according to the Globally Harmonized System



Ovipast Plus Formulation

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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 Restrictions on use : Not applicable

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:

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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

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Aluminum hydroxide	21645-51-2	25
Antigen	Not Assigned	> 1.5 - < 2.5
Maleic acid	110-16-7	0.23
Thiomersal	54-64-8	0.013

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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. Flush eyes with water as a precaution.

In case of eye contact 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

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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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 absor-

bent.

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 deter-

mine 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

Advice on safe handling : Do not

Do not get on skin or clothing. Avoid breathing mist or vapours.

Use only with adequate ventilation.

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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 as-

sessment

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Aluminum hydroxide	21645-51-2	TWA (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ACGIH
Thiomersal	54-64-8	TWA	0.01 mg/m3 (Mercury)	IN OEL
	Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.			
		STEL	0.03 mg/m3 (Mercury)	IN OEL
	Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.			
		TWA	0.01 mg/m3 (Mercury)	ACGIH
		STEL	0.03 mg/m3 (Mercury)	ACGIH

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

Particulates type

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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.

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

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Relative density : 1

Density : 1 g/cm³

similar to water

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 reac- : Can react with strong oxidizing agents.

tions

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 : Inhalation

exposure 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

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Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

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 inhala-

tion 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 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.

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

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Serious eye damage/eye irritation

Not classified based on available information.

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

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Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

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 aberra-

tion 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

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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

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Thiomersal:

Effects on foetal develop-

ment

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, and/or on development, based on animal experiments

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STOT - single exposure

Not classified based on available information.

Components:

Maleic acid:

Assessment : May cause respiratory irritation.

Remarks : Based on national or regional regulation.

STOT - repeated exposure

Not classified based on available information.

Components:

Thiomersal:

Target Organs : Central nervous system, Cardio-vascular system, Gastrointes-

tinal 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

Species : Rat

NOAEL : > 0.2 mg/kg

Application Route : inhalation (dust/mist/fume)

Exposure time : 12 Months

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.

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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 (Chron-

ic 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

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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 tox- :

icity)

10

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

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 : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

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dling 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

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

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

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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 Agen-

cy, http://echa.europa.eu/

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)

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AIIC - 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; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate: NOM - Official Mexican Norm: NTP - National Toxicology Program: 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN