Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP – hsCRP – ASLO ELISA

## PRODUCT IDENTIFICATION

| Product Name | Catalogue Number (REF) |
|---|---|
| CRP ELISA | 740001 |
| hsCRP ELISA | 740011 |
| ASLO ELISA | 740201 |

**Intended use**: The apDia (hs)CRP ELISA is an Enzyme-Linked ImmunoSorbent Assay for the quantitative (high sensitive) determination of C-Reactive Protein in human serum and plasma.

The apDia ASLO ELISA is an Enzyme-Linked ImmunoSorbent Assay for the quantitative determination of Anti-Streptolysin O in human serum and plasma.

**Company/Manufacturer identification:**

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Address: Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact: Tel. +32 (0)14 45 35 99
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E-mail admin@apdia.be
Web site www.apdiagroup.com

## COMPOSITION/INFORMATION ON INGREDIENTS

| ELISA Kit Component | Composition |
|---|---|
| Coated Microtiter Strips | Plastic 96-well microtiter plate coated with monoclonal antibodies to human CRP/Streptolysin O antigen. |
| Calibrators/ASLO CTL | CRP/Streptolysin O positive serum in a buffered protein matrix. |
| Specimen Dilution Buffer 5x | Protein-based aqueous buffered solution with preservatives. |
| Conjugate | Horseradish peroxidase(HRP)-conjugated monoclonal antibodies to CRP/Streptolysin O in a stabilized buffer solution and preservatives. |
| Washing Solution 20x | Concentrated buffered salt solution containing detergent and preservatives. |

| ELISA Kit Component | Composition |
|---|---|
| Chromogen Solution | Aqueous solution of TMB and hydrogen peroxide. |
| Stopping Solution | Aqueous solution of 0,5 M sulphuric acid. |

## HAZARD INFORMATION

Apart from Chromogen Solution, the components of the apDia CRP – hsCRP - ASLO ELISA kit are are not classified as hazardous mixtures according to EC Regulation N° 1272/2008/EC.
They contain no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC.
The kit components are in small sizes/volumes with a concentration below the acceptable limit for hazardous ingredients.
The usual precautionary measures are to be adhered to when handling chemicals.

No toxicological experiments have been performed on the product/kit and its different components. Quantitative data on the toxicity or the ecological effects of the individual mixtures in the kit are not available
When used and handled according to specifications, the product does not have any harmful effects to our knowledge. Use the product according to GLP and avoid dispersion into the environment to minimize the ecological risk.

**Summary Hazard Information**:

| ELISA Kit Component | Safety Information |
|---|---|
| Coated Microtiter Strips | Contains no hazardous ingredients. |
| Calibrators/ASLO CTL | See included SDS. |
| Specimen Dilution Buffer 5x | See included SDS. |
| Conjugate | See included SDS. |
| Washing Solution 20 x | See included SDS. |
| Chromogen Solution | See included SDS. |
| Stopping Solution | See included SDS. |

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# CRP - hsCRP - ASLO ELISA: CALIBRATORS/ASLO CTL

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : CALIBRATORS for CRP – hsCRP ELISA (REF 740001 – REF 740011)
CALIBRATORS and ASLO CTL for ASLO ELISA (REF 740201)

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

The CALIBRATORS and ASLO CONTROL are standard sera in a protein-based aqueous buffer solution to be used as a reagent in the *in vitro* diagnostic determinations of human samples. They are intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

These components of the apDia CRP – hsCRP - ASLO ELISA kit are not classified as hazardous mixtures according to EC Regulation N° 1272/2008/EC.
They contain no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC regulation N° 1272/2008/EC..
The usual precautionary measures are to be adhered to when handling chemicals.

### 2.2. Label elements

These products do not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.

Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

- Some ingredients of the CALIBRATORS/ASLO CTL mixture are derived from materials of biological origin. No known tests can guarantee that such materials are completely free from infectious agents. Caution should be exercised while handling the product: treat as potentially infectious.
- These products contain sodium azide as a preservative. Sodium azide is toxic and may react with lead and copper plumbing to form explosive compounds. It is harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.
- None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

Human source material (positive serum or plasma) used in the preparation of the CALIBRATORS has been tested and found non-reactive for HIV-1/2 antibodies, HCV and HbsAg.

Bovine material (Fetal Bovine Serum) used in the buffer preparation is from sources where origin information is available. It is derived from US origin or processed in USDA licensed facilities. Areas of origin are categorized by the World Organization for Animal Health (O.I.E.) as a controlled risk for BSE.

The following substances used in the CALIBRATORS/ASLO CTL are considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen-tration |
|---|---|---|---|---|---|
| **Kit Component:** CALIBRATORS/ASLO CTL | | | | | |
| **ProClin™ 300**<br>(Mixture 3:1 of:<br>• 5-chloro-2-methyl-2H-isothiazol-3-one<br>• 2-methyl-2H-isothiazol-3-one)<br>  | 01-2120764691-48-xxxx | 911-828-1 | 55965-84-9 | Acute Tox. 2 – H330<br>Acute Tox. 2 – H310<br>Acute Tox. 3 – H301<br>Skin Corr. 1C – H314<br>Eye Dam. 1 – H318<br>Skin Sens. 1A – H317<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br>EUH071<br><br>P261, P273, P280,<br>P303+P361+P353<br>P304+P340<br>P305+P351+P338,<br>P310 | 0,025 % (v/v)<br>[~ 0,0008 % (w/v)] |
| **5-Bromo-5-nitro-1,3-dioxane (Bronidox L)**<br>  | 01-2120770242-61-xxxx | 250-001-7 | 30007-47-7 | Acute Tox. 4 – H302<br>Skin Corr. 1A – H314<br>Eye Dam. 1 – H318<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br><br>P273 , P280 ,<br>P301+P330+P331,<br>P305+P351+P338 | 0,21 % (v/v)<br>[~ 0,0225 % (w/v)] |

| | | | | | |
|---|---|---|---|---|---|
| **Chloramphenicol**  | 01-2120774093-54-xxxx | 200-287-4 | 56-75-7 | Eye Dam. 1 – H318<br>Carc. 2 – H351<br>Repr. 2 – H361<br><br>P202, P280,<br>P308+P313,<br>P305+P351+P338 | 0,0005 % (w/v) |
| **Sodium azide**  | 01-2119457019-37-xxxx | 247-852-1 | 26628-22-8 | Acute Tox. 2 – H300<br>Acute Tox. 1 – H310<br>Acute Tox. 2 – H330<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br><br>EUH032<br><br>P260, P262, P273, P280,<br>P312, P302+P352,<br>P301+P310<br>P304+P340 | 0,09 % (w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

### 5.2. Special hazards

These product are aqueous liquids and not likely to combust. Large quantities of these products, especially sodium azide, may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes.
Hazardous thermal decomposition products arising from the ingredients may include carbon oxides, nitrogen oxides, sulphur oxides, hydrogen chloride gas.

### 5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP - ASLO ELISA kit.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

CALIBRATORS/ASLO CTL do not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: Sodium azide<br>CAS N°. 26628-22-8** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Australia | / | 0,3 mg/m³ | |
| Canada | / | 0,3 mg/m³ | |
| European Union | 0,1 mg/m³ | 0,3 mg/m³ | |
| New Zealand | / | 0,29 mg/m³ | |
| China | / | 0,3 mg/m³ | |
| South Korea | / | 0,29 mg/m³ | |
| Switzerland | 0,2 mg/m³ | 0,4 mg/m³ | |
| USA | / | 0,3 mg/m³ | |
| United Kingdom | 0,1 mg/m³ | 0,3 mg/m³ | |

| **Substance: ProClin™ 300<br>CAS N°. 55965-84-9** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Austria | 0,05 mg/m³ | / | |
| Germany | 0,2 mg/m³ | 0,4 mg/m³ | |
| Switzerland | 0,2 mg/m³ | 0,4 mg/m³ | |

| **Substance: 5-Bromo-5-nitro-1,3-dioxane (Bronidox L)<br>CAS N°. 30007-47-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

| **Substance: Chloramphenicol<br>CAS N°. 56-75-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

Other exposure limits

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For CALIBRATORS/ASLO CTL:

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For Sodium azide, ProClin™ 300 and Bronidox-L:

| DNEL (Derived no effect level) | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| ProClin™ 300 | DNEL | no data | no data | no data | no data |
| Sodium azide | DNEL | Long term, Inhalation | 0,164 mg/m³ | Workers | Systemic |
| Sodium azide | DNEL | Long term, dermal | 46,7 µg/kg bw/day | Workers | Systemic |
| 5-Bromo-5-nitro-1,3-dioxane | DNEL | Long term, inhalation | 0,0274 mg/m³ | Workers | Systemic |

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

**Hygiene measures:** Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

**Eye/face protection:** Wear safety glasses with side-shields or goggles conforming to EN 166.

**Skin protection:** Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

**Respiratory protection:** Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387)).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

**Physical appearance:** CALIBRATORS/ASLO CTL are slightly straw-coloured liquids.
**Odour:** Odourless.
**Odour threshold:** No data available.
**pH value:** 7,2 – 7,5

| | |
|---|---|
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | Not considered to be a fire hazard. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Miscible with water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |
| **Viscosity:** | No data available. |
| **Explosive properties:** | Sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass. |
| **Oxidizing properties:** | Not fire-propagating. |

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

No test data related to reactivity available for this product.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

Plumbing metals (lead, copper) and many other metals including mercury and silver may react explosively with sodium azide. Acids may react with sodium azide and form very toxic hydrogen azide. Avoid contact with strong oxidizing agents, acids, peroxides, acid chlorides.

### 10.6. Hazardous decomposition products

Thermal decomposition may produce small quantities of nitrogen oxides, sodium oxide fumes and oxides of carbon.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for the CALIBRATORS/ASLO CTL as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Sodium Azide**:

**Acute toxicity:**

| Acute toxicity data for Sodium azide | |
|---|---|
| $LD_{50}$,oral, mouse | 27,0 mg/kg |
| $LD_{50}$,oral, rat | 27,0 mg/kg |
| $LD_{50}$,inhalation, mouse | 32,4 mg/$m^3$ |
| $LD_{50}$,inhalation, rat | 37,0 mg/$m^3$ |
| $LD_{50}$,skin, rat | 50,0 mg/kg |
| $LD_{50}$,skin, rabbit | 20,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Mild eye irritation.
Ingestion: Harmful for digestive system, toxic neurological effects.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness, possible absorption of sodium azide through skin, causing systemic toxicity.

