

# SAFETY DATA SHEET

Product name	Product reference
ZYMUTEST <sup>TM</sup> HIA (Heparin Induced Antibodies) IgG	RK040A
ZYMUTEST <sup>™</sup> HIA (Heparin Induced Antibodies) MonoStrip IgG	RK041A

R1	COAT
R2	SD
R3	C+
R4	C-
R5	CLy
R6	IC
R7	CD
R8	WS
R9	ТМВ
R10	SA

In accordance with OSHA Regulations 1910.1200 (g), a Safety Data Sheet is required only for reagents R1, R7, R8 and R10 (see SDS below).



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# Safety Data Sheet

## acc. to OSHA HCS

Printing date 05/22/2024

Version Number 6

Reviewed on 05/21/2024

## **1** Identification

- · Product identifier
- · Trade name: COAT
- · Article number: R1
- · 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
- Information department: info@hyphen-biomed.com +33/1/34 40 65 10
- Emergency telephone number: INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053 (24-hours)

# 2 Hazard(s) identification

#### • **Classification of the substance or mixture** The product is not classified, according to the Globally Harmonized System (GHS).

#### · Label elements

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

# **3 Composition/information on ingredients**

· Chemical characterization: Mixtures

- · Description: Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

57-50-1 sucrose, pure

# 4 First-aid measures

- · Description of first aid measures
- · General information:
- No special measures required.
- Seek immediate medical advice.
- · After inhalation:
- Supply fresh air and to be sure call for a doctor.
- In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.

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<7.5%

<sup>-</sup> US



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#### Trade name: COAT

- · 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** Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- 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

Wear protect Environmen Dilute with p Do not allow Methods an Absorb with Reference t See Section See Section See Section	recautions, protective equipment and emergency procedures stive clothing. <b>Intal precautions:</b> lenty of water. to enter sewers/ surface or ground water. <b>Ind material for containment and cleaning up:</b> liquid-binding material (sand, diatomite, acid binders, universal binders, sa <b>to other sections</b> 7 for information on safe handling. 8 for information on personal protection equipment. 13 for disposal information. <b>Action Criteria for Chemicals</b>	awdust).
· PAC-1:		
1310-73-2	sodium hydroxide	0.5 mg/m <sup>3</sup>
26628-22-8	sodium azide	0.026 mg/m <sup>3</sup>
· PAC-2:		
1310-73-2	sodium hydroxide	5 mg/m³
26628-22-8	sodium azide	0.29 mg/m <sup>3</sup>
· PAC-3:		
1310-73-2	sodium hydroxide	50 mg/m <sup>3</sup>
26628-22-8	sodium azide	5.3 mg/m <sup>3</sup>

## 7 Handling and storage

- · Handling:
- · Precautions for safe handling
- No special measures required.

Open and handle receptacle with care.

· Information about protection against explosions and fires: No special measures required.

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#### Trade name: COAT

· 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 systems: No further data; see section 7.

Control parameters

· Components with limit values	that require monitoring at the workplace:
	· · · · · · · · · · · · · · · · · · ·

#### 57-50-1 sucrose, pure

- PEL Long-term value: 15\* 5\*\* mg/m<sup>3</sup>
  - \*total dust \*\*respirable fraction
- REL Long-term value: 10\* 5\*\* mg/m<sup>3</sup>
  - \*total dust \*\*respirable fraction
- TLV Long-term value: 10 mg/m<sup>3</sup> A4

• Additional information: The lists that were valid during the creation 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.
- · Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

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.

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#### Trade name: COAT

· Eye protection: Face protection

9 Physical and chemical prope	rties
<ul> <li>Information on basic physical and General Information</li> </ul>	chemical properties
· Appearance:	
Form:	Fluid
Color:	According to product specification
· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
<ul> <li>Danger of explosion:</li> </ul>	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not determined.
· Partition coefficient (n-octanol/wate	er): Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· 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.

