

Kit components

Product code	Description
3308-0010	GSP Neonatal Phenylalanine kit 3308-0010, 3308-001B, 3308-0010Z, 3308-001BZ

Components:

13807549	Neonatal Extraction Solution
13807547	Neonatal Phenylalanine Enzyme Reagent
13807546	Neonatal Phenylalanine Assay Buffer
13807548	Neonatal Phenylalanine Substrate Reagent

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Neonatal Extraction Solution
- **Article number:** 13807549
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
Laboratory chemicals
In vitro diagnostics
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391
•3YE

2 Hazard(s) Identification

- **Classification of the substance or mixture**



Flam. Liq. 2 H225 Highly flammable liquid and vapour.



Eye Dam. 1 H318 Causes serious eye damage.



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STOT SE 3 H336 May cause drowsiness or dizziness.

- **Label elements**

- **GHS label elements**

The product is labelled according to the IVD regulation

The product is classified and labelled according to the Globally Harmonised System (GHS).

- **Hazard pictograms**



GHS02

GHS05

GHS07

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Zinc sulfate heptahydrate (≥3-≤5 %)

- **Hazard statements**

Highly flammable liquid and vapour.

Causes serious eye damage.

May cause drowsiness or dizziness.

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

67-63-0	propan-2-ol ⚠ Flam. Liq. 2, H225; ⚠ Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H336	25-50%
7446-20-0	Zinc sulfate heptahydrate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302	≥3-≤5%

- **Other ingredients**

7732-18-5	water	50-75%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

- **After skin contact:** Immediately rinse with water.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:** If symptoms persist consult doctor.

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Prevent seepage into sewage system, workpits and cellars.
Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **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

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

- **Ingredients with limit values that require monitoring at the workplace:**

67-63-0 propan-2-ol

WES	Short-term value: 1230 mg/m ³ , 500 ppm
	Long-term value: 983 mg/m ³ , 400 ppm

- **Additional information:** The lists valid during the making were used as basis.

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- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

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.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:** Solution

- **Colour:** Clear

- **Odour:** Sulfurous

- **Odour threshold:** Not determined.

- **pH-value at 20 °C:** 4.5

- **Change in condition**

- **Melting point/freezing point:** Undetermined.

- **Initial boiling point and boiling range:** 82 °C

- **Flash point:** 13 °C

- **Flammability (solid, gas):** Highly flammable.

- **Auto-ignition temperature:** 425 °C

- **Decomposition temperature:** Not determined.

- **Ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Explosion limits:**

- **Lower:** 2 Vol %

- **Upper:** 12 Vol %

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· Vapour pressure at 20 °C:	43 hPa
· Density at 20 °C:	0.96 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· Organic solvents:	32.8 %
· Water:	64.3 %
· Solids content:	0.0 %
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

67-63-0 propan-2-ol

Oral	LD50	5,045 mg/kg (rat)
Dermal	LD50	12,800 mg/kg (rabbit)
Inhalative	LC50/4 h	30 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye damage.
- **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** May cause drowsiness or dizziness.
- **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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
*Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
 Do not allow product to reach ground water, water course or sewage system.
 Must not reach sewage water or drainage ditch undiluted or unneutralised.
 Danger to drinking water if even small quantities leak into the ground.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|--|---|
| <ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA | <p style="text-align: right;">UN1993</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG · IATA | <p style="text-align: right;"><i>1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)), ENVIRONMENTALLY HAZARDOUS</i></p> <p style="text-align: right;"><i>FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), Zinc sulfate heptahydrate), MARINE POLLUTANT</i></p> <p style="text-align: right;"><i>FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL) solution)</i></p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG, IMDG | <div style="display: flex; align-items: center; gap: 10px;">   </div> <p style="text-align: right;">3 Flammable liquids.</p> <p style="text-align: right;">3</p> |
| <ul style="list-style-type: none"> · IATA | <div style="display: flex; align-items: center; gap: 10px;">  </div> <p style="text-align: right;">3 Flammable liquids.</p> <p style="text-align: right;">3</p> |
| <ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA | <p style="text-align: right;">II</p> |

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Trade name: Neonatal Extraction Solution

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· Environmental hazards:	Product contains environmentally hazardous substances: Zinc sulfate heptahydrate
· Marine pollutant:	Not applicable
· Special marking (ADG):	Symbol (fish and tree) Symbol (fish and tree)
· Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E, <u>S-E</u>
· Stowage Category	B
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	

· ADG	IL
· Limited quantities (LQ)	Code: E2
· Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E

· IMDG	IL
· Limited quantities (LQ)	Code: E2
· Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)), 3, II, ENVIRONMENTALLY HAZARDOUS

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02

GHS05

GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**

Zinc sulfate heptahydrate (≥3-≤5 %)

· **Hazard statements**

Highly flammable liquid and vapour.