**Sensitisation:** No information available.

**Germ cell mutagenicity:** No data available on humans.

**Carcinogenicity:** Sodium azide is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.

**Mutagenicity:** Sodium azide is mutagenic in vitro for bacteria and mammalian cells, no data available on humans.

**Reproductive toxigenicity:** No data available on humans.

**Specific target organ toxicity:**
– **single exposure** Respiratory system, Central Nervous System (CNS).

**Specific target organ toxicity:**
– **repeated exposure** Cardiovascular system, respiratory and digestive organs. Liver, kidney, heart, spleen.

**Aspiration hazard:** No information available.

**Signs and symptoms of exposure:**

Symptoms of acute ingestion of sodium azide may include sweating, headache, increased puls rate, decreased blood pressure, blurred vision and faintness.
Oedema of brain and lungs, abdominal organ congestion and diffuse redness of mucous membranes are also reported in severe cases of intoxication.
Inhalation of sodium azide may cause acute hypotension, nausea, vomiting and weakness.
Dermal exposure in general only causes mild skin irritation. In extreme cases, skin burns or blisters have been reported.

Following toxicological information is available for **ProClin™ 300**:

**Acute toxicity:**

| Acute toxicity data for ProClin™ 300 | |
|---|---|
| $LD_{50}$,oral, rat | 852,0 mg/kg |
| $LD_{50}$,skin, rabbit | 2800,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Corrosive. Causes eye burns.
Ingestion: May be harmful if swallowed. Causes burns.
Inhalation: May be harmful if inhaled. Destructive to mucous membranes and upper respiratory tract. Causes respiratory tract irritation.
Skin contact: May be harmful if absorbed through skin. Causes skin burns.

**Sensitisation:** May cause allergic skin reactions.

May provoke asthmatic response in persons with asthma who are sensitive to airway irritants.

**Germ cell mutagenicity:** Data conclusive but not sufficient for classification.

**Carcinogenicity:** Data conclusive but not sufficient for classification.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – repeated exposure** Data conclusive but not sufficient for classification.

**Aspiration hazard:** Data conclusive but not sufficient for classification.

**Signs and symptoms of exposure:**

Burning sensation. Cough and wheezing. Shortness of breath, spasm. Oedema and inflammation of larynx, pulmonary oedema, laryngitis and pulmonitis.

Following toxicological information is available for **Bronidox L**:

**Acute toxicity:**

| Acute toxicity data for Bronidox L | |
|---|---|
| $LD_{50}$,oral, mouse | 550,0 mg/kg |
| $LD_{50}$,oral, rat | 455,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 31,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Undiluted substance causes serious eye damage. SCL = 0,1 %.

Ingestion: Possibly toxic with neurological and behavioural effects (tremor, convulsions, excitement).

Inhalation: May be harmful if inhaled. Causes respiratory tract and mucous membrane irritation.

Skin contact: Undiluted substance causes severe burns. SCL = 0,1 %.

**Sensitisation:** Respiratory sensitisation: data lacking.
Skin sensitisation: data conclusive but not sufficient for classification.

**Germ cell mutagenicity:** Data inconclusive.

**Carcinogenicity:** Data lacking.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – repeated exposure** May cause damage to organs through prolonged or repeated exposure. Affected organs: stomach, liver, hart.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Chloramphenicol**:

**Acute toxicity:**

| Acute toxicity data for Chloramphenicol | |
|---|---|
| $LD_{50}$,oral, rat | 2500,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 1811,0 mg/kg |
| $LD_{50}$,intraperitoneal, mouse | 1100,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Data lacking.
Ingestion: Data lacking.
Inhalation: Data lacking.
Skin contact: Data lacking.

**Sensitization:** Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

**Germ cell mutagenicity:** Laboratory experiments have shown mutagenic effects in rats (liver, DNA damage) and mice (cytogenetic analysis).

**Carcinogenicity:** Chloramphenicol is listed as a possible human carcinogen by IARC (IARC: Group 2A: probably carcinogenic to humans).

**Reproductive toxicity:** Data lacking.

**Specific target organ toxicity:**
– **single exposure** Data lacking.

**Specific target organ toxicity:**
– **repeated exposure** Data lacking.

**Aspiration hazard:** Data lacking.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Nausea, headache, vomiting. liver irregularities, based on human evidence.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of CALIBRATORS/ASLO CTL as mixtures are not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of the CALIBRATORS/ASLO CTL:

| Eco-toxicity data for Sodium Azide | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Bluegill sunfish | 0,68 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $LC_{50}$ Water flea | 9,0 mg/L/48 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 4,2 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Algae | 0,348 mg/L/96 hr |

| Eco-toxicity data for ProClin™ 300 | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Rainbow trout | 0,19 mg/L/96 hr |
| Fish Toxicity: | $LC_{50}$ Bass | 0,28 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 0,16 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Marine Algae | 0,003 mg/L/48 hr |

| Eco-toxicity data for Bronidox L | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Fish | > 1 – 10 mg/L/96 hr |

| Eco-toxicity data for Chloramphenicol | | |
|---|---|---|
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 345,0 mg/L/48 hr |

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

### 12.6. Endocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

Sodium azide, ProClin® 300 are very toxic and Bronidox L is toxic to aquatic organisms. They may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

These products contain no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

### 14.1. UN number or ID number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

### 15.2. Chemical safety assessment

No data available. No chemical safety assessment carried out on the product.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS05 – Danger/Warning - Corrosive |
|  | GHS06 – Danger - Toxic |
|  | GHS07 – Warning - Irritant |
|  | GHS08 – Danger/Warning – Systemic health hazards |
|  | GHS09 – Warning - Environment |

| Hazard Statements | |
|---|---|
| H300 | Fatal if swallowed. |
| H301 | Toxic if swallowed. |
| H302 | Harmful id swallowed. |
| H310 | Fatal in contact with skin |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H330 | Fatal if inhaled. |
| H351 | Suspected of causing cancer. |
| H361 | Suspected of damaging fertility of the unborn child. |
| H373 | Causes damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| EUH071 | Corrosive to the respiratory tract. |

| Precautionary Statements | |
|---|---|
| P202 | Do not handle until all safety precautions have been read and understood. |
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P262 | Do not get in eyes, on skin, or on clothing. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… |
| P310 | Immediately call a POISON CENTER/doctor/… |
| P312 | Call a POISON CENTER/doctor/… if you feel unwell. |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor…. |
| P301+P330+P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. |
| P302+P352 | IF ON SKIN: Wash with plenty of water/… |
| P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.

$LC_{50}$ : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
$LD_{50}$ : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
$EC_{50}$ : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
STOT RE : Specific Target Organ Toxicity – Repeated Exposure.
TWA : Time Weighted Average 8 hours day.

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP - hsCRP - ASLO ELISA: SPECIMEN DILUTION BUFFER 5x

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : SPECIMEN DILUTION BUFFER 5x for CRP – hsCRP – ASLO ELISA (REF 740001 – REF 740011 – REF 740201).

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

The SPECIMEN DILUTION BUFFER 5x is a protein-based aqueous buffer solution to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This component of the apDia CRP – hsCRP - ASLO ELISA kit is not classified as a hazardous mixture according to EC Regulation N° 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC.
The usual precautionary measures are to be adhered to when handling chemicals.

### 2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.

Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

- Some ingredients of the SPECIMEN DILUTION BUFFER 5x mixture are derived from materials of biological origin. No known tests can guarantee that such materials are completely free from infectious agents. Caution should be exercised while handling the product: treat as potentially infectious.
- This product contains sodium azide as a preservative. Sodium azide is toxic and may react with lead and copper plumbing to form explosive compounds. It is harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.
- None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

Bovine material (Bovine Serum Albumin) used in the buffer preparation is from sources where origin information is available. It is derived from US origin or processed in USDA licensed facilities. Areas of origin are categorized by the World Organization for Animal Health (O.I.E.) as a controlled risk for BSE.

The following substances used in the SPECIMEN DILUTION BUFFER 5x are considered hazardous. At the indicated applied concentrations, it does not warrant hazard labelling.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen-tration |
|---|---|---|---|---|---|
| **Kit Component:** SPECIMEN DILUTION BUFFER 5x | | | | | |
| **Chloramphenicol**  | 01-2120774093-54-xxxx | 200-287-4 | 56-75-7 | Eye Dam. 1 – H318<br>Carc. 2 – H351<br>Repr. 2 – H361<br><br>P202, P280,<br>P308+P313,<br>P305+P351+P338 | 0,025 % (w/v) |
| **5-Bromo-5-nitro-1,3-dioxane (Bronidox L)**  | 01-2120770242-61-xxxx | 250-001-7 | 30007-47-7 | Acute Tox. 4 – H302<br>Skin Corr. 1A – H314<br>Eye Dam. 1 – H318<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br><br>P273 , P280 ,<br>P301+P330+P331,<br>P305+P351+P338 | 0,5 % (v/v) [~ 0,0054 % (w/v)] |

| | | | | | |
|---|---|---|---|---|---|
| **Sodium azide**  | 01-2119457019-37-xxxx | 247-852-1 | 26628-22-8 | Acute Tox. 2 – H300<br>Acute Tox. 1 – H310<br>Acute Tox. 2 – H330<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br>EUH032<br>P260, P262, P273, P280, P312, P302+P352, P301+P310, P304+P340 | 0,09 % (w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

### 5.2. Special hazards

This product is an aqueous liquid and not likely to combust. Large quantities of these products, especially sodium azide, may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes.
Hazardous thermal decomposition products arising from the ingredients may include carbon oxides, nitrogen oxides, sulphur oxides, hydrogen chloride gas.

