

Ferrous Fumarate / Manganese Sulfate Formulation

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|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: - |
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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

| | | |
|--------------|---|--|
| Trade name | : | Ferrous Fumarate / Manganese Sulfate Formulation |
| Product code | : | BIO-GAMMAMIX |

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

| | | |
|---------------------------------|---|--------------------|
| Use of the Substance/Mixture | : | Veterinary product |
| Recommended restrictions on use | : | Not applicable |

1.3 Details of the supplier of the safety data sheet

| | | |
|--|---|--|
| Company | : | MSD 20 Spartan Road 1619 Spartan, South Africa |
| Telephone | : | +27119239300 |
| 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)**

| | |
|--|--|
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Long-term (chronic) aquatic hazard, Category 3 | H412: Harmful to aquatic life with long lasting effects. |

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

| | | |
|-------------------|---|---|
| Hazard pictograms | : |   |
| Signal word | : | Warning |

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Hazard statements : H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.
Response:
P314 Get medical advice/ attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Manganese sulfate

Additional Labelling

EUH208 Contains Dimethyl octadienol, 3,7-Dimethyl 2,6-octadienal. May produce an allergic reaction.

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 81 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 81 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 81 %

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 87,5 %

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.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|--|---|--|--------------------------|
| 3- α ,6- α -Dihydroxy-5- β -cholan-24-oic acid | 83-49-8 201-483-2 | Acute Tox. 4; H302 Acute Tox. 4; H312 | $\geq 1 - < 10$ |

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|--|--|--|------------------|
| Iron(II) fumarate | 141-01-5 205-447-7 | | $\geq 1 - < 10$ |
| Manganese sulfate | 10034-96-5 | Eye Dam. 1; H318 STOT RE 1; H372 (Brain) Aquatic Chronic 2; H411 | $\geq 2,5 - < 3$ |
| Dimethyl octadienol | 78-70-6 201-134-4 603-235-00-2 | Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1B; H317 | $\geq 0,1 - < 1$ |
| 3,7-Dimethyl 2,6-octadienal | 5392-40-5 226-394-6 605-019-00-3 | Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 | $\geq 0,1 - < 1$ |
| Substances with a workplace exposure limit : | | | |
| Ascorbic acid | 50-81-7 200-066-2 | | $\geq 1 - < 10$ |

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 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.

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Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.
May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.

May produce an allergic 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 fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
Sulphur 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.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.

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Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|------------|-------------------------------|------------------------------------|-------------|
| Iron(II) fumarate | 141-01-5 | OEL-RL | 2 mg/m ³ (Iron) | ZA OEL |
| Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | | |
| Manganese sulfate | 10034-96-5 | OEL-RL | 0,2 mg/m ³ (Manganese) | ZA OEL |
| Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | | |
| | | TWA (inhalable fraction) | 0,2 mg/m ³ (Manganese) | 2017/164/EU |
| | | TWA (Respirable fraction) | 0,05 mg/m ³ (Manganese) | 2017/164/EU |
| Ascorbic acid | 50-81-7 | TWA | 5000 µg/m ³ (OEB 1) | Internal |

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Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-----------------------------|-----------|-----------------|----------------------------|-------------------|
| Manganese sulfate | Workers | Inhalation | Long-term systemic effects | 0,2 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 2,86 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 0,043 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 3,33 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,67 mg/kg bw/day |
| Dimethyl octadienol | Workers | Inhalation | Long-term systemic effects | 24,58 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 3,5 mg/kg bw/day |
| | Workers | Skin contact | Long-term local effects | 3 mg/cm2 |
| | Workers | Skin contact | Acute local effects | 3 mg/cm2 |
| | Consumers | Inhalation | Long-term systemic effects | 4,33 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 1,25 mg/kg bw/day |
| | Consumers | Skin contact | Long-term local effects | 1,5 mg/cm2 |
| | Consumers | Skin contact | Acute local effects | 1,5 mg/cm2 |
| | Consumers | Ingestion | Long-term systemic effects | 2,49 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 9 mg/m3 |
| 3,7-Dimethyl 2,6-octadienal | Workers | Skin contact | Long-term systemic effects | 1,7 mg/kg bw/day |
| | Workers | Skin contact | Long-term local effects | 0,140 mg/cm2 |
| | Consumers | Inhalation | Long-term systemic effects | 2,7 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 1 mg/kg bw/day |
| | Consumers | Skin contact | Long-term local effects | 0,140 mg/cm2 |
| | Consumers | Ingestion | Long-term systemic effects | 0,6 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,6 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,6 mg/kg bw/day |

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

| Substance name | Environmental Compartment | Value |
|-------------------|---------------------------|-------------------------------|
| Manganese sulfate | Fresh water | 1,249 mg/l |
| | Marine water | 0,015 mg/l |
| | Sewage treatment plant | 56 mg/l |
| | Fresh water sediment | 1,587 mg/kg dry weight (d.w.) |

