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# **IMMUNOGUIDE TRASTUZUMAB ELISA IG-AB105**

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

#### 1.1. Product Identifier

| PRODUCT NAME           | ImmunoGuide Trastuzumab ELISA (mAb-based)                           |
|------------------------|---|
| CATALOGUE NUMBER (REF) | IG-AB105  |
| INTENDED USE           | The <i>Trastuzumab ELISA (mAb-based)</i> is an Enzyme-Linked        |
|                        | ImmunoSorbent Assay (ELISA) Kit for the quantitative in vitro       |
|                        | determination of <i>free Trastuzumab</i> in human serum and plasma. |

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

The components of ImmunoGuide-AybayTech ELISA Kits are used as reagents 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: AybayTech Biyoteknoloji İmalat San. ve Tic. Ltd. Sti.

Address: Macun Mah. Batı Blv. No: 1/285

06374-Yenimahalle, Ankara

Turkiye

Contact: Tel. +90 312 397 88 05

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E-mail: info@aybaytech.com and info@immunoguide.com Web site: www.aybaytech.com and www.immunoguide.com

# 1.4. Emergency Telephone Number

Phone: +90 312 397 88 05 (available during office hours)

#### SECTION 2-HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture.

- The components of the ImmunoGuide ELISA kits 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

#### 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



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#### 2.3. Other hazards.

\*Some ingredients (monoclonal antibodies and albumin) of the ImmunoGuide-AybayTech ELISA Kit 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 taken into account while handling the product: treat as potentially infectious.

\*Some components, as indicated below, 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).

**Note:** This product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

#### **SECTION 3-COMPOSITION AND INFORMATION ON INGREDIENTS**

#### 3.1. Substances.

Not applicable:

#### 3.2. Mixtures.

Human source material (recombinant human monoclonal antibody, positive serum or plasma) if used in the preparation of the STANDARDS/CONTROLS/CALIBRATORS has been tested and found non-reactive for HIV-1/2 antibodies, HCV and HbsAg. No known test method can offer complete assurance that Hepatitis B virus, HIV, HCV, or other infectious agents are absent. Handle all biological materials as through capable of transmitting infection.

Purified Albumin protein is used for blocking of "Coated Microtiter Plate" and for that of stabilization purpose in the Standards, Dilution Buffer, Assay Buffer and Conjugate at a concentration less than 1%.

The following substances used in the Kit Components are considered hazardous.

However, at the indicated applied concentrations, it does not warrant hazard labelling.

# **ELISA KIT COMPONENTS:-COMPOSITION**

| KIT COMPONENT AND COMPOSITION |            |   |  |
|-------------------------------|------------|---|--|
| COMPONENT                     | LABEL/REF  | COMPOSITION   |  |
| Coated                        | MTP        | 96-well microtiter plate coated with monoclonal antibody specific for the       |  |
| Microtitre Plate              |            | drug in concern.  |  |
| Standards                     | STND       | Buffered protein matrix containing drug in concern at defined                   |  |
|                               |            | concentrations.   |  |
|                               |            | Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).                |  |
| Dilution Buffer 5X            | DIL BUF 5X | Protein-based aqueous buffered solution.  |  |
|                               |            | Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).                |  |
| Assay Buffer                  | ASSAYBUF   | Prote in-based aqueous buffered solution.                                       |  |
|                               |            | Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).                |  |
| Washing Solution              | WASHBUF    | 20X Concentrated buffered salt solution containing detergent.                   |  |
| 20X                           | 20X        | Preserved with ProClin <sup>™</sup> 300 (CAS: 55965-84-9; N°-CE: 911-828-1) and |  |
|                               |            | 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7; N°-CE:              |  |
|                               |            | 250-001-7).   |  |
| Conjugate                     | ENZCONJ    | Horseradish peroxidase (HRP) conjugated monoclonal antibody in a                |  |
|                               |            | stabilized buffer solution.   |  |
|                               |            | Preserved with ProClin <sup>™</sup> 300 (CAS: 55965-84-9; N°-CE: 911-828-1) and |  |
|                               |            | 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7; N°-CE:              |  |
| 01                            | TMPOLIDO   | 250-001-7).   |  |
| Chromogen                     | TMBSUBS    | Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidin) (CAS: 54827-17-         |  |
| Solution                      |            | 7; N°-CE: 259-364-6) and Hydrogen Peroxide (CAS: 7722-84-1; N°-CE:              |  |
|                               |            | 231-765-0).   |  |
| Otan Calutian                 | CTOD       | Preserved with ProClin <sup>™</sup> 300 (CAS: 55965-84-9; N°-CE: 911-828-1).    |  |
| Stop Solution                 | STOP       | Aqueous solution of 1 N HCl Hydrochloric Acid (CAS: 7647-01-0; N°-CE:           |  |
|                               |            | 231-595-7).   |  |