### 5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP - ASLO ELISA kit.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

SPECIMEN DILUTION BUFFER 5x does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: Sodium azide<br>CAS N°. 26628-22-8** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Australia | / | 0,3 mg/m³ | |
| Canada | / | 0,3 mg/m³ | |
| European Union | 0,1 mg/m³ | 0,3 mg/m³ | |
| New Zealand | / | 0,29 mg/m³ | |
| China | / | 0,3 mg/m³ | |
| South Korea | / | 0,29 mg/m³ | |
| Switzerland | 0,2 mg/m³ | 0,4 mg/m³ | |
| USA | / | 0,3 mg/m³ | |
| United Kingdom | 0,1 mg/m³ | 0,3 mg/m³ | |

| **Substance: 5-Bromo-5-nitro-1,3-dioxane (Bronidox L)<br>CAS N°. 30007-47-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

| **Substance: Chloramphenicol<br>CAS N°. 56-75-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

Other exposure limits

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For CALIBRATORS/ASLO CTL:

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For Sodium azide and Bronidox-L:

| **DNEL (Derived no effect level)** | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| Sodium azide | DNEL | Long term, Inhalation | 0,164 mg/m³ | Workers | Systemic |
| Sodium azide | DNEL | Long term, dermal | 46,7 µg/kg bw/day | Workers | Systemic |
| 5-Bromo-5-nitro-1,3-dioxane | DNEL | Long term, inhalation | 0,0274 mg/m³ | Workers | Systemic |

Other exposure limits

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

**Hygiene measures:** Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

**Eye/face protection:** Wear safety glasses with side-shields or goggles conforming to EN 166.

**Skin protection:** Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

**Respiratory protection:** Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Physical appearance:** | SPECIMEN DILUTION BUFFER 5x is a liquid.<br>It contains an inert dye, making it green in colour. |
| **Odour:** | Odourless. |
| **Odour threshold:** | No data available. |
| **pH value:** | 7,0 – 7,4 |
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | Not considered to be a fire hazard. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Miscible with water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |

**Viscosity:** No data available.

**Explosive properties:** The ingredient sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass.

**Oxidizing properties:** Not fire-propagating.

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

No test data related to reactivity available for this product.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

Plumbing metals (lead, copper) and many other metals including mercury and silver may react explosively with sodium azide. Acids may react with sodium azide and form very toxic hydrogen azide. Avoid contact with strong oxidizing agents, acids, peroxides, acid chlorides and acid anhydrids.

### 10.6. Hazardous decomposition products

Thermal decomposition may produce small quantities of nitrogen oxides, sodium oxide fumes and oxides of carbon.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for SPECIMEN DILUTION BUFFER 5x as a mixture. However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Sodium Azide**:

**Acute toxicity:**

| Acute toxicity data for Sodium azide | |
|---|---|
| $LD_{50}$,oral, mouse | 27,0 mg/kg |
| $LD_{50}$,oral, rat | 27,0 mg/kg |
| $LD_{50}$,inhalation, mouse | 32,4 mg/m$^3$ |
| $LD_{50}$,inhalation, rat | 37,0 mg/m$^3$ |
| $LD_{50}$,skin, rat | 50,0 mg/kg |
| $LD_{50}$,skin, rabbit | 20,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Mild eye irritation.
Ingestion: Harmful for digestive system, toxic neurological effects.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness, possible absorption of sodium azide through skin, causing systemic toxicity.

**Sensitisation:** No information available.

**Germ cell mutagenicity:** No data available on humans.

**Carcinogenicity:** Sodium azide is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.

**Mutagenicity:** Sodium azide is mutagenic in vitro for bacteria and mammalian cells, no data available on humans.

**Reproductive toxigenicity:** No data available on humans.

**Specific target organ toxicity:**
– **single exposure** Respiratory system, Central Nervous System (CNS).

**Specific target organ toxicity:**
– **repeated exposure** Cardiovascular system, respiratory and digestive organs. Liver, kidney, heart, spleen.

**Aspiration hazard:** No information available.

**Signs and symptoms of exposure:**

Symptoms of acute ingestion of sodium azide may include sweating, headache, increased puls rate, decreased blood pressure, blurred vision and faintness.
Oedema of brain and lungs, abdominal organ congestion and diffuse redness of mucous membranes are also reported in severe cases of intoxication.
Inhalation of sodium azide may cause acute hypotension, nausea, vomiting and weakness.
Dermal exposure in general only causes mild skin irritation. In extreme cases, skin burns or blisters have been reported.

Following toxicological information is available for **Bronidox L**:

**Acute toxicity:**

| Acute toxicity data for Bronidox L | |
|---|---|
| $LD_{50}$,oral, mouse | 550,0 mg/kg |
| $LD_{50}$,oral, rat | 455,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 31,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Undiluted substance causes serious eye damage. SCL = 0,1 %.
Ingestion: Possibly toxic with neurological and behavioural effects (tremor, convulsions, excitement).
Inhalation: May be harmful if inhaled. Causes respiratory tract and mucous membrane irritation.
Skin contact: Undiluted substance causes severe burns. SCL = 0,1 %.

**Sensitisation:** Respiratory sensitisation: data lacking.
Skin sensitisation: data conclusive but not sufficient for classification.

**Germ cell mutagenicity:** Data inconclusive.

**Carcinogenicity:** Data lacking.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **repeated exposure** May cause damage to organs through prolonged or repeated exposure. Affected organs: stomach, liver, hart.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Chloramphenicol**:

**Acute toxicity:**

| Acute toxicity data for Chloramphenicol | |
|---|---|
| $LD_{50}$,oral, rat | 2500,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 1811,0 mg/kg |
| $LD_{50}$,intraperitoneal, mouse | 1100,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Data lacking.
Ingestion: Data lacking.
Inhalation: Data lacking.
Skin contact: Data lacking.

**Sensitization:** Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

**Germ cell mutagenicity:** Laboratory experiments have shown mutagenic effects in rats (liver, DNA damage) and mice (cytogenetic analysis).

**Carcinogenicity:** Chloramphenicol is listed as a possible human carcinogen by IARC (IARC: Group 2A: probably carcinogenic to humans).

**Reproductive toxicity:** Data lacking.

**Specific target organ toxicity: – single exposure** Data lacking.

**Specific target organ toxicity: – repeated exposure** Data lacking.

**Aspiration hazard:** Data lacking.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Nausea, headache, vomiting. liver irregularities, based on human evidence.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of SPECIMEN DILUTION BUFFER 5x as a mixture is not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of the SPECIMEN DILUTION BUFFER 5x:

| Eco-toxicity data for Sodium Azide | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Bluegill sunfish | 0,68 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $LC_{50}$ Water flea | 9,0 mg/L/48 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 4,2 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Algae | 0,348 mg/L/96 hr |

| Eco-toxicity data for Bronidox L | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Fish | > 1 – 10 mg/L/96 hr |

| Eco-toxicity data for Chloramphenicol | | |
|---|---|---|
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 345,0 mg/L/48 hr |

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

### 12.6. Endocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

Sodium azide is very toxic and Bronidox L is toxic to aquatic organisms. They may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

### 14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

### 15.2. Chemical safety assessment

No data available. No chemical safety assessment carried out on the product.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS05 – Danger/Warning - Corrosive |
|  | GHS06 – Danger - Toxic |
|  | GHS07 – Warning - Irritant |
|  | GHS08 – Danger/Warning – Systemic health hazards |
|  | GHS09 – Warning - Environment |

| Hazard Statements | |
|---|---|
| H300 | Fatal if swallowed. |
| H302 | Harmful if swallowed. |
| H310 | Fatal in contact with skin. |
| H314 | Causes severe skin burn and eye damage. |
| H318 | Causes serious eye damage. |
| H330 | Fatal If inhaled. |
| H351 | Suspected of causing cancer. |
| H361 | Suspected of damaging fertility of the unborn child. |
| H373 | Causes damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| EUH032 | Contact with acids liberates very toxic gas. |

| Precautionary Statements | |
|---|---|
| P202 | Do not handle until all safety precautions have been read and understood. |
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P262 | Do not get in eyes, on skin, or on clothing. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P312 | Call a POISON CENTER/doctor/… /if you feel unwell. |
| P301+P330+P331 | IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor/… |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
$LC_{50}$ : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
$LD_{50}$ : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
$EC_{50}$ : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.

STOT RE : Specific Target Organ Toxicity – Repeated Exposure.
TWA : Time Weighted Average 8 hours day.

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP - hsCRP - ASLO ELISA: CONJUGATE

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : CONJUGATE for CRP – hsCRP – ASLO ELISA
(REF 740001 – REF 740011 – REF 740201).

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

CONJUGATE is a Horseradish peroxidase (HRP)-conjugated monoclonal antibody to CRP or Streptolysin O in a stabilized aqueous buffer solution to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This component of the apDia CRP – hsCRP - ASLO ELISA kit is not classified as a hazardous mixture according to EC Regulation N° 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC.
The usual precautionary measures are to be adhered to when handling chemicals.

### 2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.

Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

- Some ingredients of the CONJUGATE mixture are derived from materials of biological origin. No known tests can guarantee that such materials are completely free from infectious agents. Caution should be exercised while handling the product: treat as potentially infectious.
- None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

Bovine material (Bovine Serum Albumin) used in the buffer preparation is from sources where origin information is available. It is derived from US origin or processed in USDA licensed facilities. Areas of origin are categorized by the World Organization for Animal Health (O.I.E.) as a controlled risk for BSE.

The following substances used in the CONJUGATE are considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen-tration |
|---|---|---|---|---|---|
| **Kit Component:** CONJUGATE | | | | | |
| **ProClin™ 300**<br>(Mixture 3:1 of:<br>• 5-chloro-2-methyl-2H-isothiazol-3-one<br>• 2-methyl-2H-isothiazol-3-one)<br>  | 01-2120764691-48-xxxx | 911-828-1 | 55965-84-9 | Acute Tox. 2 – H330<br>Acute Tox. 2 – H310<br>Acute Tox. 3 – H301<br>Skin Corr. 1C – H314<br>Eye Dam. 1 – H318<br>Skin Sens. 1A – H317<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br>EUH071<br><br>P261, P273, P280,<br>P303+P361+P353<br>P304+P340<br>P305+P351+P338,<br>P310 | 00,125 %<br>(v/v)<br>[~ 0,0038 %<br>(w/v)] |
| **5-Bromo-5-nitro-1,3-dioxane (Bronidox L)**<br>  | 01-2120770242-61-xxxx | 250-001-7 | 30007-47-7 | Acute Tox. 4 – H302<br>Skin Corr. 1A – H314<br>Eye Dam. 1 – H318<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br><br>P273 , P280 ,<br>P301+P330+P331,<br>P305+P351+P338 | 0,11 %<br>(v/v)<br>[~ 0,012 %<br>(w/v)] |
| **Chloramphenicol**<br>  | 01-2120774093-54-xxxx | 200-287-4 | 56-75-7 | Eye Dam. 1 – H318<br>Carc. 2 – H351<br>Repr. 2 – H361<br><br>P202, P280,<br>P308+P313,<br>P305+P351+P338 | 0,0005 %<br>(w/v) |

| | | | | | |
|---|---|---|---|---|---|
| **Phenol**  | 01-2119471329-32-xxxx | 203-632-7 | 108-95-2 | Acute Tox. 3 – H301<br>Acute Tox. 3 – H311<br>Acute Tox. 3 – H331<br>Skin Corr. 1B – H314<br>Muta. 2 – H341<br>STOT RE 2 – H373<br><br>Spec. Conc. Limits:<br>Eye Irrit. 2: 1 % ≤ C < 3 %<br>Skin Corr. 1B: C ≥ 3 %<br>Skin Irrit. 2: 1 % ≤ C < 3 %<br><br>P261, P280, P301+P310, P302+P352, P304+P340 P305+P351+P338, P310 | 0,095 % (w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

### 5.2. Special hazards

This product may be combustible at high temperatures. Thermal decomposition products may include carbon oxides, nitrogen oxides, halogenated compounds.
Reaction of phenol with aldehydes, nitrides, nitrates, oxidizing agents, strong acids, strong bases, sodium nitrile, sodium hypochlorite may result in heating, generation of flammable gas or toxic fumes. Hazard of fire or explosion.

