

20.11.2018

**Kit components**

Product code	Description
<b>A032-310</b>	<b>DELFLA Neonatal hTSH kit A032-310</b>

Components:

13803241	Anti-hTSH-Eu tracer
13801809	Neo-hTSH / Neo-IRT Assay buffer
B117-100	DELFLA/AutoDELFLA Wash Concentrate
B118-100	DELFLA /AutoDELFLA Enhancement Solution

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Anti-hTSH-Eu tracer
- **Article number:** 13803241, 13806268, 13801085
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
In vitro diagnostics  
Laboratory chemicals
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
PerkinElmer  
Wallac Oy  
P.O. Box 10  
FI-20101 Turku  
Finland
- **Further information obtainable from:**  
Product safety department.  
MSDS\_Turku@perkinelmer.com
- **1.4 Emergency telephone number:**  
CHEMTREC (whithin U.S.) 800 424-9300  
CHEMTREC (from outside U.S.) +1-703-572-3887

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**  
The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

## SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

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- **4.3 Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

### SECTION 5: Firefighting measures

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

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**  
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.
- **8.2 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

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

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· **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

### SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Solution
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	100 °C

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	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.

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

· **Viscosity:**

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

· **Solvent content:**

· **Water:** 98.2 %

· **Solids content:** 0.9 %

· **9.2 Other information** No further relevant information available.

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

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### SECTION 10: Stability and reactivity

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

### SECTION 11: Toxicological information

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

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

**26628-22-8 sodium azide**

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

- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

### SECTION 12: Ecological information

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

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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

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

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	Not applicable
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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@perkinelmer.com
- **Abbreviations and acronyms:**  
*ADR: Accord européen sur le transport 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*  
*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*  
*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*

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Neo-hTSH / Neo-IRT Assay buffer
- **Article number:** 13801809, 13801043
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
In vitro diagnostics  
Laboratory chemicals
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
PerkinElmer  
Wallac Oy  
P.O. Box 10  
FI-20101 Turku  
Finland
- **Further information obtainable from:**  
Product safety department.  
MSDS\_Turku@perkinelmer.com
- **1.4 Emergency telephone number:**  
CHEMTREC (within U.S.) 800 424-9300  
CHEMTREC (from outside U.S.) +1-703-572-3887

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**  
The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

## SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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**Trade name: Neo-hTSH / Neo-IRT Assay buffer**

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- **4.3 Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

### **SECTION 5: Firefighting measures**

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

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**  
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.
- **8.2 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

(Contd. on page 3)



**Trade name: Neo-hTSH / Neo-IRT Assay buffer**

(Contd. of page 2)

· **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

### SECTION 9: Physical and chemical properties

· **9.1 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 at 20 °C:** 7.8

· **Change in condition**

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

**Initial boiling point and boiling range:** 100 °C

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-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 determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:**

Fully miscible.

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

· **Viscosity:**

**Dynamic:** Not determined.

**Kinematic:** Not determined.

· **Solvent content:**

**Water:** 95.3 %

**Solids content:** 1.5 %

· **9.2 Other information** No further relevant information available.

**Trade name: Neo-hTSH / Neo-IRT Assay buffer**

(Contd. of page 3)

### SECTION 10: Stability and reactivity

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

### SECTION 11: Toxicological information

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

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

**26628-22-8 sodium azide**

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

- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

### SECTION 12: Ecological information

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

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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**Trade name: Neo-hTSH / Neo-IRT Assay buffer**

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

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	Not applicable
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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@perkinelmer.com

· **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport 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*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*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*

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** DELFLIA/AutoDELFLIA Wash Concentrate
- **Article number:** B117-100, B117-100J, 4010-0010, 1244-114, 3014-0010
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
 No further relevant information available.
- **Application of the substance / the mixture**  
 In vitro diagnostics  
 Laboratory chemicals
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
 PerkinElmer  
 Wallac Oy  
 P.O. Box 10  
 FI-20101 Turku  
 Finland
- **Further information obtainable from:**  
 Product safety department.  
 MSDS\_Turku@perkinelmer.com
- **1.4 Emergency telephone number:**  
 CHEMTREC (whithin U.S.) 800 424-9300  
 CHEMTREC (from outside U.S.) +1-703-572-3887

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**  
 The product is labelled according to the IVD regulation  
 The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
*N*-(Hydroxymethyl)-*N*-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-*N'*-(hydroxymethyl)urea
- **Hazard statements**  
 H317 May cause an allergic skin reaction.
- **Precautionary statements**  
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves.  
 P362+P364 Take off contaminated clothing and wash it before reuse.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P321 Specific treatment (see on this label).  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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**Trade name: DELFIA/AutoDELFLIA Wash Concentrate**

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 78491-02-8	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl)urea	1-2.5%
EINECS: 278-928-2	⚠ Skin Sens. 1, H317	

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

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

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

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 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: DELFIA/AutoDELFLIA Wash Concentrate**

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### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· **Information about fire - and explosion protection:** No special measures required.

#### · 7.2 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.

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

### SECTION 8: Exposure controls/personal protection

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

#### · 8.1 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.

#### · 8.2 Exposure controls

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· **Respiratory protection:**

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

· **Protection of hands:**



Protective gloves

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

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

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

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

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

· **Eye protection:** Goggles recommended during refilling

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(Contd. on page 4)

Trade name: DELFIA/AutoDELFIA Wash Concentrate

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## SECTION 9: Physical and chemical properties

### · 9.1 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:	Undetermined.
· Initial boiling point and boiling range:	100 °C

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Decomposition temperature: Not determined.

· Auto-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 determined.

· Evaporation rate: Not determined.