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KIT COMPONENTS:-HAZARDOUS INGREDIENTS

| Hazardous<br>Ingredient  | REACH Registration N°  | CAS N°     | EC N°     | Classification + H- and P-<br>Statements  | Concentratio                          |
|--|------------------------|------------|-----------|---|---------------------------------------|
| Sodium azide   | 01-2119457019- 37-xxxx | 26628-22-8 | 247-852-1 | 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<br>P312, P302+P352<br>P301+P310<br>P304+P340  | 0,09 % (w/v)                          |
| ProClin™ 300<br>(Mixture 3:1 of:<br>• 5-chloro-2-methyl-<br>2H-isothiazol-3-one<br>• 2-methyl-2H-<br>isothiazol-3-one) | 01-2120764691-48-xxxx  | 55965-84-9 | 911-828-1 | 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>P261, P273, P280,<br>P303+P361+P353<br>P304+P340<br>P305+P351+P338,<br>P310   | 0,025 % (v/v)<br>[~ 0,0008%<br>(w/v)] |
| 5-Bromo-5-nitro-1,3-dioxane (Bronidox L)   | 01-2120770242-61-xxxx  | 30007-47-7 | 250-001-7 | 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>P273, P280,<br>P301+P330+P331,<br>P305+P351+P338  | 0,21 % (v/v)<br>[~ 0,0225 %<br>(w/v)] |
| TMB (3,3',5,5'-<br>Tetramethylbenzidin)  | Not listed             | 54827-17-7 | 259-364-6 | Skin Irrit. 2 – H315<br>Eye Irrit. 2 – H319<br>STOT SE 3 – H335<br>P261,<br>P305+P351+P338  | <0,1 % (w/v)                          |
| Hydrogen peroxide  | Not listed             | 7722-84-1  | 231-765-0 | Ox. Liq. 1 – H271<br>Skin Corr. 1A – H314<br>Acute Tox. 4 – H302<br>Acute Tox. 4 – H332<br>Spec. Conc. Limits:<br>STOT SE 3, $C \ge 35\%$<br>Eye Dam. 1, $8\% \le C<50\%$<br>Eye Irrit. 2, $5\% \le C<8\%$<br>Ox. Liq. 1, $C \ge 70\%$<br>Ox. Liq. 1, $C \ge 70\%$<br>Skin Corr. 1A, $C \ge 70\%$<br>Skin Corr. 1B,50% $C< 70\%$<br>Skin Irrit. 2, $C< 70\%$<br>Skin Irrit. 2, $C< 70\%$<br>P220, P280,<br>P305+P351+P338 | <1 % (w/v)                            |
| Hydrochloric Acid  | 017-002-01-xxxx        | 7647-01-0  | 231-595-7 | Skin Corr. 1B-H314  Spec. Conc. Limits: Eye Irrit. 2; H319:10 %≤C<25% Skin Corr. 1B: C ≥ 25 % Skin Irrit. 2: H315:10 %≤C<25% STOT SE 3; H335: C ≥ 10 % P280 P302+P352 P305+P351+P338  | <4 % (w/v)*                           |

<sup>\*</sup>Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1999/45/EC or 1272/2008/EC

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



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#### **SECTION 4-FIRST AID MEASURES**

## 4.1. Description of first aid measures.

In general, it is advised to consult a doctor/physician and showing this safety data sheet to the doctor/physician. Consult doctor/physician in case of complaints.