### 5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP - ASLO ELISA kit.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

CONJUGATE does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: ProClin™ 300 CAS N°. 55965-84-9** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Austria | 0,05 mg/m³ | / | |
| Germany | 0,2 mg/m³ | 0,4 mg/m³ | |
| Switzerland | 0,2 mg/m³ | 0,4 mg/m³ | |

| **Substance: 5-Bromo-5-nitro-1,3-dioxane (Bronidox L) CAS N°. 30007-47-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

| **Substance: Chloramphenicol CAS N°. 56-75-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

| **Substance: Phenol CAS N°. 108-95-2** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Australia | 4 mg/m³ | / | |
| Canada | 19 mg/m³ | / | |
| Denmark | 4 mg/m³ | 8 mg/m³ | |
| European Union | 8 mg/m³ | 16 mg/m³ | |
| Hungary | 7,8 mg/m³ | 7,8 mg/m³ | |
| Latvia | 7,8 mg/m³ | / | |
| New Zealand | 5 ppm | / | |
| China | 10 mg/m³ | / | |
| Poland | 7,8 mg/m³ | 16 mg/m³ | |
| South Korea | 19 mg/m³ | / | |
| Switzerland | 19 mg/m³ | 19 mg/m³ | |
| USA | 19 mg/m³ | / | |
| United Kingdom | 2 ppm | / | |

Other exposure limits

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For CONJUGATE as a mixture:

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For ingredients of the mixture:

| DNEL (Derived no effect level) | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| Phenol | DNEL | Long term, Inhalation | 8 mg/m$^3$ | Workers | Systemic |
| 5-Bromo-5-nitro-1,3-dioxane | DNEL | Long term, inhalation | 0,0274 mg/m$^3$ | Workers | Systemic |
| Chloramphenicol | DNEL | no data | no data | no data | no data |
| ProClin™ 300 | DNEL | no data | no data | no data | no data |

| PNEC (Predicted No Effect Concentration) | | | |
|---|---|---|---|
| **Substance** | **Parameter** | **Ecosystem** | **Concentration** |
| Phenol | PNEC | Fresh water | 0,0077 mg/L |
| Phenol | PNEC | Marine water | 0,00077 mg/L |
| Phenol | PNEC | Fresh water sediment | 0,0915 mg/kg |
| Phenol | PNEC | Marine water sediment | 0,00915 mg/kg |
| Phenol | PNEC | Soil | 0,136 mg/kg |

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

**Hygiene measures:** Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

**Eye/face protection:** Wear safety glasses with side-shields or goggles conforming to EN 166.

**Skin protection:** Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

**Respiratory protection:** Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Physical appearance:** | CONJUGATE is a clear liquid.<br>It contains an inert dye, making it red in colour. |
| **Odour:** | Phenolic, aromatic, somewhat sweet and acrid. |
| **Odour threshold:** | No data available. |
| **pH value:** | 7,0 – 7,5 |
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | No data available. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Miscible with water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |
| **Viscosity:** | No data available. |
| **Explosive properties:** | Phenol is reactive with oxidizing agents, metals, acids and alkalis. |
| **Oxidizing properties:** | Not fire-propagating. |

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

No test data related to reactivity available for this product.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected. Phenol may give strong exothermal reactions with aldehydes, halogens, peroxides, strong acids and bases; risk of explosion with nitrites and nitrates.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

Avoid contact with strong oxidizing agents, strong acids, strong bases. Phenol is very corrosive to copper and brass.

### 10.6. Hazardous decomposition products

Thermal decomposition may produce small quantities of nitrogen oxides, sodium oxide fumes and oxides of carbon.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for CONJUGATE as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **ProClin™ 300**:

**Acute toxicity:**

| Acute toxicity data for ProClin™ 300 | |
|---|---|
| $LD_{50}$,oral, rat | 852,0 mg/kg |
| $LD_{50}$,skin, rabbit | 2800,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Corrosive. Causes eye burns.
Ingestion: May be harmful if swallowed. Causes burns.
Inhalation: May be harmful if inhaled. Destructive to mucous membranes and upper respiratory tract. Causes respiratory tract irritation.
Skin contact: May be harmful if absorbed through skin. Causes skin burns.

**Sensitisation:** May cause allergic skin reactions.
May provoke asthmatic response in persons with asthma who are sensitive to airway irritants.

**Germ cell mutagenicity:** Data conclusive but not sufficient for classification.

**Carcinogenicity:** Data conclusive but not sufficient for classification.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **repeated exposure** Data conclusive but not sufficient for classification.

**Aspiration hazard:** Data conclusive but not sufficient for classification.

**Signs and symptoms of exposure:**

Burning sensation. Cough and wheezing. Shortness of breath, spasm. Oedema and inflammation of larynx, pulmonary oedema, laryngitis and pulmonitis.

Following toxicological information is available for **Bronidox L**:

**Acute toxicity:**

| Acute toxicity data for Bronidox L | |
|---|---|
| $LD_{50}$,oral, mouse | 550,0 mg/kg |
| $LD_{50}$,oral, rat | 455,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 31,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Undiluted substance causes serious eye damage. SCL = 0,1 %.
Ingestion: Possibly toxic with neurological and behavioural effects (tremor, convulsions, excitement).
Inhalation: May be harmful if inhaled. Causes respiratory tract and mucous membrane irritation.
Skin contact: Undiluted substance causes severe burns. SCL = 0,1 %.

**Sensitisation:** Respiratory sensitisation: data lacking.
Skin sensitisation: data conclusive but not sufficient for classification.

**Germ cell mutagenicity:** Data inconclusive.

**Carcinogenicity:** Data lacking.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – repeated exposure** May cause damage to organs through prolonged or repeated exposure. Affected organs: stomach, liver, hart.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Chloramphenicol**:

**Acute toxicity:**

| Acute toxicity data for Chloramphenicol | |
|---|---|
| $LD_{50}$,oral, rat | 2500,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 1811,0 mg/kg |
| $LD_{50}$,intraperitoneal, mouse | 1100,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Data lacking.
Ingestion: Data lacking.
Inhalation: Data lacking.
Skin contact: Data lacking.

**Sensitization:** Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

**Germ cell mutagenicity:** Laboratory experiments have shown mutagenic effects in rats (liver, DNA damage) and mice (cytogenetic analysis).

**Carcinogenicity:** Chloramphenicol is listed as a possible human carcinogen by IARC (IARC: Group 2A: probably carcinogenic to humans).

**Reproductive toxicity:** Data lacking.

**Specific target organ toxicity: – single exposure** Data lacking.

**Specific target organ toxicity: – repeated exposure** Data lacking.

**Aspiration hazard:** Data lacking.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Nausea, headache, vomiting. liver irregularities, based on human evidence.

Following toxicological information is available for **Phenol**:

**Acute toxicity:**

| Acute toxicity data for Phenol | |
|---|---|
| $LD_{50}$,oral, mouse | 270,0 mg/kg |
| $LC_{50}$,inhalation, mouse | 177,0 mg/m$^3$ |
| $LD_{50}$,oral, rat | 410,0 – 650,0 mg/kg |
| $LC_{50}$,inhalation, rat | 90,0 mg/m$^3$/8 hr |
| $LD_{50}$,skin, rabbit | 630,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Mild to severe eye irritation. Causes eye burns.
Ingestion: May be harmful if swallowed. Causes burns.
Inhalation: Toxic if inhaled. Destructive to mucous membranes and upper respiratory tract.
Skin contact: Toxic if absorbed through skin. Causes skin burns.

**Sensitisation:** Data conclusive but not sufficient for classification.

**Germ cell mutagenicity:** No data available on humans.

**Carcinogenicity:** Data conclusive but not sufficient for classification.

**Mutagenicity:** Phenol is mutagenic *in vitro* for bacteria and/or yeast and mammalian somatic cells. No data available on humans.

**Reproductive toxigenicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – repeated exposure** Central nervous system and cardiovascular system, kidney, liver and skin.

**Aspiration hazard:** Data conclusive but not sufficient for classification.

**Signs and symptoms of exposure:**

Symptoms of systemic phenol poisoning by any route (skin or eye contact, inhalation, ingestion) may include nausea, excessive sweating, headache, dizziness, blood pressure elevation. Oedema of brain and lungs, abdominal organ congestion and diffuse redness of mucous membranes are also reported in severe cases of intoxication.
Renal failure has been reported in acute poisoning. Over-exposure may lead eventually to seizures, loss of consciousness, coma, respiratory depression after which death may ensue.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of CONJUGATE as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of CONJGATE:

| Eco-toxicity data for ProClin™ 300 | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Rainbow trout | 0,19 mg/L/96 hr |
| Fish Toxicity: | $LC_{50}$ Bass | 0,28 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 0,16 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Marine Algae | 0,003 mg/L/48 hr |

| Eco-toxicity data for Bronidox L | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Fish | > 1 – 10 mg/L/96 hr |

| Eco-toxicity data for Chloramphenicol | | |
|---|---|---|
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 345,0 mg/L/48 hr |

| Eco-toxicity data for Phenol | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ *Leuciscus idus* | 36,1 – 68,8 mg/L/96 hr |
| Fish Toxicity: | $LC_{50}$ Gold fish | 14,0 – 25,0 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 12,0 mg/L/24 hr |
| Algae Toxicity: | $EC_{50}$ Fresh water algae | 370,0 mg/L/96 hr |

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

### 12.6. Endocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

ProClin™ 300 and Bronidox L are toxic to aquatic organisms. They may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