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Causes serious eye damage.

May cause drowsiness or dizziness.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category**

E2 Hazardous to the Aquatic Environment

P5c FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

· **Department issuing SDS:** Product safety department.

· **Contact:** MSDS_Turku@revvity.com

· **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 relatif au transport international 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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

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1 Identification

- **Product identifier**
- **Trade name:** Neonatal Phenylalanine Enzyme Reagent
- **Article number:** 13807547
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
In vitro diagnostics
Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Neonatal Phenylalanine Enzyme Reagent

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3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **Other ingredients**

9048-46-8	Albumins, bovine serum	85-90%
9001-18-7	Dehydrogenase, lipoamide	5-10%
10049-21-5	phosphoric acid, monosodium salt, monohydrate	2.5-5%
62758-13-8	7-sodiooxy-3H-phenoxazin-3-one 10-oxide	1-2.5%
69403-12-9	L-Phenylalanine Dehydrogenase	<1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.

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· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Solid
- **Colour:** Blue
- **Odour:** Sulfurous
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Soluble.

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- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.
- **Solvent content:**
- **Solids content:** 3.8 %
- **Other information** No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.

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· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, ADN, IMDG, IATA	Void
· UN proper shipping name · ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	Not applicable
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Australian Inventory of Industrial Chemicals**

9048-46-8	Albumins, bovine serum
10049-21-5	phosphoric acid, monosodium salt, monohydrate
62758-13-8	7-sodiooxy-3H-phenoxazin-3-one 10-oxide

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** Void· **Hazard pictograms** Void· **Signal word** Void· **Hazard statements** Void· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Product safety department.· **Contact:** MSDS_Turku@revvity.com· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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Safety Data Sheet
according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

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IATA: International Air Transport Association
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Neonatal Phenylalanine Assay Buffer
- **Article number:** 13807546
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
In vitro diagnostics
Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023


Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 1)

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void

- **Other ingredients**

7732-18-5	water		95-100%
56-40-6	glycine		2.5-5%
26628-22-8	sodium azide	 Acute Tox. 1, H300; Acute Tox. 1, H310	≥0.025-<0.1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

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8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Fluid
- **Colour:** Colourless
- **Odour:** Sulfurous
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 9.6
- **Change in condition**
- **Melting point/freezing point:** 0 °C
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density at 20 °C:** 1.02 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **water:** Fully miscible.
- **Partition coefficient: n-octanol/water:** Not determined.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

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· Viscosity:	
· Dynamic at 20 °C:	0.952 mPas
· Kinematic:	Not determined.
· Solvent content:	
· Water:	96.3 %
· VOC (EC)	0.00 %
· Solids content:	0.0 %
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 4)

- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number
· ADG, IMDG, IATA | Void |
| · UN proper shipping name
· ADG, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADG, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADG, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | Not applicable |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

- **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **GHS label elements** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

- **Department issuing SDS:** Product safety department.

- **Contact:** MSDS_Turku@revvity.com

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Safety Data Sheet
according to WHS Regulations

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

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Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

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)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Neonatal Phenylalanine Substrate Reagent
- **Article number:** 13807548
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
In vitro diagnostics
Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 1)

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void

- **Other ingredients**

53-84-9	nadide	90-95%
9048-46-8	Albumins, bovine serum	5-10%
10049-21-5	phosphoric acid, monosodium salt, monohydrate	1-2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
No dangerous substances are released.
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

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 2)

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Solid
- **Colour:** White
- **Odour:** Sulfurous
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Soluble.
- **Partition coefficient: n-octanol/water:** Not determined.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 3)

- | | |
|----------------------------|--|
| · Viscosity: | |
| · Dynamic: | Not applicable. |
| · Kinematic: | Not applicable. |
| · Solvent content: | |
| · Solids content: | 100.0 % |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.

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Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

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· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, ADN, IMDG, IATA	Void
· UN proper shipping name · ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	Not applicable
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Product safety department.

· **Contact:** MSDS_Turku@revvity.com

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

(Contd. on page 6)

Safety Data Sheet
according to WHS Regulations

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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