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#### Trade name: COAT

- · 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:

## · LD/LC50 values that are relevant for classification:

57-50-1 sucrose, pure

- Oral LD50 29,700 mg/kg (rat)
- Additional toxicological information:
- The product is not subject to classification according to internally approved calculation methods for preparations:
- When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

#### · Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

#### • NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

# **12 Ecological information**

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- Behavior 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 (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.

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Trade name: COAT

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# 13 Disposal considerations

#### Waste treatment methods

· Recommendation:

Smaller quantities can be disposed of with household waste.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- Recommendation:

Disposal must be made according to official regulations.

- Dispose of packaging according to regulations on the disposal of packagings.
- $\cdot$  Recommended cleansing agent: Water, if necessary with cleansing agents.

4 Transport information	
· UN-Number · DOT, IMDG, IATA	not regulated
<ul> <li>UN proper shipping name</li> <li>DOT, IMDG, IATA</li> </ul>	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA · Class	not regulated
<ul> <li>Packing group</li> <li>DOT, IMDG, IATA</li> </ul>	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
<ul> <li>Transport in bulk according to Annex MARPOL73/78 and the IBC Code</li> </ul>	II of Not applicable.
· UN "Model Regulation":	not regulated

# 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - No further relevant information available.

· Sara

· Section 355	o (extremely hazardous substances):	
26628-22-8	sodium azide	
· Section 313	(Specific toxic chemical listings):	
26628-22-8	sodium azide	
· TSCA (Toxi	c Substances Control Act):	
7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
50-99-7	glucose	ACTIVE
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Trade name: COA	Γ
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57-50-1       sucrose, pure         7647-14-5       sodium chloride         1310-73-2       sodium hydroxide         6628-22-8       sodium azide         Iazardous Air Pollutants       Ione of the ingredients is listed.         Proposition 65       Schemicals known to cause cancer:	ACTIVE ACTIVE ACTIVE ACTIVE
1310-73-2       sodium hydroxide         6628-22-8       sodium azide         Iazardous Air Pollutants         Ione of the ingredients is listed.         Proposition 65         Chemicals known to cause cancer:	ACTIVE
6628-22-8       sodium azide         Iazardous Air Pollutants         Ione of the ingredients is listed.         Proposition 65         Chemicals known to cause cancer:	
Iazardous Air Pollutants         Ione of the ingredients is listed.         Proposition 65         Chemicals known to cause cancer:	
lone of the ingredients is listed. Proposition 65 Chemicals known to cause cancer:	
Proposition 65 Chemicals known to cause cancer:	
Chemicals known to cause cancer:	
ten e efite e in sue die ste ie liete d	
lone of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for females:	
lone of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for males:	
lone of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
lone of the ingredients is listed.	
Carcinogenic categories	
PA (Environmental Protection Agency)	
lone of the ingredients is listed.	
LV (Threshold Limit Value)	
57-50-1 sucrose, pure	A
6628-22-8 sodium azide	A4
IIOSH-Ca (National Institute for Occupational Safety and Health)	
lone of the ingredients is listed.	

· Signal word Void

· Hazard statements Void

· 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.

· Contact:

· Date of preparation / last revision 05/21/2024 Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health



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Trade name: COAT

TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

\* Data compared to the previous version altered.

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### **1** Identification

- · Product identifier
- · Trade name: CD
- · Article number: R7 Conjugate Diluent
- · 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
- **Information department:** info@hyphen-biomed.com +33/1/34 40 65 10
- Emergency telephone number: INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053 (24-hours)

# 2 Hazard(s) identification

· Classification of the substance or mixture

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements
- The product is classified and labeled according to the Globally Harmonized System (GHS).
- · Hazard pictograms



- · Signal word Warning
- Hazard-determining components of labeling: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)
   Hazard statements
- May cause an allergic skin reaction.
- · Precautionary statements

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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

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#### Trade name: CD

#### · Other hazards

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

## **3** Composition/information on ingredients

#### · Chemical characterization: Mixtures

· **Description:** Mixture of the 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] <0.06% and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

## 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** Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- 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). 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.

