

Ferrous Fumarate / Manganese Sulfate Formulation

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Acute toxicity (Oral) : Category 5
Serious eye damage/eye irritation : Category 2A
Skin sensitization : Category 1
Specific target organ toxicity - repeated exposure : Category 1 (Brain)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H372 Causes damage to organs (Brain) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.

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P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor/ physician if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labeling

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 %

Other hazards

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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
3- α ,6- α -Dihydroxy-5- β -cholan-24-oic acid	83-49-8	≥ 5 -< 10
Iron(II) fumarate	141-01-5	≥ 5 -< 10
Manganese sulfate	10034-96-5	≥ 1 -< 3
Ascorbic acid	50-81-7	≥ 1 -< 5
3,7-Dimethyl 2,6-octadienal	5392-40-5	≥ 0.1 -< 1

SECTION 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.

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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. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
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 Sulfur 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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SECTION 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.
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 : 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.

SECTION 7. HANDLING AND STORAGE

- 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.
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.

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- 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.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Iron(II) fumarate	141-01-5	VLE-PPT	1 mg/m ³ (Iron)	NOM-010-STPS-2014
		TWA	1 mg/m ³ (Iron)	ACGIH
Manganese sulfate	10034-96-5	VLE-PPT	0.2 mg/m ³ (Manganese)	NOM-010-STPS-2014
		TWA (Inhalable particulate matter)	0.1 mg/m ³ (Manganese)	ACGIH
		TWA (Respirable particulate matter)	0.02 mg/m ³ (Manganese)	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m ³ (OEB 1)	Internal
3,7-Dimethyl 2,6-octadienal	5392-40-5	VLE-PPT (Inhalable fraction and vapour)	5 ppm	NOM-010-STPS-2014
		TWA (Inhalable fraction and vapor)	5 ppm	ACGIH

- Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

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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

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
Remarks	:	Consider double gloving.
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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	brown
Odor	:	No data available
Odor 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.

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Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 2,710 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

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

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Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11,900 mg/kg

3,7-Dimethyl 2,6-octadienal:

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: vapor

Acute dermal toxicity : LD50 (Rabbit): 2,250 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

Ascorbic acid:

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

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Manganese sulfate:**

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

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Ascorbic acid:

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

3,7-Dimethyl 2,6-octadienal:

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

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

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

Test Type	:	Maximization Test
Routes of exposure	:	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)
Routes of exposure	:	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

Ascorbic acid:

Test Type	:	Maurer optimisation test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

3,7-Dimethyl 2,6-octadienal:

Test Type	:	Human repeat insult patch test (HRIPT)
Routes of exposure	:	Skin contact
Result	:	positive

Assessment	:	Probability or evidence of skin sensitization in humans
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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

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

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

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Application Route: Ingestion
Result: negative

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 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

Ascorbic acid:

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

3,7-Dimethyl 2,6-octadienal:

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

Reproductive toxicity

Not classified based on available information.

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Components:**Manganese sulfate:**

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

Ascorbic acid:

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

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Brain) through prolonged or repeated exposure.

Components:**Manganese sulfate:**

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

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

Species : Rat, male

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NOAEL : 1,700 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Ascorbic acid:

Species : Rat, male
NOAEL : $\geq 8,100$ mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

3,7-Dimethyl 2,6-octadienal:

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****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

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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 plants : NOEC (Desmodesmus subspicatus (green algae)): 1 mg/l
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 fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): > 1 mg/l
Exposure time: 65 d
Method: OECD Test Guideline 210
Remarks: The test was conducted equivalent or similar 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

Ascorbic acid:

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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

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

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

Persistence and degradability

Components:

Ascorbic acid:

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

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.

Bioaccumulative potential

Components:

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

Partition coefficient: n-octanol/water : log Pow: 3.08

Ascorbic acid:

Partition coefficient: n-octanol/water : log Pow: -1.85

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octanol/water

3,7-Dimethyl 2,6-octadienal:Partition coefficient: n- : log Pow: 2.76
octanol/water**Mobility in soil**

No data available

Other adverse effects

No data available

SECTION 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for
producing capsules, tablets and pills.**The ingredients of this product are reported in the following inventories:**

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1.0	22.08.2025	11571029-00001	Date of first issue: 22.08.2025

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 22.08.2025
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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT

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; TECl - 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

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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