO_x).

5.3. Fire fighting instructions

Wear self-contained breathing apparatus (SCBA) complying with EN 137 and full protective clothing.
Cool exposed containers with water spray.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear a laboratory coat, protective gloves (EN ISO 374-1), and safety goggles (EN 166).
Avoid the formation and inhalation of dust.
Keep unprotected persons away from the affected area.
Wash contaminated clothing before reuse.

6.2. Environment precautions

Do not release into the environment. Do not discharge into surface waters or sewer systems.

6.3. Methods and material for containment and cleaning up

Powder : Cover with damp absorbent paper and collect without generating dust. Do not dry sweep; if necessary, use a vacuum cleaner equipped with a HEPA filter.
Solutions : Absorb with an inert absorbent material.
After cleanup : Clean the area with water and detergent. Place waste in a closed, labelled container for disposal in accordance with Section 13 (p. 6).

6.4. Reference to other sections

See sections 7 (p. 3), 8 (p. 4) and 13 (p. 6).

7. Handling and Storage

7.1. Precautions for safe handling

Open vials and reconstitute the lyophilized material in a fume hood or ventilated enclosure; avoid the generation of dust.
Avoid contact with skin and eyes.
Wear the personal protective equipment described in Section 8 (p. 4).
Handle reaction mixtures (which contain released pNA) using the same precautions and dispose of them in accordance with Section 13 (p. 6).
Do not eat, drink, or smoke in work areas.
Wash hands thoroughly with soap and water or another suitable cleansing agent after handling.
Remove potentially contaminated laboratory coats and personal protective equipment before entering eating or break areas.

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed to prevent accidental leakage, at the temperature indicated on the label, kit, or certificate of analysis, protected from moisture and light.
Keep away from food and beverages.
Incompatible materials : See Section 10.5 (p. 5).

7.3. Specific End Uses

Laboratory reagent. Use in accordance with Good Laboratory Practice (GLP).

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8. EXPOSURE CONTROL / PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Occupational Exposure Limit Values

Substance	Country / organization	Value	Remark
p-Nitroaniline (CAS 100-01-6)	France – Indicative 8 hour OEL	3 mg/m³	Potential for skin absorption
	United States – ACGIH TLV-TWA	3 mg/m³	« Skin » notation (dermal absorption)

8.1.2. Biological monitoring

Blood methemoglobin, a biological indicator used for methemoglobin-forming agents.

8.1.3. DNEL / PNEC

Not available for the mixture.

8.2. Exposure controls

Appropriate risk management measures shall be selected, adopted, and implemented in the workplace following the risk assessment carried out by the employer in relation to the specific professional activity. If the results of this assessment indicate that general and collective preventive measures are insufficient to reduce the risk and exposure to the mixture cannot be prevented by other means, suitable personal protective equipment shall be used in accordance with applicable national and international technical standards.

Engineering Controls : Handle the powder in a fume hood or ventilated enclosure. Ensure adequate general ventilation.

Eye / Face Protection : Safety glasses with side shields complying with EN 166.

Hand Protection : Chemical protective gloves compliant with EN ISO 374-1, suitable for the intended task (chemical compatibility, dexterity requirements, operating conditions, etc.), for example nitrile gloves (thickness ≥ 0.11 mm).
Replace gloves immediately if contaminated.
Consult the glove manufacturer for permeation time data.
Remove gloves carefully to avoid contamination.
Take into account the specific local conditions under which the products are used.

Body Protection : Buttoned laboratory coat and appropriate protective gloves.

Respiratory Protection : Not required when working in a fume hood.
In the absence of adequate ventilation and where dust generation may occur, wear an FFP2 filtering half-mask (EN 149) or a P2 filter (EN 143).
The most appropriate respiratory protective equipment should be determined in consultation with the designated safety representative, taking into account the risk assessment for the specific task.

Environmental Exposure Controls : Prevent release to drains and sewer systems.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Propriété	Valeur
Physical state	Solid (lyophilized powder)
Color	White to pale yellow
Odor	Odorless
Melting point / Freezing point	Not determined
Boiling point or boiling range	Not applicable
Flammability	Non-flammable
Lower and upper explosion limits	Not applicable
Flash point	Not applicable (solid)
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
pH	1–7 (aqueous solution, 20–25 °C; depending on the product)
Kinematic viscosity	Not applicable
Solubility	Soluble in water
n-Octanol/water partition coefficient (log value)	Not determined for the mixture (pNA: log K_{ow} 1.39)

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Propriété	Valeur
Vapor pressure	Not determined
Density and/or relative density	Not determined
Relative vapor density	Not applicable
Particle characteristics	Not determined

9.2. Other informations

Explosive properties : None
Oxidizing properties : None known

10. Stability and Reactivity

10.1. Reactivity

No particular reactivity under normal conditions of use and storage.