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#### Trade name: CD

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

· PAC-1:

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

# 7 Handling and storage

- · Handling:
- · Precautions for safe handling Open and handle receptacle with care.
- · Information about protection against explosions and fires: 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 systems: No further data; see section 7.
- · Control parameters
- Components 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 that were valid during the creation 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.

Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air. **Protection of hands:** 



Protective gloves

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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

General Information Appearance:	
Form:	Fluid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not determined.
Partition coefficient (n-octanol/wa	ter): Not determined



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#### Trade name: CD

· Viscosity: Dynamic: Kinematic:

Not determined. Not determined.

 Solvent content: VOC content:

· Other information

0.0 g/l / 0.00 lb/gal

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:
- · Primary irritant effect:
- on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

- Irritant
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

- · NTP (National Toxicology Program)
- None of the ingredients is listed.
- · OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

# **12 Ecological information**

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.

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#### Trade name: CD

· Mobility in soil No further relevant information available.

· Additional ecological information:

#### · General notes:

Water hazard class 2 (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

- 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 of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- Recommendation:

Disposal must be made according to official regulations.

Dispose of packaging according to regulations on the disposal of packagings.

UN-Number DOT, IMDG, IATA	not regulated	
UN proper shipping name DOT, IMDG, IATA	not regulated	
Transport hazard class(es)		
DOT, ADN, IMDG, IATA Class	not regulated	
Packing group DOT, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	<b>II of</b> Not applicable.	
UN "Model Regulation":	not regulated	

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Trade name: CD

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# 15 Regulatory information

No further relevant information available. Sara	
Section 355 (extremely hazardous substances):	
None of the ingredients is listed.	
Section 313 (Specific toxic chemical listings):	
None of the ingredients is listed.	
TSCA (Toxic Substances Control Act):	
7732-18-5 water, distilled, conductivity or of similar purity	ACTIVE
7647-14-5 sodium chloride	ACTIVE
555-06-6 sodium 4-aminobenzoate	ACTIVE
9005-64-5 Polysorbate 20	ACTIVE
Hazardous Air Pollutants	
None of the ingredients is listed.	
Proposition 65	
Chemicals known to cause cancer:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
Carcinogenic categories	
EPA (Environmental Protection Agency)	
None of the ingredients is listed.	
TLV (Threshold Limit Value)	
None of the ingredients is listed.	
NIOSH-Ca (National Institute for Occupational Safety and Health)	
None of the ingredients is listed.	
<b>GHS label elements</b> The product is classified and labeled according to the Globally Harmonized S <b>Hazard pictograms</b>	System (GHS).



· Signal word Warning

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#### Trade name: CD

(Contd. of page 7) · Hazard-determining components of labeling: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1) · Hazard statements May cause an allergic skin reaction. **Precautionary statements** Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents/container in accordance with local/regional/national/international regulations. 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. · Contact: Date of preparation / last revision 05/22/2024 Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association 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) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Sensitization - Skin 1: Skin sensitisation - Category 1 \*\* Data compared to the previous version altered.



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# Safety Data Sheet acc. to OSHA HCS

Printing date 05/22/2024

Version Number 6

Reviewed on 05/22/2024

### **1** Identification

- · Product identifier
- · Trade name: WS
- · Article number: R8 Wash Solution
- · 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
- Information department: info@hyphen-biomed.com +33/1/34 40 65 10
- Emergency telephone number: INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053 (24-hours)

# 2 Hazard(s) identification

· Classification of the substance or mixture

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements
- The product is classified and labeled according to the Globally Harmonized System (GHS).
- · Hazard pictograms



- · Signal word Warning
- Hazard-determining components of labeling: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)
   Hazard statements
- May cause an allergic skin reaction.
- · Precautionary statements

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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

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#### Trade name: WS

#### · Other hazards

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

## **3** Composition/information on ingredients

#### · Chemical characterization: Mixtures

• **Description:** Mixture of the 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] <0.06% and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

## 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** Fire-fighting measures

- Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- 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:
- 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.

