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

1.1 Product identifier
   Trade name : Ovipast Plus Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Kilshealan
             Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Skin sensitisation, Category 1  H317: May cause an allergic skin reaction.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :

   Signal word : Warning
   Hazard statements : H317  May cause an allergic skin reaction.
   Precautionary statements :

   Prevention:
   P272  Contaminated work clothing should not be allowed out of the workplace.
   P280  Wear protective gloves.

   Response:
   P333 + P313  If skin irritation or rash occurs: Get medical advice/attention.
Hazardous components which must be listed on the label:
Maleic acid
Formaldehyde

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.

Ecological information: 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.

Toxicological information: 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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen</td>
<td>Not Assigned</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt; 1,5 - &lt; 2,5</td>
</tr>
<tr>
<td>Maleic acid</td>
<td>110-16-7</td>
<td>203-742-5</td>
<td>607-095-00-3</td>
<td></td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1; H317 STOT SE 3; H335</td>
<td>0,23</td>
</tr>
</tbody>
</table>

specific concentration limit
Skin Sens. 1; H317 >= 0,1 %

Acute toxicity estimate
Acute oral toxicity: 300,03 mg/kg
Acute dermal toxici-
# Ovipast Plus Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Health Statements</th>
<th>Specific Concentration Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>Flam. Gas 1B; H221</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>200-001-8</td>
<td>Acute Tox. 3; H301</td>
<td></td>
</tr>
<tr>
<td></td>
<td>605-001-00-5</td>
<td>Acute Tox. 2; H330</td>
<td></td>
</tr>
<tr>
<td></td>
<td>01-2119488953-20</td>
<td>Acute Tox. 3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Corr. 1B; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Sens. 1A; H317</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Muta. 2; H341</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carc. 1B; H350</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE 3; H335</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>specific concentra-</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>tion limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Corr. 1B; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 25 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 - &lt; 25 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 - &lt; 25 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE 3; H335</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 5 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Sens. 1A; H317</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 0.2 %</td>
<td></td>
</tr>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>Acute Tox. 2; H300</td>
<td>0.013</td>
</tr>
<tr>
<td></td>
<td>200-210-4</td>
<td>Acute Tox. 2; H330</td>
<td></td>
</tr>
<tr>
<td></td>
<td>080-004-00-7</td>
<td>Acute Tox. 1; H310</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repr. 1B; H360</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Central nervous system, Cardiovascular system, Gastrointestinal tract, Kidney)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
</tbody>
</table>
### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

<table>
<thead>
<tr>
<th>General advice</th>
<th>Protection of first-aiders</th>
<th>If inhaled</th>
<th>In case of skin contact</th>
<th>In case of eye contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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).</td>
<td>If inhaled, remove to fresh air. Get medical attention if symptoms occur.</td>
<td>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.</td>
<td>Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</td>
</tr>
<tr>
<td>Aquatic Chronic 1; H410</td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>Acute oral toxicity: 10 mg/kg Acute inhalation toxicity (dust/mist): 0.1 mg/l</td>
<td>Acute dermal toxicity: 10 mg/kg</td>
<td>STOT RE 2; H373 &gt;= 0.1%</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
If swallowed

- If swallowed, DO NOT induce vomiting.
- Get medical attention if symptoms occur.
- Rinse mouth thoroughly with water.

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

Risks

- May cause an allergic skin reaction.

### 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
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media

- None known.

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

Specific hazards during firefighting

- Exposure to combustion products may be a hazard to health.

Hazardous combustion products

- Carbon oxides
- Metal 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.

### 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. Local authorities should be advised if significant spillages cannot be contained.

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 disposal 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: Use only with adequate ventilation.

Advice on safe handling: Do not get on skin or clothing. Avoid breathing mist or vapours. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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. Wash contaminated clothing before re-use. 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 in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents.

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>TWA</td>
<td>0,5 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0,6 mg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>T</td>
<td>1 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,2 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>TWA</td>
<td>0,01 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Mercury)</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin.

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>Mercury (Mercury): 30 µg/g creatinine (Urine)</td>
<td>AN 361</td>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:
# Safety Data Sheet

**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Ovipast Plus Formulation**

## Version
1.2

## Revision Date
27.08.2021

## SDS Number
6362767-00003

## Date of last issue
09.04.2021

## Date of first issue
16.09.2020

### Substance name

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum hydroxide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10,76 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10,76 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4,74 mg/kg bw/day</td>
</tr>
<tr>
<td>Maleic acid</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>9 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0,375 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>240 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>0,75 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>102 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4,1 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0,037 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0,1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0,012 mg/cm²</td>
</tr>
</tbody>
</table>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maleic acid</td>
<td>Fresh water</td>
<td>0,1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0,428 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,01 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>44,6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0,334 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,033 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,042 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Fresh water</td>
<td>0,44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>4,44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0,19 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2,3 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>2,3 mg/kg</td>
</tr>
</tbody>
</table>
Soil

0.2 mg/kg

8.2 Exposure controls

Engineering measures
Use appropriate engineering controls and manufacturing technologies to control airborne concentra-
tions (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 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 expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.
Equipment should conform to EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: suspension
Colour: off-white to beige, opaque
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature : No data available
pH : 6,1 - 6,9

Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available

Solubility(ies)
  Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : similar to water
Relative density : 1
Density : 1 g/cm³ similar to water
Relative vapour density : No data available

Particle characteristics
  Particle size : Not applicable

9.2 Other information
  Explosives : Not explosive
  Oxidizing properties : The substance or mixture is not classified as oxidizing.
  Evaporation rate : No data available
  Molecular weight : Not applicable

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.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity
Not classified based on available information.

