

01.03.2024

Kit components

Product code	Description
B024-112	AutoDELFIA Neonatal 17a-OH-progesterone kit B024-104Z, B024-112, B024-112Z, B024-112J, B024-01C

Components:

13806174	17-OHP-Eu (~40 nmol/L)
13806175	17-OHP Antiserum
13802021	17-OHP assay buffer

Safety Data Sheet according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

1 Identification

- **Product identifier**
- **Trade name:** 17-OHP-Eu (~40 nmol/L)
- **Article number:** 13806174
- **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

2 Hazard identification

- **Classification of the substance or mixture**



Acute Tox. 4 H302 Harmful if swallowed.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Harmful

R22: Harmful if swallowed.

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Information concerning particular hazards for human and environment:** Not applicable.

- **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **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).

(Contd. on page 2)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 1)

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labelling:

sodium azide

Hazard statements

Harmful if swallowed.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Avoid release to the environment.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Rinse mouth.

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 / information on ingredients

Chemical characterisation: Mixtures

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

Dangerous components:

7647-14-5	sodium chloride Acute Tox. 5, H303	10-15%
26628-22-8	sodium azide T+ R28; N R50/53 R32 Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.25-<1%

Other ingredients

9004-54-0	Dextran 10	50-75%
77-86-1	trometamol	5-10%
90604-29-8	Albumins, blood plasma, Cohn fraction V	1-2.5%

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

4 First-aid measures

Description of first aid measures

General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **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:** Call for a doctor immediately.

(Contd. on page 3)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 2)

- **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

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

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **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 precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

* 8 Exposure controls / personal protection

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

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

26628-22-8 sodium azide

REL (USA) Ceiling limit: 0.3** mg/m³, 0.1* ppm
*as HN₃; **as NaN₃; SkinTLV (USA) Ceiling limit: 0.29** mg/m³, 0.11* ppm
*as HN₃ vapor **as NaN₃, A4

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 3)

Wash hands before breaks and at the end of work.

· **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

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Solid material

Colour: White

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: 100 °C

· **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.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

(Contd. on page 5)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 4)

· **Solvent content:**· **Solids content:** 100.0 %· **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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**

· **LD/LC50 values relevant for classification:**

26628-22-8 sodium azide

Oral	LD50 (dynamic)	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:** Harmful

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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Harmful to aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

PH

(Contd. on page 6)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 5)

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 · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | Not applicable |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

15 Regulatory information

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

- **Philippines Inventory of Chemicals and Chemical Substances**

9004-54-0	Dextran 10
7647-14-5	sodium chloride
77-86-1	trometamol
26628-22-8	sodium azide

- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
sodium azide
- **Hazard statements**
Harmful if swallowed.

(Contd. on page 7)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 6)

Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Avoid release to the environment.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Rinse mouth.

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.

· **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.

H303 May be harmful if swallowed.

H310 Fatal in contact with skin.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **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

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

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 5: Acute toxicity – Category 5

Acute Tox. 1: Acute toxicity – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Safety Data Sheet according to GHS

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

1 Identification

- **Product identifier**
- **Trade name:** 17-OHP Antiserum
- **Article number:** 13806175
- **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

2 Hazard identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **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.

3 Composition / information on ingredients

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

(Contd. on page 2)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

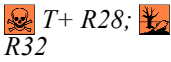

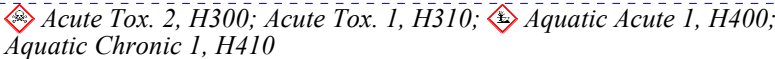

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 1)

· **Dangerous components:** Void· **Other ingredients**

7732-18-5	water	95-100%
7647-14-5	sodium chloride Acute Tox. 5, H303	<1%
77-86-1	trometamol	<1%
90604-29-8	Albumins, blood plasma, Cohn fraction V	<0.1%
26628-22-8	sodium azide  T+ R28;  N R50/53 R32  Acute Tox. 2, H300; Acute Tox. 1, H310;  Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%

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

4 First-aid measures

- **Description of 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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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**
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.

(Contd. on page 3)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 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:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls / personal protection

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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Liquid
Colour:	Colourless
Odour:	Sulfurous
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.75
- **Change in condition**

Melting point/freezing point:	0 °C
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.

(Contd. on page 4)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 3)

· 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/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 at 20 °C:	0.952 mPas
Kinematic:	Not determined.
· Solvent content:	
Water:	98.0 %
Solids content:	0.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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**
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

PH

(Contd. on page 5)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 4)

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

14 Transport information

- | | |
|--|-----------------|
| <ul style="list-style-type: none"> · UN-Number · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | Not applicable |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

15 Regulatory information

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

- **Philippines Inventory of Chemicals and Chemical Substances**

7732-18-5	water
7647-14-5	sodium chloride
77-86-1	trometamol

(Contd. on page 6)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 5)

26628-22-8 | sodium azide

- **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.

H303 May be harmful if swallowed.

H310 Fatal in contact with skin.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

PH

Safety Data Sheet according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

1 Identification

- **Product identifier**
- **Trade name:** 17-OHP assay buffer
- **Article number:** 13802021
- **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

2 Hazard identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **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.

3 Composition / information on ingredients

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

(Contd. on page 2)

Safety Data Sheet

according to GHS

Printing date 01.03.2024







Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

(Contd. of page 1)

· **Dangerous components:** Void· **Other ingredients**

7732-18-5	water	95-100%
9048-46-8	Albumins, bovine serum	1-2.5%
7647-14-5	sodium chloride	<1%
	Acute Tox. 5, H303	
77-86-1	trometamol	<1%
25322-68-3	Polyethylene glycol	<1%
64-17-5	ethanol	<0.1%
	 F R11	
	 Flam. Liq. 2, H225	
26628-22-8	sodium azide	≥0.025-<0.1%
	 T+ R28;  N R50/53	
	R32	
	 Acute Tox. 2, H300; Acute Tox. 1, H310;  Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

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

4 First-aid measures

· **Description of 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

· **Extinguishing media**· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.· **Special hazards arising from the substance or mixture** No further relevant information available.· **Advice for firefighters**· **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**

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.

PH

(Contd. on page 3)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

(Contd. of page 2)

7 Handling and storage

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

8 Exposure controls / personal protection

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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Solution
- **Colour:** Red
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 7.75
- **Change in condition**
- **Melting point/freezing point:** 0 °C

(Contd. on page 4)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

(Contd. of page 3)

Initial boiling point and boiling range: 100 °C	
· 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/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 at 20 °C:	0.952 mPas
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.1 %
Water:	96.5 %
· Solids content:	0.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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**
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

(Contd. on page 5)

PH

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

(Contd. of page 4)

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADR, 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**

- **Philippines Inventory of Chemicals and Chemical Substances**

All ingredients are listed.

(Contd. on page 6)

Safety Data Sheet

according to GHS

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

(Contd. of page 5)

- **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**

H225 Highly flammable liquid and vapour.

H300 Fatal if swallowed.

H303 May be harmful if swallowed.

H310 Fatal in contact with skin.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R11 Highly flammable.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

PH