10.2. Chemical stability

Stable under the recommended storage and handling conditions.
Hygroscopic.

10.3. Possibility of hazardous reactions

None known. No hazardous polymerization expected.

10.4. Conditions to avoid

High temperatures, moisture, and prolonged exposure to light.

10.5. Incompatible marerials

Strong oxidizing agents, strong acids, and strong bases.

10.6. Hazardous decomposition products

Thermal decomposition may produce carbon oxides and nitrogen oxides.

11. Toxicological Informations

11.1. Informations on toxological effects

The mixture has not been tested. The assessment is based on the CLP calculation method and on data relating to p-nitroaniline (pNA), present at less than 0.5%.

Hazard Class	Mixture	Data for p-nitroaniline (CAS 100-01-6)
Acute Toxicity	Not classified (calculated ATE > 2,000 mg/kg)	Oral LD_{50}, rat: 750 mg/kg. Harmonized classification: Acute Toxicity Category 3 (oral, dermal, and inhalation routes).
Skin Corrosion/Irritation	Not classified	Not irritating.
Serious Eye Damage/Eye Irritation	Not classified	No conclusive data available.
Respiratory or Skin Sensitization	Not classified	Not classified. Allergic reactions have been reported for the aromatic amine family.
Germ Cell Mutagenicity	Not classified	Positive in certain in vitro assays (Ames test, chromosomal aberrations); negative in vivo (micronucleus, UDS). Not classified.
Carcinogenicity	Not classified	No harmonized EU carcinogenicity classification. Not evaluated by IARC; not listed as a carcinogen by the NTP (Report on Carcinogens) or OSHA. NTP TR-418 study: equivocal evidence in male mice (vascular tumors), no evidence in females.
Reproductive Toxicity	Not classified	No relevant effects reported.
STOT - Single Exposure	Not classified	Methemoglobinemia following significant exposure.
STOT - Repeated Exposure	Not classified (pNA below the 10% threshold)	Harmonized STOT RE Category 2: methemoglobinemia, anemia, effects on the liver and spleen.
Aspiration Hazard	Not applicable (solid)	

For symptoms, see Section 3.2 (p. 2).

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11.2. Information on Other Hazards

Endocrine disruption : No component has been identified as having endocrine-disrupting properties at a concentration of 0.1% or greater.

Other informations : pNA is covalently bound to the peptide; it is released by enzymatic hydrolysis during use (see Section § 2.3, p. 2).

12. Ecological Informations

12.1. Toxicity

The mixture is not classified as hazardous to the environment.
p-Nitroaniline (pNA) : Aquatic Chronic Toxicity Category 3 (H412).

12.2. Persistance and degradability

No data are available for the mixture. In the absence of conclusive data, p-nitroaniline should not be considered readily biodegradable.

12.3. Bioaccumulative potential

Low bioaccumulation potential (pNA: log K_{ow} = 1.39)

12.4. Mobility in soil

No data available. The mixture is soluble in water and therefore potentially mobile in soil and aquatic environments.

12.5. Results of PBT and vPvB assessment

No component meets the criteria for PBT or vPvB substances as defined in Annex XIII of REACH.

12.6. Endocrine Disrupting Properties

No component has been identified as having endocrine-disrupting properties at a concentration of 0.1% or greater.

12.7. Other adverse effects

None known.

13. Disposal Considerations

13.1. Waste treatment methods

Product and Residues : Dispose of unused product and reaction solutions as laboratory chemical waste through an authorized waste disposal contractor, in accordance with Directive 2008/98/EC and applicable local regulations. Do not discharge to drains or sewer systems.

Waste Code (Indicative) : European Waste Catalogue (Decision 2000/532/EC): 16 05 06 - Laboratory chemicals consisting of or containing hazardous substances. This code is assigned as a precautionary measure for reaction solutions containing released p-nitroaniline (pNA). The final waste code shall be assigned by the waste producer.

Contaminated Packaging : Dispose of contaminated packaging in the same manner as the product. Rinsed containers may be disposed of in accordance with local regulations.

13.2. Waste from residues / unused products

The product shall be disposed of as a laboratory chemical in suitable containers and in accordance with local regulations.
Do not dispose of via the sewer system.

13.3. Contaminated packaging

Packaging shall be disposed of in suitable waste containers in accordance with local regulations.

14. Transport Informations (International Regulations)

Not regulated as dangerous goods under the transport regulations ADR, RID, ADN, IMDG, or IATA.

