

## SAFETY DATA SHEET

### WIESLAB® kits

#### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

##### 1.1 Product identifier

|                            |  |
|----------------------------|--|
| <b>PRODUCT NAME:</b>       | <b>WIESLAB® kits:</b><br>WIESLAB® Anti-GBM, ANCA screen<br>WIESLAB® Anti-GBM semi quantitative kit<br>WIESLAB® ANCA panel<br>WIESLAB® ASCA IgA semi quant.<br>WIESLAB® ASCA IgG semi quant.<br>WIESLAB® Capture MPO-ANCA<br>WIESLAB® Capture PR3-ANCA<br>WIESLAB® MPO-ANCA<br>WIESLAB® PR3-ANCA<br>WIESLAB® Vasculitis screen  |
| <b>Product description</b> | <b>Kit consisting of following reagents:</b> <ul style="list-style-type: none"> <li>• Reagent A: Wash buffer 30 x Conc.</li> <li>• Reagent B: Diluent</li> <li>• Reagent C: Conjugate</li> <li>• Reagent D: Calibrator</li> <li>• Reagent E: Positive Control</li> <li>• Reagent F: Negative Control</li> <li>• Reagent G: Stop Solution</li> <li>• Reagent H: Substrate pNPP</li> <li>• Antigen coated plate</li> </ul> |
| <b>Product code</b>        | GCP 100<br>GP 104X<br>PAN 106<br>ASCA 150<br>ASCA 151<br>Cap MPO IU<br>Cap PR3 IU<br>MPO IU<br>PR3 IU<br>GCP-CAP   |

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

|                           |  |
|---------------------------|--|
| <b>Use of the product</b> | Kit consisting of different reagents for in vitro diagnostic and research use. |
|---------------------------|--|

##### 1.3 Details of the supplier of the safety data sheet

|                       |  |
|-----------------------|--|
| <b>Company</b>        | Svar Life Science AB   |
| <b>Address</b>        | Lundavägen 151   |
| <b>Zip code/Place</b> | SE-212 24 Malmö, Sweden  |
| <b>Telephone</b>      | +46 40 53 76 00  |
| <b>Internet</b>       | <a href="http://www.svarlifescience.com">www.svarlifescience.com</a>   |
| <b>E-mail</b>         | <a href="mailto:info@svarlifescience.com">info@svarlifescience.com</a> |

##### 1.4 Emergency telephone number

|                                   |   |
|-----------------------------------|---|
| <b>Emergency telephone number</b> | +46-010-456 6700 Swedish Poisons Information Centre |
|-----------------------------------|---|

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

**Product definition:** In vitro device kit and research use kit consisting of different reagents.

The antigen coated plate is not classified as dangerous.

**Classification according to the Regulation (EC) No. 1272/2008 (CLP)**

**Reagent A, B, C, D, E, F, G, and H:** Skin Irrit. 1; H317

The antigen coated plate is not classified as dangerous.

### 2.2 Label elements according the Regulation (EC) No. 1272/2008 (CLP)

#### 2.2.1 Reagent A, B, C, D, E, F, G, and H

**Hazard pictogram:**



GHS07: Exclamation mark

**Signal word:** Warning

|                  |  |
|------------------|--|
| <b>Contains:</b> | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) |
|------------------|--|

#### Hazard statements

|             |                                      |
|-------------|--------------------------------------|
| <b>H317</b> | May cause an allergic skin reaction. |
|-------------|--------------------------------------|

#### Precautionary statements

|                 |  |
|-----------------|--|
| <b>P264</b>     | Wash hands thoroughly after handling.                                      |
| <b>P280</b>     | Wear protective gloves/protective clothing/eye protection/face protection. |
| <b>P302+352</b> | IF ON SKIN: Wash with plenty of soap and water.                            |
| <b>P333+313</b> | If skin irritation or rash occurs: Get medical advice/attention.           |

#### 2.2.2 Antigen coated plate

The antigen coated plate is not labeled because it is not classified as dangerous.