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| | Marine sediment | 0,159 mg/kg dry weight (d.w.) |
| | Soil | 40,028 mg/kg dry weight (d.w.) |
| Dimethyl octadienol | Fresh water | 0,2 mg/l |
| | Freshwater - intermittent | 2 mg/l |
| | Marine water | 0,02 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 2,22 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,222 mg/kg dry weight (d.w.) |
| | Soil | 0,327 mg/kg dry weight (d.w.) |
| | Secondary Poisoning | 7,8 mg/kg food |
| 3,7-Dimethyl 2,6-octadienal | Fresh water | 0,007 mg/l |
| | Freshwater - intermittent | 0,068 mg/l |
| | Marine water | 0,001 mg/l |
| | Sewage treatment plant | 1,6 mg/l |
| | Fresh water sediment | 0,125 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,013 mg/kg dry weight (d.w.) |
| | Soil | 0,021 mg/kg dry weight (d.w.) |

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

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
- Remarks : Consider double gloving.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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|------------------------|---|--|
| 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 (P) |

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

| | | |
|--|---|---|
| Appearance | : | powder |
| Colour | : | brown |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | Not applicable |

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Explosive properties : Not explosive

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

9.2 Other information

Molecular weight : No data available

Particle size : No data available

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 : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

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 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 dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

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Components:**3- α ,6- α -Dihydroxy-5- β -cholan-24-oic acid:**

Acute oral toxicity : LD50 (Rat): 1.500 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 2.000 mg/kg

Iron(II) fumarate:

Acute oral toxicity : LD50 (Rat): 3.850 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1,306 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): 20.000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Manganese sulfate:

Acute oral toxicity : LD50 (Rat): > 2.000 - 5.000 mg/kg
Remarks: No test guideline followed

Acute inhalation toxicity : LC50 (Rat): > 4,98 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: The test was conducted according to guideline

Dimethyl octadienol:

Acute oral toxicity : LD50 (Rat): 2.790 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Mouse): > 3,2 mg/l
Exposure time: 90 min
Test atmosphere: vapour
Remarks: No test guideline followed

Acute dermal toxicity : LD50 (Rabbit): 5.610 mg/kg
Method: OECD Test Guideline 402
Remarks: The test was conducted equivalent or similar to guideline

3,7-Dimethyl 2,6-octadienal:

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Acute oral toxicity : LD50 (Rat, female): 4.895 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,68 mg/l
Exposure time: 7 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 2.250 mg/kg

Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11.900 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Iron(II) fumarate:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Manganese sulfate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : The test was conducted according to guideline

Dimethyl octadienol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation
Remarks : The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit
Result : Skin irritation

Ascorbic acid:

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Manganese sulfate:**

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| | | |
|---------|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irreversible effects on the eye |
| Remarks | : | The test was conducted according to guideline |

Dimethyl octadienol:

| | | |
|---------|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |
| Remarks | : | The test was conducted equivalent or similar to guideline |

3,7-Dimethyl 2,6-octadienal:

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Result | : | Irritation to eyes, reversing within 21 days |

Ascorbic acid:

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | No eye irritation |

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Iron(II) fumarate:**

| | | |
|-----------------|---|--------------------------------------|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

Manganese sulfate:

| | | |
|-----------------|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Method | : | OECD Test Guideline 429 |
| Result | : | negative |
| Remarks | : | The test was conducted equivalent or similar to guideline Based on data from similar materials |

Dimethyl octadienol:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |

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Species : Mouse
Method : OECD Test Guideline 429
Result : positive
Remarks : The test was conducted according to guideline

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

3,7-Dimethyl 2,6-octadienal:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

Ascorbic acid:

Test Type : Maurer optimisation test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Iron(II) fumarate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Manganese sulfate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

Dimethyl octadienol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo)

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cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Ascorbic acid:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Manganese sulfate:**

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

3,7-Dimethyl 2,6-octadienal:

Species : Mouse
Application Route : Ingestion
Exposure time : 104 - 105 weeks
Result : negative

Ascorbic acid:

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

Reproductive toxicity

Not classified based on available information.

Components:**Manganese sulfate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study

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Species: Rat
Application Route: inhalation (dust/mist/fume)
Method: OECD Test Guideline 416
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

Dimethyl octadienol:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: No test guideline followed

3,7-Dimethyl 2,6-octadienal:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: negative

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: negative

Ascorbic acid:

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.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**Manganese sulfate:**

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Brain
Assessment : Causes damage to organs through prolonged or repeated exposure.
Remarks : Based on data from similar materials

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Repeated dose toxicity**Components:****Manganese sulfate:**

| | |
|-------------------|---------------|
| Species | : Rat, male |
| NOAEL | : 1.700 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 13 Weeks |

Dimethyl octadienol:

| | |
|-------------------|---|
| Species | : Rat, male |
| NOAEL | : >= 497,9 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 96 Days |
| Method | : OECD Test Guideline 408 |
| Remarks | : The test was conducted according to guideline |

| | |
|-------------------|---|
| Species | : Rat |
| NOAEL | : 250 mg/kg |
| Application Route | : Skin contact |
| Exposure time | : 91 Days |
| Method | : OECD Test Guideline 411 |
| Remarks | : The test was conducted equivalent or similar to guideline |

3,7-Dimethyl 2,6-octadienal:

| | |
|-------------------|---------------|
| Species | : Rat, female |
| LOAEL | : 335 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 14 Weeks |

Ascorbic acid:

| | |
|-------------------|------------------|
| Species | : Rat, male |
| NOAEL | : >= 8.100 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 13 Weeks |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Manganese sulfate:**

| | |
|------------|--|
| Inhalation | : Target Organs: Brain Symptoms: Tremors, Lack of coordination Remarks: Based on data from similar materials |
|------------|--|

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SECTION 12: Ecological information

12.1 Toxicity

Components:

3- α ,6- α -Dihydroxy-5- β -cholan-24-oic acid:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Iron(II) fumarate:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 300 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Manganese sulfate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 1 - 10 mg/l
Exposure time: 96 h
Remarks: No test guideline followed

Toxicity to daphnia and other aquatic invertebrates : EC50 (Hyalella azteca (Amphipod)): > 1 - 10 mg/l
Exposure time: 48 h
Remarks: No test guideline followed
Based on data from similar materials

Toxicity to algae/aquatic : NOEC (Desmodesmus subspicatus (green algae)): 1 mg/l

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plants

Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline

ErC50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline

Toxicity to microorganisms : NOEC (activated sludge): 560 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: The test was conducted according to guideline

Toxicity to fish (Chronic toxicity) : NOEC: > 1 mg/l
Exposure time: 65 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210
Remarks: The test was conducted equivalent or similar to guideline

Dimethyl octadienol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 27,8 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 59 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 156,7 mg/l
Exposure time: 96 h

EC10 (Desmodesmus subspicatus (green algae)): 54,3 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC10 (activated sludge): > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 6,78 mg/l
Exposure time: 96 h
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6,8 mg/l
Exposure time: 48 h

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Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 103,8 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 3 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50 (activated sludge): 160 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50 : 140 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

12.2 Persistence and degradability**Components:****Dimethyl octadienol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 64,2 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 90 %
Exposure time: 28 d
Method: Directive 67/548/EEC Annex V, C.4.D.

Ascorbic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 5 d
Method: OECD Test Guideline 302

12.3 Bioaccumulative potential**Components:****3- α ,6- α -Dihydroxy-5- β -cholan-24-oic acid:**

Partition coefficient: n-octanol/water : log Pow: 3,08

Dimethyl octadienol:

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Partition coefficient: n-octanol/water : log Pow: 2,84
Method: OECD Test Guideline 107
Remarks: The test was conducted equivalent or similar to guideline

3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-octanol/water : log Pow: 2,76

Ascorbic acid:

Partition coefficient: n-octanol/water : log Pow: -1,85

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 Other adverse effects**Product:**

Endocrine disrupting potential : 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 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. |

SECTION 14: Transport information**14.1 UN number**

ADN : Not regulated as a dangerous good

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| | |
|------|-------------------------------------|
| 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

| | |
|------|-------------------------------------|
| 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**

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

| | |
|------|------------------|
| AICS | : not determined |
|------|------------------|

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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

H302 : Harmful if swallowed.
 H312 : Harmful in contact with skin.
 H315 : Causes skin irritation.
 H317 : May cause an allergic skin reaction.
 H318 : Causes serious eye damage.
 H319 : Causes serious eye irritation.
 H372 : Causes damage to organs through prolonged or repeated exposure.
 H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
 Aquatic Chronic : Long-term (chronic) aquatic hazard
 Eye Dam. : Serious eye damage
 Eye Irrit. : Eye irritation
 Skin Irrit. : Skin irritation
 Skin Sens. : Skin sensitisation
 STOT RE : Specific target organ toxicity - repeated exposure
 2017/164/EU : Europe. Commission Directive 2017/164/EU establishing a fourth list of indicative occupational exposure limit values
 ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
 2017/164/EU / TWA : Limit Value - eight hours
 ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

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

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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 - (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:

| | |
|-------------------|------|
| Eye Irrit. 2 | H319 |
| STOT RE 2 | H373 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| 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.

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