### 14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

### 15.2. Chemical safety assessment

No data available. No chemical safety assessment carried out on the product.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS05 – Danger/Warning - Corrosive |
|  | GHS06 – Danger - Toxic |
|  | GHS07 – Warning - Irritant |
|  | GHS08 – Danger/Warning – Systemic health hazards |
|  | GHS09 – Warning - Environment |

| Hazard Statements | |
|---|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H310 | Fatal in contact with skin. |
| H311 | Toxic in contact with skin |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H330 | Fatal if inhaled. |
| H331 | Toxic if inhaled. |
| H341 | Suspected of causing genetic defects. |
| H351 | Suspected of causing cancer. |
| H361 | Suspected of damaging fertility of the unborn child. |
| H373 | Causes damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| EUH071 | Corrosive to respiratory tract. |

| Precautionary Statements | |
|---|---|
| P202 | Do not handle until all safety precautions have been read and understood. |
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… |
| P310 | Immediately call a POISON CENTER/doctor/… |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor/… |
| P301+P330+P331 | IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. |
| P302+P352 | IF ON SKIN: Wash with plenty of water/… |
| P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse SKIN with water [or shower]. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
$LC_{50}$ : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
$LD_{50}$ : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.

| | | |
|---|---|---|
| $EC_{50}$ | : | Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time. |
| OEL | : | Occupational Exposure Limit (European threshold limit value). |
| REACH | : | Registration, Evaluation, Authorization and Restriction of Chemicals. |
| RID | : | Regulation concerning the International Transport of Dangerous Goods by Rail. |
| STEL | : | Short Term Exposure Limit. |
| STOT RE | : | Specific Target Organ Toxicity – Repeated Exposure. |
| TWA | : | Time Weighted Average 8 hours day. |

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP - hsCRP - ASLO ELISA: WASHING SOLUTION 20x

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : WASHING SOLUTION 20x for CRP – hsCRP – ASLO ELISA
(REF 740001 – REF 740011 – REF 740201)

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

WASHING SOLUTION 20x is a concentrated buffered salt solution containing detergent and preservatives to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This component of the apDia CRP – hsCRP - ASLO ELISA kit is not classified as a hazardous mixture according to EC Regulation N° 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC..
The usual precautionary measures are to be adhered to when handling chemicals.

### 2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.

Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

None of the components of this product are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

The following substances used in the WASHING SOLUTION 20x are considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen-tration |
|---|---|---|---|---|---|
| **Kit Component:** WASHING SOLUTION 20x | | | | | |
| **ProClin™ 300**<br>(Mixture 3:1 of:<br>• 5-chloro-2-methyl-2H-isothiazol-3-one<br>• 2-methyl-2H-isothiazol-3-one)<br>  | 01-2120764691-48-xxxx | 911-828-1 | 55965-84-9 | Acute Tox. 2 – H330<br>Acute Tox. 2 – H310<br>Acute Tox. 3 – H301<br>Skin Corr. 1C – H314<br>Eye Dam. 1 – H318<br>Skin Sens. 1A – H317<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br>EUH071<br><br>P261, P273, P280,<br>P303+P361+P353<br>P304+P340<br>P305+P351+P338,<br>P310 | 0,05 %<br>(v/v)<br>[~ 0.0015 %<br>(w/v)] |
| **5-Bromo-5-nitro-1,3-dioxane (Bronidox L)**<br>  | 01-2120770242-61-xxxx | 250-001-7 | 30007-47-7 | Acute Tox. 4 – H302<br>Skin Corr. 1A – H314<br>Eye Dam. 1 – H318<br>STOT RE 2 – H373<br>Aquatic Acute 1 – H400<br>Aquatic Chronic 1 – H410<br><br>P273 , P280 ,<br>P301+P330+P331,<br>P305+P351+P338 | 0.1 %<br>(v/v)<br>[~ 0.011 %<br>(w/v)] |
| **Chloramphenicol**<br>  | 01-2120774093-54-xxxx | 200-287-4 | 56-75-7 | Eye Dam. 1 – H318<br>Carc. 2 – H351<br>Repr. 2 – H361<br><br>P202, P280,<br>P308+P313,<br>P305+P351+P338 | 0.01 %<br>(w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

### 5.2. Special hazards

This product is an aqueous liquid and not likely to combust. Large quantities of these products may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes.
Hazardous thermal decomposition products arising from the ingredients may include carbon oxides, nitrogen oxides, sulphur oxides, hydrogen chloride gas.

### 5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP - ASLO ELISA kit.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

WASHING SOLUTION 20x does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: ProClin™ 300 CAS N°. 55965-84-9** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Austria | 0,05 mg/m³ | / | |
| Germany | 0,2 mg/m³ | 0,4 mg/m³ | |
| Switzerland | 0,2 mg/m³ | 0,4 mg/m³ | |

| **Substance: 5-Bromo-5-nitro-1,3-dioxane (Bronidox L) CAS N°. 30007-47-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

| **Substance: Chloramphenicol CAS N°. 56-75-7** | | | Not listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| n/a | n/a | n/a | |

Other exposure limits

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For WASHING SOLUTION 20x as a mixture:

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For ingredients of the mixture:

| DNEL (Derived no effect level) | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| ProClin™ 300 | DNEL | no data | no data | no data | no data |
| 5-Bromo-5-nitro-1,3-dioxane | DNEL | Long term, inhalation | 0,0274 mg/m³ | Workers | Systemic |
| Chloramphenicol | DNEL | no data | no data | no data | no data |

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

**Hygiene measures:** Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

**Eye/face protection:** Wear safety glasses with side-shields or goggles conforming to EN 166.

**Skin protection:** Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

**Respiratory protection:** Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Physical appearance:** | WASHING SOLUTION 20x is a clear, colourless liquid. |
| **Odour:** | Odourless. |
| **Odour threshold:** | No data available. |
| **pH value:** | 7,0 – 7,4 |
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | No data available. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Miscible with water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |
| **Viscosity:** | No data available. |
| **Explosive properties:** | No data available. |
| **Oxidizing properties:** | Not fire-propagating. |

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

No test data related to reactivity available for this product.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

No data available.

### 10.6. Hazardous decomposition products

Thermal decomposition may produce small quantities of nitrogen oxides, sodium oxide fumes and oxides of carbon.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for the WASHING SOLUTION 20x as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **ProClin™ 300**:

**Acute toxicity:**

| Acute toxicity data for ProClin™ 300 | |
|---|---|
| $LD_{50}$,oral, rat | 852,0 mg/kg |
| $LD_{50}$,skin, rabbit | 2800,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Corrosive. Causes eye burns.
Ingestion: May be harmful if swallowed. Causes burns.
Inhalation: May be harmful if inhaled. Destructive to mucous membranes and upper respiratory tract. Causes respiratory tract irritation.
Skin contact: May be harmful if absorbed through skin. Causes skin burns.

**Sensitisation:** May cause allergic skin reactions.
May provoke asthmatic response in persons with asthma who are sensitive to airway irritants.

**Germ cell mutagenicity:** Data conclusive but not sufficient for classification.

**Carcinogenicity:** Data conclusive but not sufficient for classification.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity: – repeated exposure** Data conclusive but not sufficient for classification.

**Aspiration hazard:** Data conclusive but not sufficient for classification.

**Signs and symptoms of exposure:**

Burning sensation. Cough and wheezing. Shortness of breath, spasm. Oedema and inflammation of larynx, pulmonary oedema, laryngitis and pulmonitis.

Following toxicological information is available for **Bronidox L**:

**Acute toxicity:**

| Acute toxicity data for Bronidox L | |
|---|---|
| $LD_{50}$,oral, mouse | 550,0 mg/kg |
| $LD_{50}$,oral, rat | 455,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 31,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Undiluted substance causes serious eye damage. SCL = 0,1 %.
Ingestion: Possibly toxic with neurological and behavioural effects (tremor, convulsions, excitement).
Inhalation: May be harmful if inhaled. Causes respiratory tract and mucous membrane irritation.
Skin contact: Undiluted substance causes severe burns. SCL = 0,1 %.

**Sensitisation:** Respiratory sensitisation: data lacking.
Skin sensitisation: data conclusive but not sufficient for classification.

**Germ cell mutagenicity:** Data inconclusive.

**Carcinogenicity:** Data lacking.

**Reproductive toxicity:** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **single exposure** Data conclusive but not sufficient for classification.

**Specific target organ toxicity:**
– **repeated exposure** May cause damage to organs through prolonged or repeated exposure. Affected organs: stomach, liver, hart.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Chloramphenicol**:

**Acute toxicity:**

| Acute toxicity data for Chloramphenicol | |
|---|---|
| $LD_{50}$,oral, rat | 2500,0 mg/kg |
| $LD_{50}$,intraperitoneal, rat | 1811,0 mg/kg |
| $LD_{50}$,intraperitoneal, mouse | 1100,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Data lacking.
Ingestion: Data lacking.
Inhalation: Data lacking.
Skin contact: Data lacking.

**Sensitization:** Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

**Germ cell mutagenicity:** Laboratory experiments have shown mutagenic effects in rats (liver, DNA damage) and mice (cytogenetic analysis).

**Carcinogenicity:** Chloramphenicol is listed as a possible human carcinogen by IARC (IARC: Group 2A: probably carcinogenic to humans).

**Reproductive toxicity:** Data lacking.

**Specific target organ toxicity:**
– **single exposure** Data lacking.

**Specific target organ toxicity:**
– **repeated exposure** Data lacking.

**Aspiration hazard:** Data lacking.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Nausea, headache, vomiting. liver irregularities, based on human evidence.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of WASHING SOLUTION 20x as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of the WASHING SOLUTION 20x:

| Eco-toxicity data for ProClin™ 300 | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Rainbow trout | 0,19 mg/L/96 hr |
| Fish Toxicity: | $LC_{50}$ Bass | 0,28 mg/L/96 hr |
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 0,16 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Marine Algae | 0,003 mg/L/48 hr |

| Eco-toxicity data for Bronidox L | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Fish | > 1 – 10 mg/L/96 hr |

| Eco-toxicity data for Chloramphenicol | | |
|---|---|---|
| Invertebrate (Crustacean) Toxicity: | $EC_{50}$ Water flea | 345,0 mg/L/48 hr |

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

### 12.6. Endocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

ProClin™ 300 and Bronidox L are toxic to aquatic organisms. They may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

### 14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

### 15.2. Chemical safety assessment

No data available. No chemical safety assessment carried out on the product.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS05 – Danger/Warning - Corrosive |
|  | GHS07 – Warning - Irritant |
|  | GHS08 – Danger/Warning – Systemic health hazards |
|  | GHS09 – Warning - Environment |

| Hazard Statements | |
|---|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H310 | Fatal in contact with skin |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H330 | Fatal if inhaled. |
| H351 | Suspected of causing cancer. |
| H361 | Suspected of damaging fertility or the unborn child. |
| H373 | Causes damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| EUH071 | Corrosive to the respiratory tract. |

| Precautionary Statements | |
|---|---|
| P202 | Do not handle until all safety precautions have been read and understood. |
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… |
| P310 | Immediately call a POISON CENTER or doctor/physician. |
| P301+P330+P331 | IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. |
| P303+P361+P353 | IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse SKIN with water [or shower]. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.