### 2.3 Other hazards

|  |   |
|--|---|
| <b>Other hazards which do not result in classification</b>                                   | None  |
| <b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b> | PBT: No<br>(refers to substances containing)  |
| <b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b> | vPvB: No<br>(refers to substances containing) |

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Reagents containing following substances classified as dangerous.

| No                                   | Product/ingredient name  | EC-number | CAS-number | REACH registration number | Conc. (weight-%) | Classification Regulation (EC) No. 1272/2008 [CLP]   |
|--------------------------------------|--|-----------|------------|---------------------------|------------------|--|
| <b>Reagent Wash Buffer 30 x Conc</b> |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,01-0,03        | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Diluent</b>               |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Conjugate</b>             |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Calibrator</b>            |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Positive Control</b>      |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Negative Control</b>      |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Stop Solution</b>         |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |
| <b>Reagent Substrate pNP</b>         |  |           |            |                           |                  |  |
|                                      | Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) | --        | 55965-84-9 | --                        | 0,0015-0,015     | Acute Tox 2, H301<br>Acute Tox 2, H311<br>Skin Corr 1B, H314<br>Skin Sens. 1, H317<br>Acute tox 2, H331<br>Aquatic Chronic 1, H410 |

The antigen coated plate contains no dangerous substances. See section 16 for the full text of the classifications declared above. Occupational exposure limits are mentioned under section 8, if such exist.

#### 4. FIRST AID MEASURES

##### 4.1 Description of first aid measures

|                      |  |
|----------------------|--|
| <b>Inhalation:</b>   | Remove to fresh air, rest. Call a physician if the complaints persist.   |
| <b>Skin contact:</b> | Remove contaminated clothing and footwear. Wash the skin properly with soap and water.   |
| <b>Eye contact:</b>  | Keep eyelids well apart. Rinse with water for a couple of minutes.<br>Call a physician if the complaints persist.  |
| <b>Ingestion</b>     | Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist. |

##### 4.2 Most important symptoms and effects, both acute and delayed potential acute health effects

|                      |  |
|----------------------|--|
| <b>Inhalation:</b>   | Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness.  |
| <b>Skin contact:</b> | Prolonged exposure to the skin may cause skin irritation.<br><b>Reagent A, B, C, D, E), F, G, and H:</b> May cause an allergic skin reaction.<br><b>Antigen coated plate:</b> May not cause any sensitizing effects. |
| <b>Eye contact:</b>  | May cause mild, reversible eye irritation.   |
| <b>Ingestion:</b>    | Ingestion of larger amounts may cause sickness and vomiting.   |

##### 4.2 Indication of any immediate medical attention and special treatment needed

|                             |                        |
|-----------------------------|------------------------|
| <b>Ingestion:</b>           | Treat symptomatically. |
| <b>Specific treatments:</b> | No specific treatment. |

#### 5. FIRE-FIGHTING MEASURES

##### 5.1 Extinguishing media

|                                       |  |
|---------------------------------------|--|
| <b>Suitable extinguishing media</b>   | Dry chemical, foam, water spray or carbon dioxide. |
| <b>Unsuitable extinguishing media</b> | Waterjet   |

##### 5.2 Special hazards arising from the substance or mixture

|   |  |
|---|--|
| <b>Hazards from the substance or mixture</b>    | None   |
| <b>Hazardous thermal decomposition products</b> | Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases. |

##### 5.3 Advice for firefighters

|   |   |
|---|---|
| <b>Special protective actions for fire-fighters</b>   | Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.   |
| <b>Special protective equipment for fire-fighters</b> | Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents. |
| <b>Further information</b>                            | Not applicable  |

## 6. ACCIDENTAL RELEASE MEASURES

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

|                                    |   |
|------------------------------------|---|
| <b>For non-emergency personnel</b> | No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment. |
|------------------------------------|---|

|                                 |   |
|---------------------------------|---|
| <b>For emergency responders</b> | If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures. |
|---------------------------------|---|

### 6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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

|                    |   |
|--------------------|---|
| <b>Small spill</b> | Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.   |
| <b>Large spill</b> | Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. |

