

22.02.2024

**Kit components**

| Product code | Description |
|--------------|-------------|
|--------------|-------------|

|                  |                               |
|------------------|-------------------------------|
| <b>3301-0010</b> | <b>GSP® Neonatal hTSH Kit</b> |
|------------------|-------------------------------|

Components:

|          |                     |
|----------|---------------------|
| 13806268 | Anti-hTSH-Eu Tracer |
|----------|---------------------|

|          |                       |
|----------|-----------------------|
| 13806798 | Neo hTSH Assay Buffer |
|----------|-----------------------|

## Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 06.11.2023

### 1 Identification

- **Product identifier**
- **Trade name:** Anti-hTSH-Eu Tracer
- **Article number:** 13806268
- **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 3

Revision: 06.11.2023


Trade name: Anti-hTSH-Eu Tracer

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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**

|            |  |              |
|------------|--|--------------|
| 7732-18-5  | water  | 95-100%      |
| 7647-14-5  | sodium chloride  | <1%          |
| 77-86-1    | trometamol   | <1%          |
| 90604-29-8 | Albumins, blood plasma, Cohn fraction V  | <0.25%       |
| 26628-22-8 | sodium azide   | ≥0.025-<0.1% |
|            |  Acute Tox. 1, H300; Acute Tox. 1, H310 |              |

- **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.

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# Safety Data Sheet

## according to WHS Regulations

Printing date 22.02.2024

Version number 3

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Trade name: Anti-hTSH-Eu Tracer

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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:** Goggles recommended during refilling

### 9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Solution
- **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.
- **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:** 1.01 g/cm<sup>3</sup>
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **water:** Fully miscible.

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# Safety Data Sheet

## according to WHS Regulations

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Version number 3

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Trade name: Anti-hTSH-Eu Tracer

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- **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:** 0.9 %
- **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

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Revision: 06.11.2023

Trade name: Anti-hTSH-Eu Tracer

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

### 14 Transport information

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

### 15 Regulatory information

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

|   |                 |    |
|---|-----------------|----|
| · <b>Australian Inventory of Industrial Chemicals</b>                 |                 |    |
| 7732-18-5   | water           |    |
| 7647-14-5   | sodium chloride |    |
| 77-86-1   | trometamol      |    |
| 26628-22-8  | sodium azide    |    |
| · <b>Standard for the Uniform Scheduling of Medicines and Poisons</b> |                 |    |
| 77-86-1   | trometamol      | S4 |
| · <b>Australia: Priority Existing Chemicals</b>                       |                 |    |
| 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.

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**Safety Data Sheet**  
**according to WHS Regulations**

Printing date 22.02.2024

Version number 3

Revision: 06.11.2023

**Trade name: Anti-hTSH-Eu Tracer**

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*H310 Fatal in contact with skin.*

- **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.**

AU

## Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 06.11.2023

### 1 Identification

- **Product identifier**
- **Trade name:** Neo hTSH Assay Buffer
- **Article number:** 13806798
- **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 3

Revision: 06.11.2023

Trade name: Neo hTSH Assay Buffer

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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**

|            |                        |         |
|------------|------------------------|---------|
| 7732-18-5  | water                  | 95-100% |
| 9048-46-8  | Albumins, bovine serum | 1-2.5%  |
| 25322-68-3 | Polyethylene glycol    | 1-2.5%  |
| 7647-14-5  | sodium chloride        | <1%     |
| 77-86-1    | trometamol             | <1%     |
| 9007-83-4  | Globulins              | <0.1%   |
| 9005-66-7  | Tween 40               | <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.

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# Safety Data Sheet

## according to WHS Regulations

Printing date 22.02.2024

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Revision: 06.11.2023

Trade name: Neo hTSH Assay Buffer

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- **Further information about storage conditions:** None.
- **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:** Goggles recommended during refilling

### 9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Solution
- **Colour:** Red
- **Odour:** Sulphurous
- **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.
- **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:** 1.01 g/cm<sup>3</sup>
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

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# Safety Data Sheet

## according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 06.11.2023

Trade name: Neo hTSH Assay Buffer

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- **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:** 95.9 %
- **Solids content:** 0.9 %
- **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

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Revision: 06.11.2023

Trade name: Neo hTSH Assay Buffer

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

### 14 Transport information

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

### 15 Regulatory information

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

|   |  |
|---|--|
| · <b>Australian Inventory of Industrial Chemicals</b> |  |
| 7732-18-5   | water  |
| 9048-46-8   | Albumins, bovine serum   |
| 25322-68-3  | Polyethylene glycol  |
| 7647-14-5   | sodium chloride  |
| 77-86-1   | trometamol   |
| 9005-66-7   | Tween 40   |
| 67-43-6   | N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)                 |
| 26628-22-8  | sodium azide   |
| 915-67-3  | trisodium 3-hydroxy-4-(4'-sulphonatophthylazo)naphthalene-2,7-disulphonate |
| 10035-04-8  | calcium chloride, dihydrate  |

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

|         |            |    |
|---------|------------|----|
| 77-86-1 | trometamol | S4 |
|---------|------------|----|

- **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.

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# Safety Data Sheet

## according to WHS Regulations

Printing date 22.02.2024

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Revision: 06.11.2023

**Trade name: Neo hTSH Assay Buffer**

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

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### 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*

*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.**

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