IMDG : International Maritime Code for Dangerous Goods.
$LC_{50}$ : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
$LD_{50}$ : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
$EC_{50}$ : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
TWA : Time Weighted Average 8 hours day.

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP - hsCRP - ASLO ELISA: CHROMOGEN SOLUTION

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : CHROMOGEN SOLUTION for CRP- hsCRP – ASLO ELISA
(REF 740001 – REF 740011 – REF 740201)

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

CHROMOGEN SOLUTION is a colorimetric substrate solution, based on the marker enzyme Horse Radish Peroxidase, to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This component of the apDia CRP – hsCRP - ASLO ELISA kit kit is classified as a hazardous mixture according to EC Regulation N° 1272/2008/EC.
It contains a hazardous substance in concentrations equal to, or exceeding the concentration limits specified in this EC Regulation.
The usual precautionary measures are to be adhered to when handling chemicals.

Classification of the hazardous substance: **N-Methyl-2-pyrrolidone**

Classification for mixtures with generic concentration limits C ≥ 0,3 % :

Reproductive Toxicant Category 1B (Repr. 1B)

### 2.2. Label elements

This product has to be labelled in accordance with EC Regulation N° 1272/2008/EC (EU-GHS/CLP):

Pictogram : 
Signal word : Danger
Hazard Statement(s) : H360D: May damage the unborn child.
Precautionary Statement(s) : P202: Do not handle until all safety precautions have been read and understood.
P280: Wear protective gloves/protective clothing/ eye protection/face protection/hearing rotection.
P308+P313: IF exposed or concerned: Get medical advice/attention.
Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

None of the components of this product are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

The following substances used in the CHROMOGEN SOLUTION are considered hazardous.
At the indicated applied concentrations, only the ingredient N-Methyl-2-pyrrolidone exceeds the threshold concentration limit to warrant hazard labelling.
As a consequence, CHROMOGEN SOLUTION is labeled as set out in Section 2.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen -tration |
|---|---|---|---|---|---|
| **Kit Component**: CHROMOGEN SOLUTION | | | | | |
| **N-Methyl-2-pyrrolidone**  | Listed as REACH candidate substance: 01-2119472430-46-XXXX | 212-828-1 | 872-50-4 | Skin Irrit. 2 – H315<br>Eye Irrit. 2 – H319<br>STOT SE 3 – H335<br>Repr. 1B – H360D<br><br>Spec. Conc. Limits:<br>STOT SE 3, C ≥ 10 %<br>Repr. 1B, C ≥ 0,3 %<br><br>P202, P261, P264, P280, P312,<br>P304+P340,<br>P308+P313,<br>P302+P352,<br>P305+P351+P338 | 1 - < 5 % |
| **TMB (3,3',5,5'-Tetramethylbenzidin)**  | Not Listed | 259-364-6 | 54827-17-7 | Skin Irrit. 2 – H315<br>Eye Irrit. 2 – H319<br>STOT SE 3 – H335<br><br>P261,<br>P305+P351+P338 | < 0,1 % (w/v) |

| | | | | | |
|---|---|---|---|---|---|
| **Hydrogen peroxide**<br>  | Not listed | 231-765-0 | 7722-84-1 | Ox. Liq. 1 – H271<br>Skin Corr. 1A – H314<br>Acute Tox. 4 – H302<br>Acute Tox. 4 – H332<br><br>Spec. Conc. Limits:<br>STOT SE 3, C ≥ 35 %<br>Eye Dam. 1, 8 % ≤ C < 50 %<br>Eye Irrit. 2, 5 % ≤ C < 8 %<br>Ox. Liq. 1, C ≥ 70 %<br>Ox. Liq. 2, 50 % ≤ C < 70 %<br>Skin Corr. 1A, C ≥ 70 %<br>Skin Corr. 1B, 50 % ≤ C < 70 %<br>Skin Irrit. 2, 35 % ≤ C < 50 %<br><br>P220, P280,<br>P305+P351+P338<br>P310 | < 1 % (w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

May cause skin irritation. May cause eye irritation. May cause irritation to respiratory system. Ingestion may cause nausea and vomiting. May cause harm to the unborn child through contact with skin.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available. Treat Symptomatically.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, water mist, carbon dioxide, dry chemical powder or foam.

### 5.2. Special hazards

Vapours may collect in confined spaces, sewers to form explosive mixtures with air. Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback. Large quantities of these products may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes, e.g. nitric oxides. Can release carbon oxides in case of fire.

### 5.3. Advice for fire-fighters

Collect contaminated fire extinguishing water separately and do not discharge into drains to prevent contamination of surface or ground water. If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable cloths or towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP – ASLO ELISA.
See exposure scenario(s) in annex to this safety data sheet.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

CHROMOGEN SOLUTION does contain relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: 3,3',5,5'-Tetramethylbenzidin (TMB)<br>CAS N°. 54827-17-7** | | Not listed |
|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** |
| n/a | n/a | n/a |

| **Substance: Hydrogen peroxide<br>CAS N°. 7722-84-1** | | Listed |
|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** |
| Australia | 1,4 mg/m³ | / |
| Austria | 1,4 mg/m³ | 2,8 mg/m³ |
| Belgium | 1,4 mg/m³ | / |
| Canada | 1,4 mg/m³ | / |
| Denmark | 1,4 mg/m³ | 2,8 mg/m³ |
| Finland | 1,4 mg/m³ | 4,2 mg/m³ |
| France | 1,5 mg/m³ | / |
| Germany | 0,71 mg/m³ | 0,71 mg/m³ |
| Ireland | 1,5 mg/m³ | 3,0 mg/m³ |
| China | 1,5 mg/m³ | / |
| Singapore | 1,4 mg/m³ | / |
| South Korea | 1,5 mg/m³ | / |
| Spain | 1,4 mg/m³ | / |
| Sweden | 1,4 mg/m³ | 3,0 mg/m³ |
| Switzerland | 0,71 mg/m³ | 0,71 mg/m³ |
| USA | 1,4 mg/m³ | / |
| United Kingdom | 1,4 mg/m³ | 2,8 mg/m³ |

| **Substance: N-Methyl-2-pyrrolidone<br>CAS N°. 872-50-4** | | Listed |
|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** |
| Australia | 103 mg/m³ | 309 mg/m³ |
| Canada | 400 mg/m³ | / |
| European Union | 40 mg/m³ | 80 mg/m³ |
| Japan | 4 mg/m³ | / |
| New Zealand | 103 mg/m³ | 309 mg/m³ |
| Switzerland | 80 mg/m³ | 160 mg/m³ |
| United Kingdom | 40 mg/m³ | 80 mg/m³ |

Other exposure limits:

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For CHROMOGEN SOLUTION as a mixture:

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For ingredients of the mixture:

| DNEL (Derived No Effect Level) | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| TMB | DNEL | No data | No data | No data | No data |
| Hydrogen peroxide | DNEL | Long term, inhalation | 1,4 mg/m$^3$ | Workers | Local |
| Hydrogen peroxide | DNEL | Acute term, inhalation | 3,0 mg/m$^3$ | Workers | Local |
| N-Methyl-2-pyrrolidone | DNEL | Long term, inhalation | 14,4 mg/m$^3$ | Workers | Systemic |
| N-Methyl-2-pyrrolidone | DNEL | Long term, inhalation | 40,0 mg/m$^3$ | Workers | Local |
| N-Methyl-2-pyrrolidone | DNEL | Long term, dermal | 4,8 mg/kg bw/day | Workers | Systemic |
| N-Methyl-2-pyrrolidone | DNEL | Long term, inhalation | 3,6 mg/m$^3$ | Consumers | Systemic |
| N-Methyl-2-pyrrolidone | DNEL | Long term, inhalation | 4,5 mg/m$^3$ | Consumers | Local |
| N-Methyl-2-pyrrolidone | DNEL | Long term, dermal | 2,5 mg/kg bw/day | Consumers | Systemic |
| N-Methyl-2-pyrrolidone | DNEL | Long term, oral | 0,85 mg/kg bw/day | Consumers | Systemic |

| PNEC (Predicted No Effect Concentration) | | | |
|---|---|---|---|
| **Substance** | **Parameter** | **Ecosystem** | **Concentration** |
| TMB | PNEC | No data | No data |
| Hydrogen peroxide | PNEC | Fresh water | 0,0126 mg/L |
| Hydrogen peroxide | PNEC | Marine water | 0,0126 mg/L |
| Hydrogen peroxide | PNEC | Fresh water sediment | 0.474 mg/kg |
| Hydrogen peroxide | PNEC | Marine sediment | 0,047 mg/kg |
| Hydrogen peroxide | PNEC | Soil | 0,0023 mg/kg |
| Hydrogen peroxide | PNEC | Sewage treatment plant | 10 mg/L |
| N-Methyl-2-pyrrolidone | PNEC | Fresh water | 0,25 mg/L |
| N-Methyl-2-pyrrolidone | PNEC | Marine water | 0,025 mg/L |
| N-Methyl-2-pyrrolidone | PNEC | Fresh water sediment | 1,09 mg/kg |
| N-Methyl-2-pyrrolidone | PNEC | Marine sediment | 0,109 mg/kg |
| N-Methyl-2-pyrrolidone | PNEC | Soil | 0,0701 mg/kg |
| N-Methyl-2-pyrrolidone | PNEC | Sewage treatment plant | 4,66 mg/L |

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Females of childbearing age should not come into contact with the product.

Personal protective equipment

| | |
|---|---|
| **Hygiene measures:** | Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place. |
| **Eye/face protection:** | Wear safety glasses with side-shields or goggles conforming to EN 166. |
| **Skin protection:** | Hand protection for users of mixture:<br>Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.<br>Mean Breakthrough Time > 480 min.<br><br>Body protection:<br>Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.<br>Change contaminated clothing immediately. |
| **Respiratory protection:** | Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.<br>If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387). |

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Physical appearance:** | CHROMOGEN SOLUTION is a colourless to slightly bluish-coloured liquid. |
| **Odour:** | Odourless. |
| **Odour threshold:** | No data available. |
| **pH value:** | No data available. |
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | No data available. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Complete in water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |
| **Viscosity:** | No data available. |
| **Explosive properties:** | No data available. |
| **Oxidizing properties:** | No information available. |

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

No test data related to reactivity available for this product.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

Avoid contact with strong oxidizing agents, metals and metal salts: possible destruction of the quality of the product. Incompatible with acids, alkalis and reducing agents.