### 6.4 Reference to other sections

|                                    |  |
|------------------------------------|--|
| <b>Reference to other sections</b> | See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information. |
|------------------------------------|--|

## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

|   |   |
|---|---|
| <b>Protective measures</b>                    | Put on appropriate personal protective equipment (see Section 8).   |
| <b>Advice on general occupational hygiene</b> | Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures. |

### 7.2 Conditions for safe storage, including any incompatibilities

|                             |   |
|-----------------------------|---|
| <b>Storage:</b>             | Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10), food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. |
| <b>Further information:</b> | Not applicable  |

### 7.3 Specific end use(s)

Reagents for in vitro diagnostic and research use.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limits

| Ingredient name | CAS nr. | Range | ppm | mg/m <sup>3</sup> | Year | Remarks |
|-----------------|---------|-------|-----|-------------------|------|---------|
| --              | --      | --    | --  | --                | --   | --      |

|  |              |
|--|--------------|
| <b>Recommended monitoring procedures</b> | Not relevant |
|--|--------------|

#### Derived effect levels

| Product/ingredient name | Type | Exposure | Value | Population | Effects |
|-------------------------|------|----------|-------|------------|---------|
| --                      | --   | --       | --    | --         | --      |

|  |               |
|--|---------------|
| <b>Predicted effect concentrations</b> | Not available |
| <b>PNEC Summary</b>                    | Not available |

### 8.2 Exposure controls

|   |   |
|---|---|
| <b>Appropriate engineering controls</b> | Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.  |
| <b>Hygiene measures</b>                 | Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location. |
| <b>Respiratory protection</b>           | Not relevant during normal condition.   |
| <b>Eye/face protection</b>              | Safety glasses or face shield shall be worn.  |
| <b>Hand protection</b>                  | Chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard shall be worn.   |
| <b>Body protection</b>                  | Wear suitable protective clothing.  |
| <b>Environmental exposure controls</b>  | Not applicable  |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1.1 Information on basic physical and chemical properties of the reagents

|  | Reagent A                | Reagent B                | Reagent C                | Reagent D                | Reagent E                | Reagent F                | Reagent G                | Reagent H                |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Physical state                               | Liquid                   | Liquid                   | Liquid                   | Liquid                   | Liquid                   | Liquid                   | Liquid                   | Liquid                   |
| Colour                                       | Colourless               | Red                      | Blue                     | Red                      | Red                      | Green                    | Colourless               | Colourless               |
| Odour  | Odourless                | Odourless                | Odourless                | Odourless                | Odourless                | Odourless                | Odourless                | Odourless                |
| Odour threshold                              | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Solubility(ies)                              | Soluble in water         | Soluble in water         | Soluble in water         | Soluble in water         | Soluble in water         | Soluble in water         | Soluble in water         | Soluble in water         |
| pH (product)                                 | n.d                      | 7,2-7,5                  | 7,4-7,6                  | 7,2-7,5                  | 7,2-7,5                  | 7,2-7,5                  | 8,0                      | 9,55-9,65                |
| Melting point/freezing point                 | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Initial boiling point and boiling range      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Flash point                                  | > 100°C                  | > 100°C                  | > 100°C                  | > 100°C                  | > 100°C                  | > 100°C                  | > 100°C                  | > 100°C                  |
| Evaporation rate (butyl acetate = 1)         | < 1                      | < 1                      | < 1                      | < 1                      | < 1                      | < 1                      | < 1                      | < 1                      |
| Flammability (solid, gas)                    | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Upper/lower flammability or explosive limits | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Combustion rate                              | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Upper/lower flammability or explosive limits | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a | Upper: n.a<br>Lower: n.a |
| Vapour pressure (at 20°C)                    | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Vapour density                               | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Relative density (Water = 1)                 | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Partition coefficient: n-octanol/water       | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Autoignition temperature                     | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Decomposition temperature                    | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Viscosity                                    | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      | n.d                      |
| Explosive properties                         | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |
| Oxidising properties                         | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      | n.a                      |