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(Contd. of page 2)

Trade name: WS

#### · Protective Action Criteria for Chemicals

· PAC-1:

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

# 7 Handling and storage

- · Handling:
- · Precautions for safe handling Open and handle receptacle with care.
- · Information about protection against explosions and fires: 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 systems: No further data; see section 7.
- · Control parameters
- Components 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 that were valid during the creation 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.
- Breathing equipment:
- In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- Protection of hands:



Protective gloves

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

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# Safety Data Sheet

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#### Trade name: WS

(Contd. of page 3) 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

General Information	
Appearance: Form:	Fluid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Not determined.
Partition coefficient (n-octanol/wa	ter): Not determined.
Viscosity:	
Dynamic:	Not determined.



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(Contd. of page 4)

#### Trade name: WS

**Kinematic:** 

Not determined.

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:
- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

#### • NTP (National Toxicology Program)

None of the ingredients is listed.

**OSHA-Ca** (Occupational Safety & Health Administration)

None of the ingredients is listed.

# **12 Ecological information**

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- · Behavior 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 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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Reviewed on 05/22/2024

Trade name: WS

Danger to drinking water if even small quantities leak into the ground.

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 of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packagings:
- Recommendation:

Disposal must be made according to official regulations.

Dispose of packaging according to regulations on the disposal of packagings.

4 Transport information	
· UN-Number · DOT, IMDG, IATA	not regulated
<ul> <li>UN proper shipping name</li> <li>DOT, IMDG, IATA</li> </ul>	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA · Class	not regulated
<ul> <li>Packing group</li> <li>DOT, IMDG, IATA</li> </ul>	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
<ul> <li>Transport in bulk according to Annex MARPOL73/78 and the IBC Code</li> </ul>	II of Not applicable.
· UN "Model Regulation":	not regulated

# 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- No further relevant information available.

· Sara

- · Section 355 (extremely hazardous substances):
- None of the ingredients is listed.

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Trade name: WS

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	(Contd. of page
Section 313 (Specific toxic chemical listings):	
None of the ingredients is listed.	
TSCA (Toxic Substances Control Act):	
7732-18-5 water, distilled, conductivity or of similar purity	ACTIVE
7647-14-5 sodium chloride	ACTIVE
555-06-6 sodium 4-aminobenzoate	ACTIVE
9005-64-5 Polysorbate 20	ACTIVE
Hazardous Air Pollutants	
None of the ingredients is listed.	
Proposition 65	
Chemicals known to cause cancer:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for fema	ales:
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for male	)S:
None of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
•	
Carcinogenic categories	
EPA (Environmental Protection Agency) None of the ingredients is listed.	
TLV (Threshold Limit Value)	
None of the ingredients is listed.	
NIOSH-Ca (National Institute for Occupational Safety and	d Health)
None of the ingredients is listed.	
GHS label elements The product is classified and labeled according to the Globall Hazard pictograms	ly Harmonized System (GHS).
GHS07	
Signal word Warning	
Hazard-determining components of labeling: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC isothiazol-3-one [EC no. 220-239-6] (3:1) Hazard statements	no. 247-500-7] and 2-methyl-2H-
May cause an allergic skin reaction.  Precautionary statements	
Contaminated work clothing must not be allowed out of the w Wear protective gloves/protective clothing/eye protection/face If on skin: Wash with plenty of soap and water.	
If skin irritation or rash occurs: Get medical advice/attention.	
Take off contaminated clothing and wash it before reuse.	(Contd on page



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#### Trade name: WS

(Contd. of page 7)

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

#### · Contact:

- Date of preparation / last revision 05/22/2024
- Abbreviations and acronyms: IMDG: International Maritime Code for Dangerou

IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association 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 NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Sensitization - Skin 1: Skin sensitisation – Category 1 • \* Data compared to the previous version altered.