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 plenty of 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-FIRST AID 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 arising from the substance or mixture.

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 8 for personal protection See section 13 for disposal considerations



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#### **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 (at 4-8°C). Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

#### 7.3. Specific end use(s).

Use only in accordance with the Instructions For Use (IFU) supplied with the related ImmunoGuide ELISA kit in concern.

#### **SECTION 8-EXPOSURE CONTROLS AND PERSONAL PROTECTION**

#### 8.1. Control parameters.

The components of ImmunoGuide-AybayTech ELISA Kits 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 (CAS N°. 26628-22-8) -LISTED |                       |                        |  |  |
|--|-----------------------|------------------------|--|--|
| Country  | OEL Long Term         | OEL Short Term         |  |  |
|  | (TWA 8 hours)         | (STEL 15 min)          |  |  |
| Australia  | /                     | 0,3 mg/m <sup>3</sup>  |  |  |
| Canada   | /                     | 0,3 mg/m <sup>3</sup>  |  |  |
| European Union                                       | 0,1 mg/m <sup>3</sup> | 0,3 mg/m <sup>3</sup>  |  |  |
| New Zealand  | /                     | 0,29 mg/m <sup>3</sup> |  |  |
| China  | /                     | 0,3 mg/m <sup>3</sup>  |  |  |
| South Korea  | /                     | 0,29 mg/m <sup>3</sup> |  |  |
| Switzerland  | 0,2 mg/m <sup>3</sup> | 0,4 mg/m <sup>3</sup>  |  |  |
| USA  | /                     | 0,3 mg/m <sup>3</sup>  |  |  |
| United Kingdom                                       | 0,1 mg/m <sup>3</sup> | 0,3 mg/m <sup>3</sup>  |  |  |

| SUBSTANCE: ProClin™ 300 (CAS N°. 55965-84-9) -LISTED |                                |                                 |  |  |
|--|--------------------------------|---------------------------------|--|--|
| Country  | OEL Long Term<br>(TWA 8 hours) | OEL Short Term<br>(STEL 15 min) |  |  |
| Australia  | 0,05 mg/m <sup>3</sup>         | /                               |  |  |
| Germany  | 0,2 mg/m <sup>3</sup>          | 0,4 mg/m <sup>3</sup>           |  |  |
| Switzerland  | 0,2 mg/m <sup>3</sup>          | 0,4 mg/m <sup>3</sup>           |  |  |

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

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



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

| SUBSTANCE: Hydrochloric Acid (CAS N°. 7647-01-0)- LISTED* |                                |                                 |  |  |
|---|--------------------------------|---------------------------------|--|--|
| Country   | OEL Long Term<br>(TWA 8 hours) | OEL Short Term<br>(STEL 15 min) |  |  |
| European Union*   | 8 mg/m <sup>3</sup>            | 15 mg/m <sup>3</sup>            |  |  |
| Great Britain**   | 2 mg/m <sup>3</sup>            | 8 mg/m <sup>3</sup>             |  |  |

<sup>\*</sup>Source: 2000/39/EC, \*\* Source: EH40/2005

# 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 each component of ELISA Kit (ImmunoGuide AybayTech) such as Coated Microtitre Plate, Standards/Controls/Calibrators, Assay Buffer, Dilution Buffer, Conjugates, TMB and Stop Solution;

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

For ingredients of the components: Sodium azide (CAS N°. 26628-22-8); ProClin™ 300 (CAS: 55965-84-9); 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7); TMB (CAS: 54827-17-7); Hydrogen Peroxide (CAS: 7722-84-1); Hydrochloric Acid (CAS: 7647-01-0).