### 10.6. Hazardous decomposition products

Hazardous thermal decomposition products in small quantities, i.e. nitric oxide vapours, nitrogen, carbon oxides are possible in a fire.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for CHROMOGEN SOLUTION as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **TMB**:

**Acute toxicity:**

| Acute toxicity data for TMB |
|---|
| no data available |

**Corrosion/Irritation:**

Eye contact: Causes serious eye irritation.
Ingestion: Harmful if swallowed.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness.

**Germ cell mutagenicity:** No data available on humans.
Genotoxicity in vitro - mouse - lymphocyte
Mutation in mammalian somatic cells.

**Carcinogenicity:** TMB is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.

**Mutagenicity:** No data available on humans.

**Reproductive toxigenicity:** No data available on humans.

**Specific target organ toxicity:**
– **single exposure** No data available.

**Specific target organ toxicity:**
– **repeated exposure** No data available.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Hydrogen peroxide**:

**Acute toxicity:**

| Acute toxicity data for Hydrogen peroxide | |
|---|---|
| $LD_{50}$,skin, rabbit | 2000,0 mg/kg |
| $LD_{50}$,oral, rabbit | 693,7 – 1270,0 mg/kg |

**Corrosion/Irritation:**

Eye contact: Causes serious eye irritation. Conjunctivitis.
Ingestion: Irritation of mucous membranes in mouth, pharynx, oesophagus, gastrointestinal tract.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation after prolonged exposure. May cause skin burns.

**Germ cell mutagenicity:** No data available on humans.

**Carcinogenicity:** Hydrogen peroxide is not listed as carcinogenic.

**Mutagenicity:** No data available on humans.

**Reproductive toxigenicity:** No data available on humans.

**Specific target organ toxicity:**
– **single exposure** Not classified as specific target organ toxicant.

**Specific target organ toxicity:**
– **repeated exposure** Not classified as specific target organ toxicant.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **N-Methyl-2-Pyrrolidone**:

**Acute toxicity:**

| Acute toxicity data for N-Methyl-2-pyrrolidone | |
|---|---|
| $LD_{50}$,dermal, rabbit | 5000,0 mg/kg |
| $LD_{50}$,oral, rat | 4150,0 mg/kg |
| $LC_{50}$,inhalation, rat | > 5,1 mg/L, 4 hr |

**Corrosion/Irritation:**

Eye contact: Causes serious eye irritation. Damage to cornea (rabbit).
Skin contact: May cause moderate skin irritation.

**Sensitisation:** Not classified based on available data.

**Germ cell mutagenicity:** Not classified: classification criteria not met based on available data.

**Carcinogenicity:** Not classified: classification criteria not met based on available data.

**Mutagenicity:** Not classified: classification criteria not met based on available data.

**Reproductive toxigenicity:** Suspected of damaging the unborn child.

NOAEL (oral, rat): 350 mg/kg (Effect on fertility)
: 125 mg/kg/day (Effect developmental toxicity)
NOAEC (inhalation, rat): 478 mg/$m^3$ (Effect on fertility)
: 360 mg/m3 (Effect developm. toxicity)
NOAEL (dermal, rat): 237/mg/kg bw/day (Effect developm. tox.)

**Specific target organ toxicity: – single exposure** May cause respiratory irritation.

**Specific target organ toxicity: – repeated exposure** Not classified as specific target organ toxicant.

**Aspiration hazard:** No data available.

**Signs and symptoms of exposure:**
Likely routes of exposure are lungs, skin and gastrointestinal tract.
May cause irritation of the mucous membranes of respiratory tract when inhaled. Large amounts of the product may cause dizziness, headache and nausea. May cause skin irritation, N-Methyl-2-pyrrolidone may be absorbed through the skin. May cause eye irritation with redness. May cause irritation to mucous membranes in mouth, throat and stomach when ingested. Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system. May cause harm to the unborn child through inhalation or contact with skin.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of CHROMOGEN SOLUTION as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for the components used in the formulation of CHROMOGEN SOLUTION:

| Eco-toxicity data for TMB |
|---|
| No data available |

| Eco-toxicity data for Hydrogen peroxide | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Fish | 22,0 – 26,7 mg/L/96 hr |
| Invertebrate Toxicity: | $EC_{50}$ Water flea | 7,7 mg/L/24 hr |
| Algae Toxicity: | $IC_{50}$ Fresh water algae | 2,5 mg/L/72 hr |

| Eco-toxicity data for N-Methyl-2-pyrrolidone | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Bluegill Sunfish | 832 mg/L/96 hr |
| Invertebrate Toxicity: | $EC_{50}$ Water flea | 4897 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Green algae | > 500 mg/L/72 hr |

### 12.2. Persistence and degradability

N-Methyl-2-pyrrolidone is readily biodegradable.

### 12.3. Bioaccumulative potential

N-Methyl-2-pyrrolidone: Log $K_{ow}$ < 1. No significant bioaccumulation.
Hydrogen peroxide: Log $K_{ow}$ < 1. No bioaccumulation potential.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

Ingredients are not considered PBT/vPvB according to criteria in REACH Annex XIII.

### 12.6. Endocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

No information available.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

| | |
|---|---|
| Land transport (road/rail) ADR/RID: | No limitations |
| Maritime transport (sea) IMDG: | No limitations |
| Air transport (air) ICAO/IATA: | No limitations |

### 14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

Contains a substance with REACH Annex XVII restrictions:

| The following restrictions are applicable according to Annex XVII of the REACH EC Regulation 1907/2006/EC: | |
|---|---|
| 3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation 1272/2008/EC:<br><br>3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation 1272/2008/EC:<br>Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10. | N-Methyl-2-pyrrolidone |
| 30. Substances which appear in Part 3 of Annex VI to Regulation 1272/2008/EC classified as Toxic to Reproduction category 1A or 1B (Table 3.1) or Toxic to Reproduction category 1 or 2 (Table 3.2) and listed as follows:<br>Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) or,<br>Reproductive toxicant category 1 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 5,<br>Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) or,<br>Reproductive toxicant category 2 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 6. | N-Methyl-2-pyrrolidone |
| Entry 71:<br>1. Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 14,4 mg/m$^3$ for exposure by inhalation and 4,8 mg/kg/day for dermal exposure.<br>2. Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.<br>3. By way of derogation from paragraph 1 and 2, the obligations laid down therein shall apply from 9 May 2024 in relation to placing on the market for use, or use, as a solvent or reactant in the process of coating wires. | N-Methyl-2-pyrrolidone |

Contains a substance on the REACH candidate list in concentration ≥ 0,1 % or with a lower specific limit, i.e. N-Methyl-2-pyrrolidone (CAS 872-50-4).

Contains no REACH Annex XIV substances.

### 15.2. Chemical safety assessment

No data available.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS03 – Danger/Warning - Oxidising |
|  | GHS05 – Danger/Warning - Corrosive |
|  | GHS07 – Warning - Irritant |
|  | GHS08 – Danger/Warning – Systemic Health Hazards |

| Hazard Statements | |
|---|---|
| H271 | May cause fire or explosion; strong oxidizer. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |
| H360D | May damage the unborn child. |

| Precautionary Statements | |
|---|---|
| P201 | Obtain special instructions before use. |
| P202 | Do not handle until all safety precautions have been read and understood. |
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P220 | Keep away from clothing and other combustible materials. |
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P264 | Wash hands thoroughly after handling. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… |
| P310 | Immediately call a POISON CENTER/doctor/… |
| P312 | Call a POISON CENTER/doctor/… if you feel unwell. |
| P302+P352 | IF ON SKIN: Wash with plenty of water/… |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308+P313 | If exposed or concerned: Get medical advice/attention. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.

| | | |
|---|---|---|
| IATA-DGR | : | Dangerous Goods Regulation by IATA. |
| ICAO | : | International Civil Aviation Organization. |
| IMDG | : | International Maritime Code for Dangerous Goods. |
| $LC_{50}$ | : | Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time. |
| $LD_{50}$ | : | Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time. |
| $EC_{50}$ | : | Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time. |
| $IC_{5O}$ | : | Inhibition concentration whereby 50 % of a sample of test organisms show an inhibition of a certain target activity following a specified exposure time. |
| $K_{ow}$ | : | Octanol-water Partition Coefficient. |
| OEL | : | Occupational Exposure Limit (European threshold limit value). |
| REACH | : | Registration, Evaluation, Authorization and Restriction of Chemicals. |
| RID | : | Regulation concerning the International Transport of Dangerous Goods by Rail. |
| STEL | : | Short Term Exposure Limit. |
| STOT SE | : | Specific Target Organ Toxicity – Single Exposure. |
| TWA | : | Time Weighted Average 8 hours day. |

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

**Annex to Safety Data Sheet**

**CHROMOGEN SOLUTION:**

**Exposure scenario for Downstream Users.**
**Widespread use by professional workers; Laboratory Chemicals (PC21).**
**Use as a laboratory reagent (PROC15).**

Life cycle stage (LCS): Widespread use by professional workers (PW)
Sector of use category (SU): SU24
Chemical product category (PC): PC21
Process category (PROC): PROC15
Environmental release category (ERC): ERC8a
Technical function (TF): Solvent

| |
|---|
| **SU24** Scientific research and development |
| **PC21** Laboratory chemicals |
| **PROC15** Use as laboratory reagent |
| **ERC8a** Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor) |

**1. Exposure Scenario: Used as a laboratory reagent**

Contributing Scenarios (CS)

**Environment**
CS1: ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)

**Worker**
CS2: PROC15 Use as a laboratory reagent – indoor, with fume cupboard/local exhaust ventilation, >4 hours
CS3: PROC15 Use as a laboratory reagent – indoor, with fume cupboard/local exhaust ventilation, 1-4 hours
CS4: PROC15 Use as a laboratory reagent – indoors, with good general ventilation, >4 hours
CS5: PROC15 Use as a laboratory reagent – indoors, with general ventilation, 1-4 hours

**2. Conditions of use affecting exposure**

Most relevant exposure scenario for users of the apDia CRP – hsCRP – ASLO ELISA:

**2.1 Contributing scenario CS5, controlling worker exposure for: PROC15 (indoors, with general ventilation, 1-4 hours)**

**Product characteristics**
Concentration of the substance in mixture: covers concentration of the substance up to 5%.
Physical Form (at time of use): low volatile liquid

**Amount used, frequency and duration of use/exposure**
Covers use up to 4 hours per day.

**Technical and organisational conditions and measures**
Provide a basic standard of general ventilation (minimum 5 air changes per hour).
Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.
Ensure control measures are regularly inspected and maintained.

