

08.02.2019

Kit components

Product code	Description
NP-1000	Neonatal Phenylalanine Kit NP-1000, NP-4000

Components:

13805236	PKU Reagent
13805243	Zinc Sulfate Reagent
13805241	Copper Reagent
13805238	PKU Reconstitution Buffer

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

- **1.1 Product identifier**
- **Trade name:** PKU Reagent
- **Article number:** 13805236
- **CAS Number:**
485-47-2
- **EC number:**
207-618-1
- **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

- Acute Tox. 4 H302 Harmful if swallowed.
- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2 H319 Causes serious eye irritation.
- STOT SE 3 H335 May cause respiratory irritation.

- **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 substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
indan-1,2,3-trione
- **Hazard statements**
H302 Harmful if swallowed.
H315 Causes skin irritation.

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Trade name: PKU Reagent

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H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves / eye protection / face protection.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterisation: Substances

CAS No. Description

485-47-2 indan-1,2,3-trione

Identification number(s)

EC number: 207-618-1

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.

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

After inhalation: *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. If symptoms persist, consult a doctor.

After swallowing: *Call for a doctor immediately.*

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: *No special measures required.*

6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

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Trade name: PKU Reagent

(Contd. of page 2)

- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **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:** Keep container tightly sealed.
- **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:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Avoid contact with the eyes and skin.
- **Respiratory protection:**
- In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
- The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **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.

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Trade name: PKU Reagent

(Contd. of page 3)

 · **Eye protection:**


Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

 · **General Information**

 · **Appearance:**

· Form:	Solid
· Colour:	Not determined.
· Odour:	Characteristic
· Odour threshold:	Not determined.

 · **pH-value:** Not applicable.

 · **Change in condition**

· Melting point/freezing point:	250 °C
· Initial boiling point and boiling range:	Undetermined.

 · **Flash point:** Not applicable.

 · **Flammability (solid, gas):** Product is not flammable.

 · **Decomposition temperature:** Not determined.

 · **Auto-ignition temperature:** Not determined.

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

 · **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

 · **Vapour pressure:** Not applicable.

 · **Density:** Not determined.

 · **Relative density** Not determined.

 · **Vapour density** Not applicable.

 · **Evaporation rate** Not applicable.

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

Not miscible or difficult to mix.

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

 · **Viscosity:**

 · **Dynamic:** Not applicable.

 · **Kinematic:** Not applicable.

 · **Solids content:** 100.0 %

 · **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.

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Trade name: PKU Reagent

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

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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 Substance is not 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
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

EU

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

- **1.1 Product identifier**
- **Trade name:** Zinc Sulfate Reagent
- **Article number:** 13805243
- **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**



GHS05 corrosive

Eye Dam. 1 H318 Causes serious eye damage.



GHS09 environmental hazard

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- **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**



GHS05 GHS09

- **Signal word** Danger
- **Hazard-determining components of labelling:**
zinc sulphate
- **Hazard statements**
H318 Causes serious eye damage.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.

(Contd. on page 2)

Trade name: Zinc Sulfate Reagent

(Contd. of page 1)

- P280 Wear eye protection / face protection.
 P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTER/doctor.
 P391 Collect spillage.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 7733-02-0	zinc sulphate	5-10%
EINECS: 231-793-3	Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302	
Index number: 030-006-00-9		

- **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**
- **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. Then consult a doctor.
- **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**
 Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
 Inform respective authorities in case of seepage into water course or sewage system.
- **6.3 Methods and material for containment and cleaning up:**
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 Use neutralising agent.
 Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.

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Trade name: Zinc Sulfate Reagent

(Contd. of page 2)

See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** Keep container tightly sealed.
- **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:**
 Keep away from foodstuffs, beverages and feed.
 Immediately remove all soiled and contaminated clothing
 Wash hands before breaks and at the end of work.
 Avoid contact with the eyes.
 Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **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.

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Trade name: Zinc Sulfate Reagent

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· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Solution
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:	Undetermined.