n.a = not applicable, n.d = not determined

### 9.2 Other information

|    |    |
|----|----|
| -- | -- |
|----|----|

## 10. STABILITY AND REACTIVITY

|   |   |
|---|---|
| 10.1 Reactivity                         | Non-reactive  |
| 10.2 Chemical stability                 | Stabile under normal conditions of use and storage.                             |
| 10.3 Possibility of hazardous reactions | Under normal conditions of storage and use, hazardous reactions will not occur. |
| 10.4 Conditions to avoid                | Avoid direct sunlight.  |
| 10.5 Incompatible materials             | None  |
| 10.6 Hazardous decomposition products   | Carbon monoxide, carbon dioxide and nitrous gases.                              |

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

Assessment of acute toxicity for the different reagents:

Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kg

LD50 dermal, rat: > 2000 mg/kg

#### Irritation/Corrosion

Assessment of the irritant effect for the different reagents:

Not irritating to eyes and skin.

Experimental/calculated data:

Corrosive or irritating to the skin, rabbit: Not irritating.

Serious eye damage/eye irritation, rabbit: Not irritating.

#### Sensitization by inhalation/skin contact

Assessment of sensibility for the different reagents:

**Reagent A, B, C, D, E, F, G, and H:** May cause an allergic skin reaction.

**Antigen coated plate:** May not cause any sensitizing effects.

#### Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any mutagenic effects.

#### Carcinogenicity

Assessment of carcinogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any carcinogenic effects.

#### Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any reproduction toxic effects.

#### Developmental toxicity

Assessment of teratogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any teratogenic effects.

#### Specific target organ toxicity (single exposure)

STOT assessment single dos toxicity:

Based on available information an organ specific toxicity is not expected for the different reagents.

#### Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information an organ specific toxicity is not expected for the different reagents.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### 12.1.1 Acute toxicity in the aquatic environment of 5-chloro-2-methyl-4-isothiazolin-3-one

| Test         | Value/unit (mg/l) | Test method | Exp. time (h) | Species           |
|--------------|-------------------|-------------|---------------|-------------------|
| Fish LC50    | 6,1               |             | 96            | Brachydanio rerio |
| Daphnia EC50 | 4,2               |             | 48            | Daphnia magna     |

BCF = 114. Bioaccumulating effects may occur. 39-62% degraded in 29 days OECD 301B. Not readily biodegradable.



**12.1.2 Acute toxicity in the aquatic environment of 2-methyl-4-isothiazolin-3-one**

| Test   | Value/unit (mg/l) | Test method | Exp. time (h) | Species       |
|--|-------------------|-------------|---------------|---------------|
| Daphnia EC50   | 0,18              |             | 48            | Daphnia magna |
| BCF = 114. Log P <sub>ow</sub> : -0,486. Bioaccumulating effects are not expected.<br>48-54% degraded in 29 days OECD 301B. Not readily biodegradable. |                   |             |               |               |

**12.1.3 Ecotoxicity**

The reagents contain low concentration of the above mentioned substances. These concentrations are below the lowest concentration limit for classification as harmful to aquatic organisms.

**12.2 Persistence and degradability**

|                           |   |
|---------------------------|---|
| <b>Conclusion/Summary</b> | The reagents as such will be classified as readily biodegradable. |
|---------------------------|---|

**12.3 Bioaccumulative potential**

|                           |   |
|---------------------------|---|
| <b>Conclusion/Summary</b> | The reagents as such will not be classified as bioaccumulative. |
|---------------------------|---|

**12.4 Mobility in soil**

|   |               |
|---|---------------|
| <b>Soil/water partition coefficient (KOC)</b> | Not available |
| <b>Mobility</b>                               | Not available |

**12.5 Results of PBT and vPvB assessment**

|                   |   |
|-------------------|---|
| <b>PBT</b>        | Not applicable  |
| <b>vPvB</b>       | Not applicable  |
| <b>Conclusion</b> | The reagents contain substances classified as dangerous for the environment. But the concentrations of these substances are very low, so the reagents as such are not classified as dangerous for the environment, according to the EU classification rules in force.<br>The antigen coated plate is not classified as dangerous for the environment. |