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# Safety Data Sheet

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### **1** Identification

- · Product identifier
- · Trade name: SA
- · Article number: R10 0.45M Sulfuric Acid
- · 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
- · Information department: info@hyphen-biomed.com +33/1/34 40 65 10
- **Emergency telephone number:** INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053 (24-hours)

## 2 Hazard(s) identification

#### Classification of the substance or mixture The product is not classified, according to the Globally Harmonized System (GHS).

#### · Label elements

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

# **3** Composition/information on ingredients

· Chemical characterization: Mixtures

- · Description: Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

7664-93-9 sulphuric acid

# **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.

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· 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** Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- 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.
- Protective Action Criteria for Chemicals
- · PAC-1:

0.20 mg/m<sup>3</sup>

8.7 mg/m<sup>3</sup>

160 mg/m<sup>3</sup>

· PAC-2:

7664-93-9 sulphuric acid

7664-93-9 sulphuric acid

· PAC-3:

7664-93-9 sulphuric acid

# 7 Handling and storage

- · Handling:
- · Precautions for safe handling Open and handle receptacle with care.
- · Information about protection against explosions and fires: 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.

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# 8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see section 7.

#### · Control parameters

· Components with limit values that require monitoring at the workplace:

#### 7664-93-9 sulphuric acid

- PEL Long-term value: 1 mg/m<sup>3</sup>
- REL Long-term value: 1 mg/m<sup>3</sup>
- TLV Long-term value: 0.2\* mg/m<sup>3</sup>
  - \*as thoracic fraction, A2

· Additional information: The lists that were valid during the creation 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.

#### · Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

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

Information on basic physi General Information	cal and chemical properties	
Appearance:		
Form:	Fluid	
Color:	Colorless	
Odor:	Odorless	
Odor threshold:	Not determined.	



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	(Contd. of page
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not determined.
Partition coefficient (n-octanol/wa	ater): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
VOC content:	0.0 g/l / 0.00 lb/gal
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:
- · Sensitization: No sensitizing effects known.

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<sup>—</sup> US



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#### · Additional toxicological information:

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

7664-93-9 sulphuric acid

• NTP (National Toxicology Program)

7664-93-9 sulphuric acid

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

# **12 Ecological information**

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.

#### · Uncleaned packagings:

· 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
- · DOT, IMDG, IATA
- · UN proper shipping name

not regulated

· DOT, IMDG, IATA

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Transport hazard class(es)		
DOT, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
DOT, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex	c II of	
MARPOL73/78 and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

# 15 Regulatory information

 Safety, health and environmental regulations/legislation specific for the substance or mixture
 No further relevant information available.

· Sara

Section 355 (extremely hazardous substances):	
7664-93-9 sulphuric acid	
Section 313 (Specific toxic chemical listings):	
7664-93-9 sulphuric acid	
TSCA (Toxic Substances Control Act):	
All components have the value ACTIVE.	
· Hazardous Air Pollutants	
None of the ingredients is listed.	
· Proposition 65	
· Chemicals known to cause cancer:	
None of the ingredients is listed.	
· Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
· Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
· Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
· Carcinogenic categories	
· EPA (Environmental Protection Agency)	
None of the ingredients is listed.	
· TLV (Threshold Limit Value)	
7664-93-9 sulphuric acid	A
·NIOSH-Ca (National Institute for Occupational Safety and Health)	
None of the ingredients is listed.	
· GHS label elements Void	(Contd. on page
	(Contu. on page



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- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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.

#### · Contact:

- · Date of preparation / last revision 05/22/2024
- Abbreviations and acronyms:
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- 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) VOC: Volatile Organic Compounds (USA, EU)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- \* \* Data compared to the previous version altered.