14.1. Sea transport (IMDG / IMO)

Not applicable

14.2. Land transport (ADR)

Not applicable

14.3. Air transport (IATA)

Not applicable

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14.4. Packing group
Not applicable

14.5. Environmental hazards
No

14.6. Special precautions for user
None

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

15. Regulatory Informations

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

15.2. European Union Regulations
- Regulation (EC) No. 1907/2006 (REACH), Annex II as amended by Regulation (EU) 2020/878.
- Regulation (EC) No. 1272/2008 (CLP), as amended, including Delegated Regulation (EU) 2023/707 and Regulation (EU) 2024/2865.
- REACH Annex XIV (Authorization), Annex XVII (Restrictions), and the Candidate List of SVHCs: p-nitroaniline is not listed.
- Directive 98/24/EC on the protection of workers from risks related to chemical agents at work applies. Directive 2004/37/EC on carcinogens, mutagens, or reproductive toxicants does not apply.
- Directive 2012/18/EU (Seveso III): not applicable.

15.3. National Regulations
- France : French Labour Code, Articles R. 4412-1 to R. 4412-58 (prevention of chemical risks). Occupational disease tables of the general social security scheme No. 15 and 15 bis (aromatic amines and their nitrated derivatives).
- United States : Not classified as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200). p-Nitroaniline (CAS 100-01-6) is listed on the TSCA Inventory.

15.4. Chemical safety assessment
A chemical safety assessment is not required for this mixture (REACH, Article 14(2)).

16. Other Informations

16.1. Full Text of Hazard Statements Referred to in Section 3
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.

16.2. Classification Method
Calculation method (CLP Articles 9 and 10, Annex I), based on the maximum guaranteed content of free p-nitroaniline (pNA) (< 0.5%).

16.3. Abbreviations
ACGIH : American Conference of Governmental Industrial Hygienists
IARC : International Agency for Research on Cancer
CLP : Classification, Labelling and Packaging
DNEL : Derived No-Effect Level
ATE : Acute Toxicity Estimate
HCS : Hazard Communication Standard
NTP : National Toxicology Program (United States)
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No-Effect Concentration
STOT RE : Specific Target Organ Toxicity - Repeated Exposure
OEL : Occupational Exposure Limit
vPvB : Very Persistent and Very Bioaccumulative

16.4. Key data Sources
CLP Annex VI (Entry 612-012-00-9); NTP Technical Report TR-418 (1993); Health Council of the Netherlands, Advisory Report 2008/08OSH; INRS (French occupational exposure limit values).

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16.5. Disclaimer

This Safety Data Sheet complements, but does not replace, the technical instructions for use.
The information contained herein is based on the current state of scientific and technical knowledge at the revision date and is provided in good faith. It describes the product solely with regard to safety requirements and shall not be construed as guaranteeing any specific properties of the product. The user is responsible for assessing risks at the workplace and for implementing the necessary precautions, particularly when the product is used for purposes other than those for which it was designed.
The manufacturer and distributor shall not be held liable for any defect in a product covered by this Safety Data Sheet if the existence of such defect could not have been detected in light of the current state of scientific and technical knowledge.

16.6. Revision History

Version	Date	Modifications
2012/05	02/05/2012	Creation
2014/03	27/03/2014	Global update by the manufacturer
2014/07	28/07/2014	Revising the presentation, introduction of new graphic of the company, adding details in the whole text, adding R and S risk phrases
2016/02	29/02/2016	Adding product : 61039502
2016/11	04/11/2016	Adding product : 61038117
2017/02	02/02/2017	Adding products : 61038703, 61038731
2017/04	25/04/2017	Adding product : 61039101
2018/04	25/04/2018	Adding product : 61039202
2019/03	11/03/2019	Adding product : 61039040
2021/10	01/10/2021	Adding product : 61011566-50, updating § 2.3, 3, 9.1, 10.3, 13, 15, 16
2022/01	19/01/2022	Adding product : 61038503, removal of products : 61011066, 61039040, 61039202, 61050220
2023/04	18/04/2023	Adding products : 61038109, 61038111, 61038305, 61038401, 61038506, 61038902, 61039035, 61039041, remove product : 61030234
2025/04	22/04/2025	Adding product : 61038109, 61038111-6
2026/10	29/10/2026	Compliance update with REACH Annex II as amended by Regulation (EU) 2020/878 and current CLP requirements; OSHA HCS status added (Sections 2 and 15); free pNA content (<0.5%) clarified; occupational exposure limit added (Section 8); methemoglobinemia and antidote information added (Section 4); Sections 1, 3, 6, 9, 11, 12, 13, 14, 15 and 16 revised; corrections to index number and obsolete references.