

## SAFETY DATA SHEET

Product name	Product reference
ZYMUTEST™ HIA (Heparin Induced Antibodies) IgGAM	RK040D
ZYMUTEST™ HIA (Heparin Induced Antibodies) MonoStrip IgGAM	RK041D

In accordance with Regulation (EC) No. 1907/2006, a Safety Data Sheet is required only for reagents Conjugate Diluent, Wash Solution, and 0.45M Sulfuric Acid (see SDS below).

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 26.02.2024

Version number 5

Revision: 26.02.2024

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

- **Product identifier**
- **Trade name:** **Conjugate diluent**
- **Article number:** CD ELISA/CD MonoStrip
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
HYPHEN BioMed  
155 rue d'Eragny  
F-95000 NEUVILLE-SUR-OISE  
FRANCE
- **Further information obtainable from:**  
info@hyphen-biomed.com  
+33/1/34 40 65 10
- **Emergency telephone number:**  
Members of the public seeking specific information on poisons should contact:  
In England and Wales: NHS 111 - dial 111  
In Scotland: NHS 24 - dial 111

## 2 Hazards identification

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



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

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



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
- **Hazard statements**  
May cause an allergic skin reaction.
- **Precautionary statements**  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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**Trade name: Conjugate diluent**

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P362+P364 Take off contaminated clothing and wash it before reuse.

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

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

### 3 Composition/information on ingredients

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

· **Dangerous components:**

55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	<0.06%
	<ul style="list-style-type: none"> <li>⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; ⚠ Skin Corr. 1C, H314; Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1A, H317</li> </ul>	

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

### 4 First aid measures

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

### 5 Firefighting measures

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

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.

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- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to section 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** 2 - 8°C
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Do not eat or drink while working.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

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

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

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several

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substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

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

· **Eye protection:** Face protection

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Fluid
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

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

· **Initial boiling point and boiling range:** Undetermined.

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

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

· **Explosion limits:**

· **Lower:** Not determined.

· **Upper:** Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

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

Not determined.

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

· **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **Other information**

No further relevant information available.

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### 10 Stability and reactivity

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

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.  
Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**  
Disposal must be made according to official regulations.  
Dispose of packaging according to regulations on the disposal of packagings.

### 14 Transport information

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

### 15 Regulatory information

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

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Relevant phrases**

- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing SDS:**

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 2: Acute toxicity – Category 2
- Skin Corr. 1C: Skin corrosion/irritation – Category 1C
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1A: Skin sensitisation – Category 1A
- Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· **\* Data compared to the previous version altered.**

GB



**Safety data sheet**  
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**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name: Wash Solution**
- **Article number:** WS/WS MonoStrip
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
HYPHEN BioMed  
155 rue d'Eragny  
F-95000 NEUVILLE-SUR-OISE  
FRANCE
- **Further information obtainable from:**  
info@hyphen-biomed.com  
+33/1/34 40 65 10
- **Emergency telephone number:**  
Members of the public seeking specific information on poisons should contact:  
In England and Wales: NHS 111 - dial 111  
In Scotland: NHS 24 - dial 111

**2 Hazards identification**

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



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

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



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
- **Hazard statements**  
May cause an allergic skin reaction.
- **Precautionary statements**  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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**Trade name: Wash Solution**

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P362+P364 Take off contaminated clothing and wash it before reuse.

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

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

### 3 Composition/information on ingredients

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

· **Dangerous components:**

55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	<0.06%
	<ul style="list-style-type: none"> <li>⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; ⚠ Skin Corr. 1C, H314; Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1A, H317</li> </ul>	

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

### 4 First aid measures

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

### 5 Firefighting measures

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

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.

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**Trade name: Wash Solution**

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- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
None.  
2 - 8°C
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Do not eat or drink while working.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

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

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

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· **Material of gloves**

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

· **Penetration time of glove material**

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

· **Eye protection:** Face protection

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Fluid
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

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

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

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

· **Explosion limits:**

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

· **Vapour pressure:** Not determined.

· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not applicable.

· **Solubility in / Miscibility with water:** Not determined.

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

· **Viscosity:**

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

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

## 10 Stability and reactivity

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

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.  
Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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**Trade name: Wash Solution**

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- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**  
Disposal must be made according to official regulations.  
Dispose of packaging according to regulations on the disposal of packagings.

### 14 Transport information

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

### 15 Regulatory information

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

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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**Trade name: Wash Solution**

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· **Relevant phrases**

- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing SDS:**

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 2: Acute toxicity – Category 2
- Skin Corr. 1C: Skin corrosion/irritation – Category 1C
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1A: Skin sensitisation – Category 1A
- Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· **\* Data compared to the previous version altered.**

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**Safety data sheet**  
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Version number 5

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**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name: 0.45M Sulfuric Acid**
- **Article number:** Stop/Stop MonoStrip
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
HYPHEN BioMed  
155 rue d'Eragny  
F-95000 NEUVILLE-SUR-OISE  
FRANCE
- **Further information obtainable from:**  
info@hyphen-biomed.com  
+33/1/34 40 65 10
- **Emergency telephone number:**  
Members of the public seeking specific information on poisons should contact:  
In England and Wales: NHS 111 - dial 111  
In Scotland: NHS 24 - dial 111


**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the GB CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**  
Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.  
Safety data sheet available on request.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

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

· **Dangerous components:**

CAS: 7664-93-9 EINECS: 231-639-5	sulphuric acid	 Skin Corr. 1A, H314	<5%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**
- **General information:** Seek immediate medical advice.
- **After inhalation:**  
In case of unconsciousness place patient stably in side position for transportation.  
Supply fresh air and to be sure call for a doctor.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

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

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
None.  
2 - 8°C

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

## 8 Exposure controls/personal protection

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

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

**7664-93-9 sulphuric acid**

WEL	Long-term value: 0.05* mg/m <sup>3</sup> *mist: defined as thoracic fraction
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- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Do not eat or drink while working.

- **Respiratory protection:**

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

- **Protection of hands:**



Protective gloves

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

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

- **Material of gloves**

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

- **Penetration time of glove material**

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

- **Eye protection:** Face protection

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

**Form:**

Fluid

**Colour:**

Colourless

- **Odour:**

Odourless

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b> <b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b> <b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Not determined.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> <b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

## 10 Stability and reactivity

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

## 11 Toxicological information

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

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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**  
Disposal must be made according to official regulations.  
Dispose of packaging according to regulations on the disposal of packagings.

### 14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** UN3264

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<ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul>	<p>3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID) Corrosive liquid, acidic, inorganic, n.o.s. (SULPHURIC ACID)</p>
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- **Transport hazard class(es)**
- **ADR, IMDG, IATA**



- **Class** 8 Corrosive substances.
- **Label** 8

- **Packing group**
- **ADR, IMDG, IATA** II

- **Environmental hazards:** Not applicable.

- **Special precautions for user** Warning: Corrosive substances.
- **Hazard identification number (Kemler code):** 80
- **EMS Number:** F-A,S-B
- **Segregation groups** (SGG1a) Strong acids
- **Stowage Category** B
- **Stowage Code** SW2 Clear of living quarters.
- **Segregation Code** SG36 Stow "separated from" SGG18-alkalis.  
SG49 Stow "separated from" SGG6-cyanides

- **Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

- **Transport/Additional information:**

- **ADR**
- **Limited quantities (LQ)** 1L
- **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml
- **Transport category** 2
- **Tunnel restriction code** E

- **IMDG**
- **Limited quantities (LQ)** 1L
- **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

- **UN "Model Regulation":** UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID), 8, II

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### 15 Regulatory information

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

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**  
H314 Causes severe skin burns and eye damage.
- **Department issuing SDS:**
- **Abbreviations and acronyms:**  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
- **\* Data compared to the previous version altered.**

GB