· 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.

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Solvent content:

Water: 94.4 %

· 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.

(Contd. on page 5)

Trade name: Zinc Sulfate Reagent

(Contd. of page 4)

- **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**
Causes serious eye damage.
- **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.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **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.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3082

(Contd. on page 6)

Trade name: Zinc Sulfate Reagent

(Contd. of page 5)

· **14.2 UN proper shipping name**
 · **ADR** 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
 LIQUID, N.O.S. (zinc sulphate)
 · **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
 LIQUID, N.O.S. (zinc sulphate)

· **14.3 Transport hazard class(es)**

· **ADR, IMDG**



· **Class** 9 Miscellaneous dangerous substances and articles.
 · **Label** 9

· **IATA**



· **Class** 9 Miscellaneous dangerous substances and articles.
 · **Label** 9

· **14.4 Packing group**

· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

Product contains environmentally hazardous substances:
 zinc sulphate

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and
 articles.

· **Danger code (Kemler):**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

· **14.7 Transport in bulk according to Annex II of
 Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

IATA: Special provision A197 Material can be
 considered as non-hazardous under 5 L or less for liquids
 or having a net mass of 5 kg or less solids.

· **ADR**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

3

· **Tunnel restriction code**

E

· **IMDG**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

(Contd. on page 7)

Trade name: Zinc Sulfate Reagent

(Contd. of page 6)

· **UN "Model Regulation":** UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ZINC SULPHATE), 9, III

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.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **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**
 H302 Harmful if swallowed.
 H318 Causes serious eye damage.
 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:**
 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
 Acute Tox. 4: Acute toxicity – Category 4
 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
 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- *** 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:** Copper Reagent
- **Article number:** 13805241
- **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

- **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.

(Contd. on page 2)

Trade name: Copper Reagent

(Contd. of page 1)

- **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:** No special measures required.
- **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: Copper Reagent

(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:	Solution
Colour:	According to product specification

Odour:	Characteristic
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Odour threshold:	Not determined.
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pH-value:	Not determined.
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· **Change in condition**

Melting point/freezing point:	Undetermined.
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Initial boiling point and boiling range:	100 °C
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Flash point:	Not applicable.
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Flammability (solid, gas):	Not applicable.
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Decomposition temperature:	Not determined.
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Auto-ignition temperature:	Product is not selfigniting.
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Explosive properties:	Product does not present an explosion hazard.
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· **Explosion limits:**

Lower:	Not determined.
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Upper:	Not determined.
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Vapour pressure at 20 °C:	23 hPa
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Density:	Not determined.
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Relative density	Not determined.
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Vapour density	Not determined.
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Evaporation rate	Not determined.
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· **Solubility in / Miscibility with water:**

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

Dynamic at 20 °C:	0.952 mPas
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Kinematic:	Not determined.
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· **Solvent content:**

Water:	99.0 %
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Solids content:	0.1 %
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· **9.2 Other information** No further relevant information available.

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(Contd. on page 4)

Trade name: Copper Reagent

(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.
- **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.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void

(Contd. on page 5)

Trade name: Copper Reagent

(Contd. of page 4)

· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	Not applicable
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	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)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
- *** 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:** PKU Reconstitution Buffer
- **Article number:** 13805238
- **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
- **Additional information:**
Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **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.

Trade name: PKU Reconstitution Buffer

(Contd. of page 1)

- **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:** No special measures required.
- **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.

(Contd. on page 3)

Trade name: PKU Reconstitution Buffer

(Contd. of page 2)

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:	Solution
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:	Undetermined.

- **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.

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

- **Solvent content:**

Organic solvents:	0.0 %
Water:	81.5 %

(Contd. on page 4)

Trade name: PKU Reconstitution Buffer

(Contd. of page 3)

· **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.

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

EU

(Contd. on page 5)

Trade name: PKU Reconstitution Buffer

(Contd. of page 4)

SECTION 14: Transport information

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

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 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**