| ,                               | DNEL (Derived no effect level) |                          |                          |            |          |
|---------------------------------|--------------------------------|--------------------------|--------------------------|------------|----------|
| Substance                       | Parameter                      | Exposure                 | Value                    | Population | Effects  |
| Sodium azide                    | DNEL                           | Long term,<br>Inhalation | 0,164 mg/m <sup>3</sup>  | Workers    | Systemic |
| Sodium azide                    | DNEL                           | Long term,<br>Inhalation | 46,7 μg/kg bw/day        | Workers    | Systemic |
| ProClin™ 300                    | DNEL                           | No data                  | No data                  | No data    | No data  |
| 5-Bromo-5-nitro-<br>1,3-dioxane | DNEL                           | Long term, inhalation    | 0,0274 mg/m <sup>3</sup> | Workers    | Systemic |
| TMB                             | DNEL                           | No data                  | No data                  | No data    | No data  |
| Hydrogen Peroxide               | DNEL                           | Long term, inhalation    | 1,4 mg/m <sup>3</sup>    | Workers    | Local    |
| Hydrogen Peroxide               | DNEL                           | Acute term, inhalation   | 3,0 mg/m <sup>3</sup>    | Workers    | Local    |
| Hydrochloric Acid               | DNEL                           | Long term, inhalation    | 8 mg/m³                  | Workers    | Local    |
| Hydrochloric Acid               | DNEL                           | Acute term, inhalation   | 15 mg/m³                 | Workers    | Local    |

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| PNEC (Predicted No Effect Concentration) |           |                              |               |  |  |
|--|-----------|------------------------------|---------------|--|--|
| Substance                                | Parameter | Ecosystem                    | Concentration |  |  |
| Sodium azide                             | PNEC      | Freshwater                   | 0,35 µg/L     |  |  |
| Sodium azide                             | PNEC      | Sewage treatment plant (STP) | 30 μg/L       |  |  |
| Sodium azide                             | PNEC      | Freshwater sediment          | 16,7 µg/kg    |  |  |
| Sodium azide                             | PNEC      | Marine sediment              | 0,72 µg/kg    |  |  |
| ProClin™ 300                             | PNEC      | No data                      | No data       |  |  |
| 5-Bromo-5-nitro-1,3-dioxane              | PNEC      | Australian river             | 7.3 µg/L      |  |  |
| 5-Bromo-5-nitro-1,3-dioxane              | PNEC      | Marine water                 | 8.8 µg/L      |  |  |
| 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       |  |  |
| Hydrochloric Acid                        | PNEC      | Freshwater                   | 0.036 mgL     |  |  |
| Hydrochloric Acid                        | PNEC      | Marine water                 | 0.036 mgL     |  |  |
| Hydrochloric Acid                        | PNEC      | Soil (Agriculture)           | 0.036 mgL dw  |  |  |

#### 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 reuse. 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



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# **SECTION 9-PHYSICAL AND CHEMICAL PROPERTIES**

# 9.1. Information on basic physical and chemical properties.

| STANDARDS/CONTROLS/CALIBRATORS                                 |  |  |
|--|--|--|
| Physical appearance & The physical state (solid, liquid, gas): | Liquid or lyophilized (has no influence to the properties of the mixture). |  |
| Color:   | Diverse (has no influence to the properties of the mixture                 |  |
| 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:  | The ingredient sodium azide may form explosive compounds with              |  |
|  | metals including copper, lead, mercury, silver and brass.                  |  |
| Oxidizing properties:  | Not fire-propagating.  |  |

| DILUTION BUFFER 5X (DIL BUF 5X) |   |  |
|---------------------------------|---|--|
| Physical appearance &           | Liquid.   |  |
| The physical state              |   |  |
| (solid, liquid, gas):           |   |  |
|                                 |   |  |
| Color:                          | It contains an inert dye, making it orange in colour.         |  |
| Odour:                          | Odourless.  |  |
| Odour threshold:                | No data available.  |  |
| pH value:                       | 7,2 – 7,5   |  |
| Melting point/freezing point:   | No data available.  |  |
| Boiling point:                  | 100°C.  |  |
| 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.   |  |

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| ASSAY BUFFER (ASSAYBUF)       |   |  |
|-------------------------------|---|--|
| Physical appearance &         | Liquid.   |  |
| The physical state            |   |  |
| (solid, liquid, gas):         |   |  |
|                               |   |  |
| Color:                        | It contains an inert dye, making it blue in colour.           |  |
| Odour:                        | Odourless.  |  |
| Odour threshold:              | No data available.  |  |
| pH value:                     | 7,2 – 7,5   |  |
| Melting point/freezing point: | No data available.  |  |
| Boiling point:                | 100°C.  |  |
| 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.   |  |

| WASHING SOLUTION 20X (WASHBUF 20X) |                                     |  |
|------------------------------------|-------------------------------------|--|
| Physical appearance &              | Liquid.                             |  |
| The physical state                 |                                     |  |
| (solid, liquid, gas):              |                                     |  |
|                                    |                                     |  |
| Color:                             | Clear-colourless.                   |  |
| 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:              | Product is not explosive.           |  |
| Oxidizing properties:              | Not fire-propagating.               |  |



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| CONJUGATE (ENZCONJ)           |  |  |
|-------------------------------|--|--|
| Physical appearance &         | Liquid.  |  |
| The physical state            |  |  |
| (solid, liquid, gas):         |  |  |
|                               |  |  |
| Color:                        | It contains an inert dye, making it red in colour. |  |
| Odour:                        | Odourless.   |  |
| Odour threshold:              | No data available.                                 |  |
| pH value:                     | 5,5 – 6,5  |  |
| Melting point/freezing point: | No data available.                                 |  |
| Boiling point:                | 100°C.   |  |
| 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:         | Product is not explosive.                          |  |
| Oxidizing properties:         | Not an Oxidizer.                                   |  |

| CHROMOGEN SOLUTION (TMBSUBS)  |                                     |  |
|-------------------------------|-------------------------------------|--|
| Physical appearance &         | Liquid.                             |  |
| The physical state            |                                     |  |
| (solid, liquid, gas):         |                                     |  |
|                               |                                     |  |
| Color:                        | Clear to light yellow               |  |
| Odour:                        | Odourless.                          |  |
| Odour threshold:              | No data available.                  |  |
| pH value:                     | 3,5 – 4,5                           |  |
| 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:         | Product is not explosive.           |  |
| Oxidizing properties:         | Not an Oxidizer.                    |  |

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| STOP SOLUTION (STOP)          |                                     |  |
|-------------------------------|-------------------------------------|--|
| Physical appearance &         | Liquid.                             |  |
| The physical state            |                                     |  |
| (solid, liquid, gas):         |                                     |  |
|                               |                                     |  |
| Color:                        | Clear-Colourless                    |  |
| Odour:                        | Odourless.                          |  |
| Odour threshold:              | No data available.                  |  |
| pH value:                     | 1                                   |  |
| 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:         | No data available.                  |  |
| Oxidizing properties:         | No data 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 stated on label and pressures. Stable until expiry date stated on label when stored as indicated.

#### 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.

For Chromogenic Substrate (TMB): 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.

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

## 10.6. Hazardous decomposition products

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



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#### 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 components of ImmunoGuide-AybayTech ELISA Kits 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 |                        |  |
|--------------------------------------|------------------------|--|
| LD50,oral, mouse                     | 27,0 mg/kg             |  |
| LD50,oral, rat                       | 27,0 mg/kg             |  |
| LD50,inhalation, mouse               | 32,4 mg/m <sup>3</sup> |  |
| LD50,inhlation, rat                  | 37,0 mg/m <sup>3</sup> |  |
| LD50,skin, rat                       | 50,0 mg/kg             |  |
| LD50,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: | Respiratory system, Central Nervous System (CNS).                     |
| (single exposure)               |   |
| Specific target organ toxicity: | Cardiovascular system, respiratory and digestive organs.              |
| (repeated exposure)             | 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<sup>™</sup> 300**:

#### **Acute toxicity**

| Acute toxicity data for ProClin <sup>™</sup> 300 |              |
|--|--------------|
| LD50,oral, rat                                   | 852,0 mg/kg  |
| LD50,skin, rabbit                                | 2800,0 mg/kg |



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#### 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 toxigenicity:      | Data conclusive but not sufficient for classification.               |  |
| Specific target organ toxicity: | Data conclusive but not sufficient for classification.               |  |
| (single exposure)               |  |  |
| Specific target organ toxicity: | Data conclusive but not sufficient for classification.               |  |
| (repeated exposure)             |  |  |
| 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 |             |  |
|------------------------------------|-------------|--|
| LD50,oral, mouse                   | 550,0 mg/kg |  |
| LD50,oral, rat                     | 455,0 mg/kg |  |
| LD50,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).

