1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ovipast Plus Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary medicine

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin sensitisation: Category 1

GHS label elements
Hazard pictograms:

Signal word: Warning

Hazard statements: H317 May cause an allergic skin reaction.

Precautionary statements:
Prevention:
P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P333 + P317 If skin irritation or rash occurs: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>25</td>
</tr>
<tr>
<td>Antigen</td>
<td>Not Assigned</td>
<td>&gt; 1.5 - &lt; 2.5</td>
</tr>
<tr>
<td>Maleic acid</td>
<td>110-16-7</td>
<td>0.23</td>
</tr>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>0.013</td>
</tr>
</tbody>
</table>

4. 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.

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

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 if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction.

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).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing: None known.
media
Specific hazards during firefighting
Hazardous combustion products

: Exposure to combustion products may be a hazard to health.
: Carbon oxides
: Metal oxides

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.

Special protective equipment for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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

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.

Methods and materials for containment and cleaning up

: Soak up with inert absorbent material.
: For large spills, provide dyeing 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.

7. HANDLING AND STORAGE

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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminium)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>TWA</td>
<td>0.01 mg/m³ (Mercury)</td>
<td>IN OEL</td>
</tr>
</tbody>
</table>

Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>STEL</th>
<th>(Mercury)</th>
<th>IN OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.03 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>TWA</th>
<th>OEB 3 (&gt;= 10 &lt; 100 µg/m³)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.01 mg/m³ (Mercury)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>0.03 mg/m³ (Mercury)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

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

Filter type: Particulates type

Hand protection Material: Chemical-resistant gloves

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
Skin and body protection: Work uniform or laboratory coat.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: suspension
- Colour: off-white to beige, opaque
- Odour: No data available
- Odour Threshold: No data available
- pH: 6.1 - 6.9
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point: Not applicable
- Evaporation rate: 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
- Vapour pressure: similar to water
- Relative vapour density: No data available
- Relative density: 1
- Density: 1 g/cm³ similar to water
SAFETY DATA SHEET

Ovipast Plus Formulation

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

Explosive properties : Not explosive

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

Molecular weight : Not applicable

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Components:

Aluminum hydroxide:
  Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity

  Acute inhalation toxicity : LC50 (Rat): > 5.09 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

**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 dermal toxicity : LD50 (Rabbit): 1,560 mg/kg

**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

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:**

**Aluminum hydroxide:**
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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

**Serious eye damage/eye irritation**
Not classified based on available information.
SAFETY DATA SHEET

Ovipast Plus Formulation

Components:

Aluminum hydroxide:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation

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

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Aluminum hydroxide:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosome aberration test in vitro
Result: positive
Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
SAFETY DATA SHEET
Ovipast Plus Formulation

Result: equivocal
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo
: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 474
  Result: negative

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

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

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

Carcinogenicity
Not classified based on available information.

Components:

Aluminum hydroxide:
Species : Rat
Application Route : Inhalation (dust/mist/fume)
Exposure time : 86 weeks
Result : negative
Remarks : Based on data from similar materials

Maleic acid:
Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials
Thiomersal:
Species: Rat
Exposure time: 1 Years
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
Aluminum hydroxide:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

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

STOT - repeated exposure
Not classified based on available information.

Components:
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:

Aluminum hydroxide:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 364 Days
Method: OECD Test Guideline 426
Remarks: Based on data from similar materials

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:

Aluminum hydroxide:
Toxicity to fish: LL50 (Salmo trutta (brown trout)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
: EL50 (Daphnia magna (Water flea)): > 100 mg/l
   Exposure time: 48 h

Toxicity to algae/aquatic plants
: EL50 (Selenastrum capricornutum (green algae)): > 100 mg/l
   Exposure time: 96 h

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
   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

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
Species: Daphnia sp. (water flea)
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity): 10

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods:
Waste from residues: Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good
15. REGULATORY INFORMATION

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

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

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

16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; KEKI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median
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.