

22.02.2024

**Kit components**

Product code	Description
<b>3306-0010</b>	<b>GSP Neonatal IRT kit 3306-0010, 3306-001U</b>

Components:

13806951	IRT Assay Buffer
13806949	Anti-IRT-Eu tracer

## Safety Data Sheet according to GHS

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

### 1 Identification

- **Product identifier**
- **Trade name:** IRT Assay Buffer
- **Article number:** 13806951
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **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).

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- **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.

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- **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: IRT Assay Buffer

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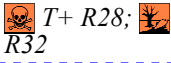

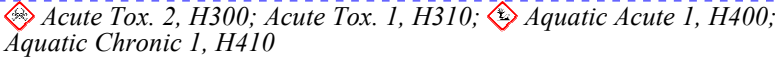

### 3 Composition / information on ingredients

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

#### · Dangerous components:

25322-68-3	Polyethylene glycol	1-2.5%
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#### · Other ingredients

7732-18-5	water	95-100%
9048-46-8	Albumins, bovine serum	1-2.5%
7647-14-5	sodium chloride Acute Tox. 5, H303	<1%
77-86-1	trometamol	<1%
9007-83-4	Globulins	<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%
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

- **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.

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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.
- **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:**

25322-68-3 Polyethylene glycol

WEEL (USA)	Long-term value: 10 mg/m <sup>3</sup> (H); MW>200
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- **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:	Fluid
Colour:	According to product specification
Odour:	Characteristic

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b> <b>Melting point/freezing point:</b>	0 °C
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic at 20 °C:</b>	0.952 mPas
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Water:</b>	95.6 %
· <b>Other information</b>	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.

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Trade name: IRT Assay Buffer

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· **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.

### 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

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | Void            |
| · <b>Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</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            |

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### 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
9048-46-8	Albumins, bovine serum
25322-68-3	Polyethylene glycol
7647-14-5	sodium chloride
77-86-1	trometamol
26628-22-8	sodium azide
9005-66-7	Tween 40

· **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.**

## Safety Data Sheet according to GHS

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

### 1 Identification

- **Product identifier**
- **Trade name:** Anti-IRT-Eu tracer
- **Article number:** 13806949
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **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).

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- **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.

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- **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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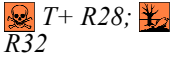

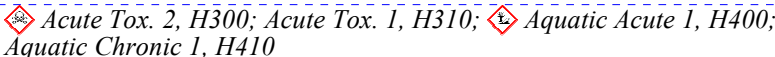
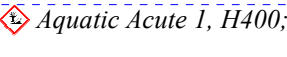
Trade name: Anti-IRT-Eu tracer

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### 3 Composition / 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 Acute Tox. 5, H303	<1%
77-86-1	trometamol	<1%
9048-46-8	Albumins, bovine serum	<0.25%
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.

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Trade name: Anti-IRT-Eu tracer

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### 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:** Fluid
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
- **Melting point/freezing point:** 0 °C

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<b>Initial boiling point and boiling range:</b> Undetermined.	
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic at 20 °C:	0.952 mPas
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Water:	98.5 %
· <b>Other information</b>	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.

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Trade name: Anti-IRT-Eu tracer

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

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void

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**Trade name: Anti-IRT-Eu tracer**

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- **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