Components:

**Maleic acid:**
- Acute oral toxicity: LD50 (Rat): > 300 - 2,000 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
  Acute toxicity estimate: 300,03 mg/kg
  Method: Calculation method

- Acute dermal toxicity: LD50 (Rabbit): 1.560 mg/kg
  Acute toxicity estimate: 1.560 mg/kg
  Method: Calculation method

**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
  Acute toxicity estimate: 270 mg/kg
  Method: Calculation method

**Thiomersal:**
- Acute oral toxicity: LD50 (Rat): 75 mg/kg
  Acute toxicity estimate: 10 mg/kg
  Method: Expert judgement
  Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
Ovipast Plus Formulation

Acute inhalation toxicity
Acute toxicity estimate: 0,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Acute dermal toxicity
Acute toxicity estimate: 10 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Skin corrosion/irritation
Not classified based on available information.

Components:

Maleic acid:
Species: in vitro membrane barrier
Method: OECD Test Guideline 435
Result: Corrosive after 3 minutes to 1 hour of exposure

Formaldehyde:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Maleic acid:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

Formaldehyde:
Species: Rabbit
Result: Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Maleic acid:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: positive
Assessment: Probability or evidence of skin sensitisation in humans

**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:**

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

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

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

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: positive

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

Carcinogenicity
Not classified based on available information.

Components:

Maleic acid:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

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
Exposure time: 1 Year
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Maleic acid:
Effects on fertility
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Formaldehyde:
Effects on foetal development
Test Type: Embryo-foetal development
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

STOT - single exposure
Not classified based on available information.

Components:

Maleic acid:
Assessment: May cause respiratory irritation.
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

 Formaldehyde:
Assessment: May cause respiratory irritation.

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 : >= 0,5 mg/kg
Application Route : Ingestion
Remarks : Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

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.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Maleic acid:
Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 - 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 42,81 mg/l
Exposure time: 48 h
Test substance: Neutralised product
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 74,35 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 11,8 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (Pseudomonas putida): 44,6 mg/l
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Exposure time:  18 h  
Test substance: Neutralised product  
Method: DIN 38 412 Part 8

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: > 1 mg/l  
Exposure time:  21 d  
Species: Daphnia magna (Water flea)  
Remarks: Based on data from similar materials

Formaldehyde:  
Toxicity to fish:  
LC50: 6.7 mg/l  
Exposure time:  96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Daphnia pulex (Water flea)): 5.8 mg/l  
Exposure time:  48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:  
EC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l  
Exposure time:  72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms:  
EC50: 34.1 mg/l  
Exposure time:  120 h

Toxicity to fish (Chronic toxicity):  
NOEC: >= 48 mg/l  
Exposure time:  28 d  
Species: Oryzias latipes (Orange-red killifish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: >= 6.4 mg/l  
Exposure time:  21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

Thiomersal:  
Toxicity to fish:  
LC50 (Poecilia reticulata (guppy)): > 0.01 - 0.1 mg/l  
Exposure time:  96 h  
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  
Exposure time:  48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:  
EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l  
Exposure time:  96 h  
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity):  
10

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: > 0.001 - 0.01 mg/l  
Exposure time:  21 d
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12.2 Persistence and degradability

**Components:**

**Maleic acid:**
- Biodegradability: Result: Readily biodegradable. Biodegradation: 97 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B

**Formaldehyde:**
- Biodegradability: Result: Readily biodegradable. Biodegradation: 91 %
  - Exposure time: 14 d
  - Method: OECD Test Guideline 301C

**Remarks:** Based on data from similar materials

12.3 Bioaccumulative potential

**Components:**

**Maleic acid:**
- Partition coefficient: n-octanol/water: log Pow: -1.3

**Formaldehyde:**
- Partition coefficient: n-octanol/water: log Pow: 0.35

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

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.
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.

SECTION 14: Transport information

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
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 Maritime transport in bulk according to IMO instruments
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
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3 Formaldehyde (Number on list 72, 28) Thiomersal (Number on list 18)
REACH - Candidate List of Substances of Very High
Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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.

Full text of H-Statements

H221: Flammable gas.
H300: Fatal if swallowed.
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H310: Fatal in contact with skin.
H311: Toxic in contact with skin.
H312: Harmful 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.
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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
AN 361: Norway. Directive on measures and limit values for physical and chemical factors in the work environment (biological limit values).
FOR-2011-12-06-1358: Norway. Occupational Exposure limits
2004/37/EC / STEL: Short term exposure limit
2004/37/EC / TWA: Long term exposure limit
FOR-2011-12-06-1358 / TWA: Long term exposure limit
FOR-2011-12-06-1358 / T: Ceiling

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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; 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 - (Quantit-
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Classification of the mixture: Skin Sens. 1  H317
Classification procedure: Calculation method

Further information

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.

NO / EN