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 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:                   | May cause damage to organs through prolonged or repeated  |
| (repeated exposure)                               | 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.



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# Following toxicological information is available for TMB:

# **Acute toxicity**

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.

| Sensitisation:                  | No data available on humans.                                    |
|---------------------------------|---|
|                                 | Genotoxicity in vitro - mouse - lymphocyte                      |
|                                 | Mutation in mammalian somatic cells.                            |
| Germ cell mutagenicity:         | TMB is not listed as carcinogenic by IARC at a concentration of |
|                                 | < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.    |
| Carcinogenicity:                | No data available on humans.                                    |
| Reproductive toxigenicity:      | No data available on humans.                                    |
| Specific target organ toxicity: | No data available.  |
| (single exposure)               |   |
| Specific target organ toxicity: | No data available.  |
| (repeated exposure)             |   |
| 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 |  |  |  |  |
|---|--|--|--|--|
| LD5O,skin, rabbit 2000,0 mg/kg            |  |  |  |  |
| LD5O,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.



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## Following toxicological information is available for **Hydrochloric 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**

| Acute toxicity data for Hydrogen peroxide |                |  |  |
|---|----------------|--|--|
| LD5O,oral, rat 238 – 277 mg/kg            |                |  |  |
| LD5O,dermal, rabbit                       | >5010 mg/kg    |  |  |
| LC5O,inhalation, rat                      | 1.68 mg/L (1h) |  |  |

| 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:                | Based on available data, the classification criteria are not met. |
| Mutagenicity                    | Based on available data, the classification criteria are not met. |
| Reproductive toxigenicity:      | Based on available data, the classification criteria are not met. |
| Specific target organ toxicity: | Based on available data, the classification criteria are not met. |
| (single exposure)               |   |
| Specific target organ toxicity: | Based on available data, the classification criteria are not met. |
| (repeated exposure)             |   |
| 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. Endocrine disrupting properties

None of the ingredients are listed

# 11.3. 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 components of ELISA Kit 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 the ingredients used in the formulation of the ELISA Kit components.

| Eco-toxicity data for Sodium Azide (CAS: 26628-22-8) |                       |                  |  |
|--|-----------------------|------------------|--|
| Fish Toxicity:                                       | LC50 Bluegill sunfish | 0,68 mg/L/96 hr  |  |
| Invertebrate (Crustacean) Toxicity:                  | LC50 Water flea       | 9,0 mg/L/48 hr   |  |
| Invertebrate (Crustacean) Toxicity:                  | EC50 Water flea       | 4,2 mg/L/48 hr   |  |
| Algae Toxicity:                                      | EC50 Algae            | 0,348 mg/L/96 hr |  |



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| Eco-toxicity data for ProClin <sup>™</sup> 300 (CAS: 55965-84-9) |                    |                  |  |
|--|--------------------|------------------|--|
| Fish Toxicity:   | LC50 Rainbow trout | 0,19 mg/L/96 hr  |  |
| Fish Toxicity:   | LC50 Bass          | 0,28 mg/L/96 hr  |  |
| Invertebrate (Crustacean) Toxicity:                              | EC50 Water flea    | 0,16 mg/L/48 hr  |  |
| Algae Toxicity:  | EC50 Marine Algae  | 0,003 mg/L/48 hr |  |

| Eco-toxicity data for Bronidox L (CAS: 30007-47-7) |  |  |  |
|--|--|--|--|
| Fish Toxicity: LC50 Fish > 1–10 mg/L/96 hr         |  |  |  |

| Eco-toxicity data for TMB (CAS: 54827-17-7) |  |  |  |  |
|---|--|--|--|--|
| No data available                           |  |  |  |  |

| Eco-toxicity data for Hydrogen Peroxide (CAS: 7722-84-1) |  |  |  |  |
|--|--|--|--|--|
| Fish Toxicity: LC50 Fish 22,0 – 26,7 mg/L/96 hr          |  |  |  |  |
| Invertebrate Toxicity: EC50 Water flea 7,7 mg/L/24 hr    |  |  |  |  |
| Algae Toxicity: IC50 Fresh water algae 2,5 mg/L/72 hr    |  |  |  |  |

| Eco-toxicity data for Hydrochloric Acid (CAS: 7647-01-0) |  |  |  |  |
|--|--|--|--|--|
| Fish Toxicity LC50 Fresh water fish 282 mg/L/96 h        |  |  |  |  |
| Invertebrate Toxicity: EC50 Water Flea 56mg/L/ 72h       |  |  |  |  |

## 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 $^{\circ}$  2017/2100/EU and N $^{\circ}$  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.