**13. DISPOSAL CONSIDERATIONS**
**13.1 Waste treatment methods**
**Product**

|                           |   |
|---------------------------|---|
| <b>Method of disposal</b> | The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.<br>Used kit may be potentially infectious material and shall be disposed as a hazardous waste. |
| <b>Hazardous waste</b>    | Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EU.   |

**European Waste Catalogue (EWC)**

| EWC Waste Code | Type of waste  |
|----------------|--|
| 18 01 06*      | Chemicals consisting of or containing dangerous substances               |
| 15 01 10*      | Packaging containing residues of or contaminated by dangerous substances |

**Packaging**

|                     |               |
|---------------------|---------------|
| Method of disposal  | Incineration. |
| Special precautions | None.         |

**14. TRANSPORT INFORMATION**

Product classified as dangerous goods:  Yes  No  Not decided

|                                   | ADR/RID  | ADN/ADNR      | IMDG          | IATA          |
|-----------------------------------|--|---------------|---------------|---------------|
| 14.1 UN number                    | Not regulated  | Not regulated | Not regulated | Not regulated |
| 14.2 UN proper shipping name      | --   | --            | --            | --            |
| 14.3 Transport hazard class(es)   | --   | --            | --            | --            |
| 14.4 Packing Group                | --   | --            | --            | --            |
| 14.5 Environmental hazards        | --   | --            | --            | --            |
| 14.6 Special precautions for user | Not available  | Not available | Not available | Not available |
| Additional information            | Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information. |               |               |               |

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

**15. REGULATORY INFORMATION**
**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
EU Regulation (EC) No. 1907/2006 (REACH)**

|              |   |
|--------------|---|
| REACH Status | In compliance.<br>Pre-registration status: All components are listed or exempted. |
|--------------|---|

**Annex XIV - List of substances subject to authorization**
**Substances of very high concern**

None of the components are listed.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles**

Not applicable.

**15.2 Chemical Safety Assessment**

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

**15.3 Other information**

|                                 |                |
|---------------------------------|----------------|
| Tariff Code – harmonized system | Not applicable |
| The EU Seveso Directive         | Not applicable |

**International regulations**

| Chemical Weapons Convention List<br>Schedule I Chemicals | Chemical Weapons Convention List<br>Schedule II Chemicals | Chemical Weapons Convention List<br>Schedule III Chemicals |
|--|---|--|
| Not regulated  | Not regulated   | Not regulated  |

## 16. OTHER INFORMATION

### Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

**Disclaimer:** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

### THE PRODUCER'S NOTES

--

### LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

| No.  | H-Statements  |
|------|---|
| H301 | Toxic if swallowed.                                   |
| H311 | Toxic in contact with skin.                           |
| H331 | Toxic if inhaled.                                     |
| H314 | Causes severe skin burns and eye damage               |
| H317 | May cause an allergic skin reaction.                  |
| H410 | Very toxic to aquatic life with long lasting effects. |

## 17. DOCUMENT HISTORY

| Version | Valid from (date) | Changes   |
|---------|-------------------|---|
| 1.0     | 01-Jun-2018       | Migrated document E-31-0001-03EN to LABEL-DOC-0254 v1.0   |
| 2.0     | 23-Oct-2020       | Following kits and information related to them has been removed: COMP 200, SSAP200, Complement Ficolin 3, CP 111 according to CR2016-049 and Celiac hs Screen according to CR2017-018. New SVAR logo and updated contact information according to CR-00019. Emergency phone number to Poison Info Center under section 1.4 has been updated. Revision history has been moved to Properties. E-31-0001-03 has been removed from file name. |
| 3.0     | 28-Apr-2023       | Following kits (IVD and RUO) and information related to them has been removed: COMPL CP310, COMPL MP320, COMPL AP330 and COMPL 300, according to CR-00522. Section 17 document history added.   |