**Conditions and measures related to personal protection, hygiene and health evaluation**
Wear suitable gloves tested to EN 374 with APF10.
Wear safety glasses approved to standard EN 166.
Wear a respirator providing a minimum efficiency of 95.0 %.
For further specification, refer to Section 8 of the SDS.

**Other conditions affecting workers exposure**
Indoor use.
Assumes process temperature up to 40 °C.

**Additional good practice advice. Obligations according to Article 37(4) of REACH do not**

**apply**
Ensure operatives are trained to minimise exposure.

**3. Exposure estimation and reference to its source**

**Environment**
A chemical safety assessment was performed by the supplier according to REACH Article 14(3), Annex I, sections 3 (Environmental Hazard assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

**Workers**

| Contributing Scenario | Exposure Assessment Method | Specific Conditions | Value | Level of Exposure | RCR* |
|---|---|---|---|---|---|
| CS5:PROC15 | ECETOC TRA | With general ventilation. 1-4 hours | Inhalation | 0.124 mg/m³ | 0.0086 |
| CS5: PROC15 | ECETOC TRA | With general ventilation, 1-4 hours | Dermal | 0.00686 mg/kg bw/day | 0.00143 |

*Risk characterisation ratio

**4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario**

Please refer to the following documents:

ECHA Document - How downstream users can handle exposure scenarios. Practical Guide 13.

ECHA Document - How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl-2- pyrrolidone).

Advanced Practical Diagnostics BV

# SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC

**Version:** 6.0
**Revision date:** 28.06.2021

# CRP - hsCRP - ASLO ELISA: STOPPING SOLUTION

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name : STOPPING SOLUTION for CRP – hsCRP – ASLO ELISA
(REF 740001 – REF 740011 – REF 740201).

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

STOPPING SOLUTION is an aqueous sulphuric acid solution to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

### 1.3. Details of the supplier of the Safety Data Sheet

Company : Advanced Practical Diagnostics BV
Address : Raadsherenstraat 3
B-2300 Turnhout
Belgium
Contact : Tel. +32 (0)14 45 35 99
Fax +32 (0)14 81 29 45
E-mail admin@apdia.be
Web site www.apdiagroup.com

### 1.4. Emergency Telephone Number

Phone : +32 (0) 14 45 35 99 (available during office hours)

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This component of the apDia CRP – hsCRP - ASLO ELISA kit is not classified as a hazardous mixture according to EC Regulation N° 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC..
The usual precautionary measures are to be adhered to when handling chemicals.

### 2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.
Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request.

### 2.3. Other hazards

None of the components of this product are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

The following substance used in the STOPPING SOLUTION is considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

| Hazardous Ingredient | REACH Registration N° | EC N° | CAS N° | Classification + H- and P-Statements | Concen-tration |
|---|---|---|---|---|---|
| **Kit Component:** STOPPING SOLUTION 0,5 M | | | | | |
| **Sulphuric acid**  | 01-2119458838-20-xxxx | 231-639-5 | 7664-93-9 | Skin Corr. 1A – H314<br><br>Spec. Conc. Limits:<br>Eye Irrit. 2: 5 % ≤ C < 15 %<br>Skin Corr. 1A: C ≥ 15 %<br>Skin Irrit. 2: 5 % ≤ C < 15 %<br><br>P280 ,<br>P302+P352,<br>P305+P351+P338 | < 5 % (w/v) |

See section 16 for the full text of Hazard- and Precautionary Statements.

## SECTION 4 - FIRST AID MEASURES

### 4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

**Eye contact:** Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

**Ingestion:** If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

**Inhalation:** If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Skin contact:** Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5 - FIRE-FIGHTING MEASURES

### 5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

### 5.1. Special hazards

This product is an aqueous liquid and not likely to combust. In case of fire, hazardous decomposition products in the form of sulphur oxide vapours ($SO_2$, $SO_3$, …) can be generated.

### 5.2. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

### 6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

### 6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

### 6.4. Reference to other sections

See section 13 for disposal considerations.

## SECTION 7 - HANDLING AND STORAGE

### 7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

### 7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

### 7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the apDia CRP – hsCRP - ASLO ELISA kit.

## SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1. Control parameters

STOPPING SOLUTION does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

| **Substance: Sulphuric acid<br>CAS N°. 7664-93-9** | | | Listed |
|---|---|---|---|
| **Country** | **OEL Long Term (TWA 8 hours)** | **OEL Short Term (STEL 15 min)** | |
| Australia | 1,0 mg/m³ | 3,0 mg/m³ | |
| Canada | 0,2 mg/m³ | / | |
| European Union | 0,05 mg/m³ | / | (Thoracic fraction) |
| Israel | 0,3 mg/m³ | / | |
| New Zealand | 1,0 mg/m³ | / | |
| China | 1,0 mg/m³ | 2,0 mg/m³ | |
| Singapore | 1,0 mg/m³ | 3,0 mg/m³ | |
| South Korea | 0,2 mg/m³ | 0,6 mg/m³ | |
| Switzerland | 0,1 mg/m³ | 0,2 mg/m³ | (Inhalable fraction) |
| USA | 1,0 mg/m³ | / | |
| United Kingdom | 0,05 mg/m³ | / | |

Other exposure limits

| **DNEL (Derived No Effect Level)** | | | | | |
|---|---|---|---|---|---|
| **Substance** | **Parameter** | **Exposure** | **Value** | **Population** | **Effects** |
| Sulphuric acid | DNEL | Acute, inhalation | 0,1 mg/m³ | Workers | Local effects |
| Sulphuric acid | DNEL | Long term, inhalation | 0,05 mg/m³ | Workers | Local effects |

| **PNEC (Predicted No Effect Concentration)** | | | |
|---|---|---|---|
| **Substance** | **Parameter** | **Ecosystem** | **Concentration** |
| Sulphuric acid | PNEC | Fresh water | 0,0025 mg/L |
| Sulphuric acid | PNEC | Marine water | 0,00025 mg/L |
| Sulphuric acid | PNEC | Fresh water sediment | 0,002 mg/kg |
| Sulphuric acid | PNEC | Marine water sediment | 0,002 mg/kg |

### 8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

**Hygiene measures:** Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

**Eye/face protection:** Wear safety glasses with side-shields or goggles conforming to EN 166.

**Skin protection:** Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

**Respiratory protection:** Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Physical appearance:** | STOPPING SOLUTION is a clear, colourless liquid. |
| **Odour:** | Odourless. |
| **Odour threshold:** | No data available. |
| **pH value:** | 1,0 |
| **Melting point/freezing point:** | No data available. |
| **Boiling point:** | No data available. |
| **Flash point:** | No data available. |
| **Evaporation rate:** | No data available. |
| **Flammability (solid,gas):** | No data available. |
| **Vapour pressure:** | No data available. |
| **Vapour density:** | No data available. |
| **Relative density:** | Not measured. |
| **Solubility:** | Miscible with water. |
| **Partition coefficient:** | No data available. |
| **Auto-ignition temperature:** | No data available. |
| **Decomposition temperature:** | No data available. |
| **Viscosity:** | No data available. |
| **Explosive properties:** | No data available. |
| **Oxidizing properties:** | No data available. |

### 9.2. Other information

No further information available.

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1. Reactivity

May be corrosive for metals.

### 10.2. Chemical stability

Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

### 10.3. Possibility of hazardous reactions

By using the product according to the requirements, no hazardous reactions are to be expected.

### 10.4. Conditions to avoid

Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

### 10.5. Incompatible materials

Avoid contact with bases, halides, organic materials, cyanides, chlorates, carbides, metals and metal salts, phosphorus.

### 10.6. Hazardous decomposition products

Hazardous thermal decomposition products in small quantities, i.e. sulphur oxide vapours are possible in a fire.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for the STOPPING SOLUTION as a mixture.
However, one can consider the effects of exposure to the individual hazardous component of the mixture, i.e. sulphuric acid, to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Sulphuric acid**:

**Acute Toxicity – Oral:** Based on available data, the classification criteria are not met.
**Acute Toxicity – Dermal:** Based on available data, the classification criteria are not met.
**Acute Toxicity – Inhalation:** Based on available data, the classification criteria are not met.

| Acute toxicity data for Sulphuric acid | |
|---|---|
| $LD_{50}$,oral, rat | 2140,0 mg/kg |
| $LD_{50}$,inhalation, rat | 375,0 mg/m³ air |

**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
**Sensitization:** Based on available data, the classification criteria are not met.
**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
**Carcinogenicity:** Data inconclusive.
**Reproductive toxigenicity:** Based on available data, the classification criteria are not met.
**Specific target organ toxicity: – single exposure** Based on available data, the classification criteria are not met.
**Specific target organ toxicity: – repeated exposure** Based on available data, the classification criteria are not met.
**Aspiration hazard:** Based on available data, the classification criteria are not met.

**Signs and symptoms of exposure:**

Eye contact: Causes severe eye irritation.
Ingestion: Harmful if swallowed.
Inhalation: Destructive to tissues of upper respiratory tract and mucous membranes.
Skin contact: Causes skin burns.

### 11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

## SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of STOPPING SOLUTION as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

### 12.1. Toxicity

Available ecological toxicity information for Sulphuric acid used in the formulation of the STOPPING SOLUTION:

| Eco-toxicity data for Sulphuric acid | | |
|---|---|---|
| Fish Toxicity: | $LC_{50}$ Bluegill sunfish | 16,0 – 28,0 mg/L/96 hr |
| Invertebrate Toxicity: | $EC_{50}$ Water flea | > 100 mg/L/48 hr |
| Algae Toxicity: | $EC_{50}$ Fresh water algae | > 100 mg/L/72 hr |

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

### 12.6. Endrocrine disrupting properties

No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

### 12.7. Other adverse effects

No information available.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical

specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

## SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

### 14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

### 14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: no

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## SECTION 15 - REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture

This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

### 15.2. Chemical safety assessment

No data available. No chemical safety assessment carried out on the product.

## SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol | |
|---|---|
|  | GHS05 – Danger/Warning - Corrosive |

| Hazard Statements | |
|---|---|
| H314 | Causes severe skin burns and eye damage. |

| Precautionary Statements | |
|---|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CPS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
$LC_{50}$ : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
$LD_{50}$ : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
$EC_{50}$ : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
TWA : Time Weighted Average 8 hours day.

Revisions since previous version

Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

**Notice to the product user:**

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.