

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Coopers Bovilis MH Single Shot RTU / MH + IBR Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 27.11.2023
4.1	08.12.2023	10876401-00008	Date of first issue: 24.10.2022

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

#### 1.1 Product identifier

Trade name : Coopers Bovilis MH Single Shot RTU / MH + IBR Formulation

Other means of identification : Coopers Bovilis MH Single-Shot Ready-to-Use MH Vaccine for Cattle (92022)  
Coopers Bovilis MH+IBR Bovine Respiratory Disease (BRD) Vaccine (64608)  
Bovilis MH+IBR (A011518)

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

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Carcinogenicity, Category 1B	H350: May cause cancer.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.  
H350 May cause cancer.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
**Storage:**  
P405 Store locked up.

Hazardous components which must be listed on the label:

Formaldehyde

### Additional Labelling

Restricted to professional users.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Antigen	Not Assigned		>= 50 - < 70
Formaldehyde	50-00-0 200-001-8	Flam. Gas 1B; H221	>= 0.2 - < 1

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	605-001-00-5 01-2119488953-20	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335  specific concentra- tion limit Skin Corr. 1B; H314 >= 25 % Skin Irrit. 2; H315 5 - < 25 % Eye Irrit. 2; H319 5 - < 25 % STOT SE 3; H335 >= 5 % Skin Sens. 1A; H317 >= 0.2 %	
Thiomersal	54-64-8 200-210-4 080-004-00-7	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 Repr. 1B; H360 STOT RE 1; H372 (Central nervous system, Cardio- vascular system, Gastrointestinal tract, Kidney) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10  specific concentra- tion limit STOT RE 2; H373 >= 0.1 %	>= 0.0025 - < 0.025

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Substances with a workplace exposure limit :			
Glycerine	56-81-5 200-289-5		>= 1 - < 10

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

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

- Risks : May cause an allergic skin reaction.  
May cause cancer.

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

- Treatment : Treat symptomatically and supportively.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam

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Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and dis-

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posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.  |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Avoid breathing mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Take care to prevent spills, waste and minimize release to the environment.  |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

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

- |   |   |  |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.                      |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

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Specific use(s) : No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	GB EH40
Formaldehyde	50-00-0	TWA	2 ppm 2.5 mg/m <sup>3</sup>	GB EH40
			Further information: Capable of causing cancer and/or heritable genetic damage.	
		STEL	2 ppm 2.5 mg/m <sup>3</sup>	GB EH40
			Further information: Capable of causing cancer and/or heritable genetic damage.	
		TWA	0.3 ppm 0.37 mg/m <sup>3</sup>	2004/37/EC
			Further information: Dermal sensitisation, Carcinogens or mutagens	
		STEL	0.6 ppm 0.74 mg/m <sup>3</sup>	2004/37/EC
			Further information: Dermal sensitisation, Carcinogens or mutagens	

##### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m <sup>3</sup>
Formaldehyde	Workers	Inhalation	Long-term systemic effects	9 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	0.375 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	0.75 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	240 mg/kg bw/day
	Workers	Skin contact	Long-term local effects	0.037 mg/cm <sup>2</sup>
	Consumers	Inhalation	Long-term systemic effects	3.2 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	0.1 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic	102 mg/kg

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			effects	bw/day
	Consumers	Skin contact	Long-term local effects	0.012 mg/cm <sup>2</sup>
	Consumers	Ingestion	Long-term systemic effects	4.1 mg/kg bw/day

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0.885 mg/l
	Marine water	0.0885 mg/l
	Intermittent use/release	8.85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3.3 mg/kg dry weight (d.w.)
	Marine sediment	0.33 mg/kg dry weight (d.w.)
Formaldehyde	Soil	0.141 mg/kg dry weight (d.w.)
	Fresh water	0.44 mg/l
	Freshwater - intermittent	4.44 mg/l
	Marine water	0.44 mg/l
	Sewage treatment plant	0.19 mg/l
	Fresh water sediment	2.3 mg/kg dry weight (d.w.)
	Marine sediment	2.3 mg/kg dry weight (d.w.)
	Soil	0.2 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection  
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.



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Filter type	:	Equipment should conform to BS EN 14387 : Combined particulates, inorganic gas/vapour and organic vapour type (AB-P)
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### SECTION 9: Physical and chemical properties

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

Appearance	:	suspension
Colour	:	white to off-white
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	6.0 - 8.0
Melting point/freezing point	:	0 °C
Initial boiling point and boiling range	:	100 °C (1000 hPa)
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	2.37 kPa (20 °C)
Relative vapour density	:	No data available
Relative density	:	1
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20000 ppm  
Exposure time: 4 h

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Test atmosphere: gas  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

### Components:

#### **Formaldehyde:**

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg  
Method: Expert judgement

Acute inhalation toxicity : Acute toxicity estimate: 100 ppm  
Exposure time: 4 h  
Test atmosphere: gas  
Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): 270 mg/kg

#### **Thiomersal:**

Acute oral toxicity : LD50 (Rat): 75 mg/kg

Acute toxicity estimate: 10 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Acute toxicity estimate: 0.1 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

Acute dermal toxicity : Acute toxicity estimate: 10 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

#### **Glycerine:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

#### **Skin corrosion/irritation**

Not classified based on available information.