#### · Solubility in / Miscibility with water:

Fully miscible.

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

#### · Viscosity:

· Dynamic:	Not determined.
· Kinematic:	Not determined.

#### · Solvent content:

· Water: 77.0 %

· 9.2 Other information: No further relevant information available.

## SECTION 10: Stability and reactivity

· 10.1 Reactivity: No further relevant information available.

#### · 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions: No dangerous reactions known.

· 10.4 Conditions to avoid: No further relevant information available.

· 10.5 Incompatible materials: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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(Contd. on page 5)

Trade name: DELFIA/AutoDELFLIA Wash Concentrate

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### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **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**  
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

### \* SECTION 12: Ecological information

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

### \* SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### \* SECTION 14: Transport information

- |  |      |
|--|------|
| · <b>14.1 UN-Number</b>                  |      |
| · <b>ADR, ADN, IMDG, IATA</b>            | Void |
| · <b>14.2 UN proper shipping name</b>    |      |
| · <b>ADR, ADN, IMDG, IATA</b>            | Void |
| · <b>14.3 Transport hazard class(es)</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>            |      |
| · <b>Class</b>                           | Void |
| · <b>14.4 Packing group</b>              |      |
| · <b>ADR, IMDG, IATA</b>                 | Void |

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**Trade name: DELFIA/AutoDELFIA Wash Concentrate**

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- |  |                        |
|--|------------------------|
| <b>· 14.5 Environmental hazards:</b>   |                        |
| <b>· Marine pollutant:</b>   | <i>Not applicable</i>  |
| <b>· 14.6 Special precautions for user</b>                                       | <i>Not applicable.</i> |
| <b>· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | <i>Not applicable.</i> |
| <b>· UN "Model Regulation":</b>  | <i>Void</i>            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- *Directive 2012/18/EU*
- *Named dangerous substances - ANNEX I None of the ingredients is listed.*
- *REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3*
- **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

**SECTION 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**  
*H317 May cause an allergic skin reaction.*
- **Department issuing SDS:** *Product safety department.*
- **Contact:** *MSDS\_Turku@perkinelmer.com*
- **Abbreviations and acronyms:**  
*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*  
*ICAO: International Civil Aviation Organisation*  
*ADR: Accord européen sur le transport 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*  
*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*  
*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*  
*Skin Sens. 1: Skin sensitisation – Category 1*
- **\* Data compared to the previous version altered.**

\* **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name:** DELFLIA /AutoDELFLIA Enhancement Solution
- **Article number:** B118-100, 1244-105, 4001-0010, B118-100J, 1244-104
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
Laboratory chemicals  
In vitro diagnostics
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
PerkinElmer  
Wallac Oy  
P.O. Box 10  
FI-20101 Turku  
Finland
- **Further information obtainable from:**  
Product safety department.  
MSDS\_Turku@perkinelmer.com
- **1.4 Emergency telephone number:**  
CHEMTREC (whithin U.S.) 800 424-9300  
CHEMTREC (from outside U.S.) +1-703-572-3887

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**  
The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

 \* **SECTION 3: Composition/information on ingredients**

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

 · **Dangerous components:**

9002-93-1	Polyethylene glycol octylphenol ether ⚠ Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315	<0.25%
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 · **SVHC**

9002-93-1	Polyethylene glycol octylphenol ether	
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

**Trade name: DELFIA /AutoDELFA Enhancement Solution**

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#### **SECTION 4: First aid measures**

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### **SECTION 5: Firefighting measures**

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

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

#### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.

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**Trade name: DELFIA /AutoDELFIA Enhancement Solution**

(Contd. of page 2)

- **8.2 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*

### SECTION 9: Physical and chemical properties

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

Form:	Fluid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 3,2
- **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.*
- **Auto-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 determined.*
- **Evaporation rate** *Not determined.*
- **Solubility in / Miscibility with water:** Soluble.
- **Partition coefficient: n-octanol/water:** *Not determined.*

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**Trade name: DELFIA /AutoDELFIA Enhancement Solution**

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· <b>Viscosity:</b>	
<b>Dynamic at 20 °C:</b>	0.952 mPas
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	0.7 %
<b>Water:</b>	99.1 %
· <b>Solids content:</b>	
	0.0 %
· <b>9.2 Other information</b>	
	No further relevant information available.

### SECTION 10: Stability and reactivity

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

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
- Do not allow product to reach ground water, water course or sewage system, even in small quantities.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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(Contd. on page 5)

**Trade name: DELFIA /AutoDELFIA Enhancement Solution**

(Contd. of page 4)

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Hand over to hazardous waste disposers.
- **Uncleaned packaging:**
- **Recommendation:**  
Packagings that may not be cleansed are to be disposed of in the same manner as the product.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.2 UN proper shipping name</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.3 Transport hazard class(es)</b>   | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  | Void            |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | Not applicable  |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· <b>LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)</b>		
9002-93-1	Polyethylene glycol octylphenol ether	Sunset date: 2021-01-04

- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
- **Substances of very high concern (SVHC) according to REACH, Article 57**

9002-93-1	Polyethylene glycol octylphenol ether
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- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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**
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.

(Contd. on page 6)

**Trade name: DELFIA /AutoDELFIA Enhancement Solution**

(Contd. of page 5)

*H400 Very toxic to aquatic life.**H410 Very toxic to aquatic life with long lasting effects.*· **Department issuing SDS:** Product safety department.· **Contact:** MSDS\_Turku@perkinelmer.com· **Abbreviations and acronyms:***RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)**ICAO: International Civil Aviation Organisation**ADR: Accord européen sur le transport 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**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**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**SVHC: Substances of Very High Concern**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*· **\* Data compared to the previous version altered.**

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