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#### **SECTION 13-DISPOSAL CONSIDERATION**

#### 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 described under the section of product just above.

## **SECTION 14-TRANSPORT INFORMATION**

These products contain no hazardous materials subjected to Transport Regulations and is not covered by international regulations on the transport of dangerous goods (ADR/RID, IATA/ICAO, IMO/IMDG, US DOT).

Land transport (road/rail) ADR/RID: No limitations/not classified Air transport (air) IATA/ ICAO: No limitations/not classified Maritime transport (sea) IMO/IMDG: No limitations/not classified US Department of transportation (US DOT): No limitations/not classified

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

#### 14.1. UN number or ID number

ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.2. UN proper shipping name

ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.3. Transport hazard class(es)

ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.4. Packing group

ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.5. Environmental hazards

ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.6. Special precautions for user

No data available.

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

Not applicable



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#### **SECTION 15-REGULATORY INFORMATION**

This product has been classified and labeled according to the European regulation (EC) N° 1272/2008 on dangerous substances and mixtures.

## 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. A chemical safety assessment has not been carried out for this product.

#### **SECTION 16-OTHER INFORMATION**

## Meaning of Hazard symbols, Hazard and Precautionary Statements used:

| Hazard symbol & meaning |  |
|-------------------------|--|
| <b>**</b>               | GHS03: Danger or Warning - Oxidising               |
| <b>(1)</b>              | GHS05: Danger or Warning - Corrosive               |
|                         | GHS06: Danger - Toxic                              |
| 1                       | GHS07: Warning - Irritant                          |
| <b>&amp;</b>            | GHS08: Danger or Warning – Systemic health hazards |
| <b>£</b>                | GHS09: Warning - Environment                       |

| Hazard Statements & meaning |   |  |
|-----------------------------|---|--|
| H271                        | May cause fire or explosion; strong oxidizer.                   |  |
| H300                        | Fatal if swallowed.   |  |
| H301                        | Toxic if swallowed.   |  |
| H302                        | Harmful if swallowed.   |  |
| H310                        | Fatal in contact with skin                                      |  |
| H314                        | Causes severe skin burns and eye damage.                        |  |
| H315                        | Causes skin irritation.   |  |
| H317                        | May cause an allergic skin reaction.                            |  |
| H318                        | Causes serious eye damage.                                      |  |
| H319                        | Causes serious eye irritation.                                  |  |
| H330                        | Fatal if inhaled.   |  |
| H332                        | Harmful if inhaled.   |  |
| H335                        | May cause respiratory irritation.                               |  |
| 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.                    |  |
| EUH071                      | Corrosive to the respiratory tract.                             |  |



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| Precautionary Statements & meaning |   |  |
|------------------------------------|---|--|
| P220                               | Keep away from clothing and other combustible materials.                          |  |
| 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.   |
| IMO :     | International Maritime Organization  |
| IMDG:     | International Maritime Code for Dangerous Goods  |
| LC50:     | Lethal concentration which kills 50 % of a sample population of a specific test animal   |
|           | following a specified exposure time.   |
| LD50:     | Lethal dose which kills 50 % of a sample of a specific test animal following a specified |
|           | exposure time.   |
| EC50:     | 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  |
| ACGIH:    | American Conference of Governmental Industrial Hygienists.                               |
| ADR:      | European Agreement concerning the International Carriage of Dangerous Goods by Road.     |
| U.S. DOT: | US Department of transportation  |

# Revisions since previous version Adaptations according to Regulation N° 2020/878/EU.

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



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## 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.