### Components:

#### **Formaldehyde:**

Species : Rabbit  
Method : OECD Test Guideline 404

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Result : Corrosive after 3 minutes to 1 hour of exposure

### Glycerine:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Formaldehyde:

Species : Rabbit  
Result : Irreversible effects on the eye

### Glycerine:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Formaldehyde:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : positive

Assessment : Probability or evidence of high skin sensitisation rate in humans

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Formaldehyde:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: positive

Test Type: Chromosome aberration test in vitro  
Result: positive

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Inhalation  
Result: positive

Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### **Thiomersal:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **Glycerine:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

### **Carcinogenicity**

May cause cancer.

### **Components:**

#### **Formaldehyde:**

Species : Rat  
Application Route : inhalation (gas)  
Exposure time : 28 Months  
Result : positive

Carcinogenicity - Assessment : Sufficient evidence of carcinogenicity in animal experiments

### **Thiomersal:**

Species : Rat

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Exposure time : 1 Years  
Result : negative

### Glycerine:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Formaldehyde:

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: inhalation (gas)  
Result: negative

#### Thiomersal:

Effects on foetal development : Species: Rat  
Application Route: Ingestion  
Result: positive  
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

#### Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT - single exposure

Not classified based on available information.

### Components:

#### Formaldehyde:

Assessment : May cause respiratory irritation.

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### STOT - repeated exposure

Not classified based on available information.

#### Components:

##### Formaldehyde:

Exposure routes : inhalation (gas)  
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

##### Thiomersal:

Target Organs : Central nervous system, Cardio-vascular system, Gastrointestinal tract, Kidney  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### Formaldehyde:

Species : Rat  
NOAEL : 6 ppm  
LOAEL : 10 ppm  
Application Route : inhalation (gas)  
Exposure time : 28 Days

##### Thiomersal:

Species : Rat  
LOAEL :  $\geq 0.5$  mg/kg  
Application Route : Ingestion  
Remarks : Based on data from similar materials

##### Glycerine:

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 0.622 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 8,000 - 10,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

Species : Rabbit  
NOAEL : 5,040 mg/kg  
Application Route : Skin contact  
Exposure time : 45 Weeks

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### Aspiration toxicity

Not classified based on available information.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Formaldehyde:

- |  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 : 6.7 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials                                |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia pulex (Water flea)): 5.8 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                  |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201      |
| Toxicity to microorganisms   | : | EC50 : 34.1 mg/l<br>Exposure time: 120 h   |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: $\geq$ 48 mg/l<br>Exposure time: 28 d<br>Species: Oryzias latipes (Orange-red killifish)                         |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: $\geq$ 6.4 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

##### Thiomersal:

- |   |   |   |
|---|---|---|
| Toxicity to fish                                    | : | LC50 (Poecilia reticulata (guppy)): $> 0.01 - 0.1$ mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials                   |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): $> 0.01 - 0.1$ mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials                    |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): $> 0.01 - 0.1$ mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials |
| M-Factor (Acute aquatic tox-                        | : | 10  |



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icity)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.001 - 0.01 mg/l  
Exposure time: 21 d  
Species: Daphnia sp. (water flea)  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 10

### **Glycerine:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l  
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

## 12.2 Persistence and degradability

### Components:

#### **Formaldehyde:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 91 %  
Exposure time: 14 d  
Method: OECD Test Guideline 301C  
Remarks: Based on data from similar materials

#### **Glycerine:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

## 12.3 Bioaccumulative potential

### Components:

#### **Formaldehyde:**

Partition coefficient: n-octanol/water : log Pow: 0.35  
Remarks: Calculation

#### **Glycerine:**

Partition coefficient: n-octanol/water : log Pow: -1.75

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### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

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**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:  
Number on list 3  
  
Thiomersal (Number on list 18)  
Formaldehyde (Number on list 72, 28)

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Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Thiomersal
Control of Major Accident Hazards Regulations 2015 (COMAH)	:	Not applicable

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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### Full text of H-Statements

H221	:	Flammable gas.
H300	:	Fatal if swallowed.

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H301	: Toxic if swallowed.
H310	: Fatal in contact with skin.
H311	: Toxic in contact with skin.
H314	: Causes severe skin burns and eye damage.
H317	: May cause an allergic skin reaction.
H318	: Causes serious eye damage.
H330	: Fatal if inhaled.
H335	: May cause respiratory irritation.
H341	: Suspected of causing genetic defects.
H350	: May cause cancer.
H360	: May damage fertility or the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Carc.	: Carcinogenicity
Eye Dam.	: Serious eye damage
Flam. Gas	: Flammable gases
Muta.	: Germ cell mutagenicity
Repr.	: Reproductive toxicity
Skin Corr.	: Skin corrosion
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long term exposure limit
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;

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IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Skin Sens. 1	H317
Carc. 1B	H350

### Classification procedure:

Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN