

SAFETY DATA SHEET



Betaine / Multivitamin Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 11513553-00004 Date of last issue: 2025/03/28
Date of first issue: 2025/02/24

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betaine / Multivitamin Formulation

Product code : Supastock

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

Other hazards which do not result in classification

Important symptoms and out-lines of the emergency assumed : Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	>= 10 - < 20	8-98
3,7-Dimethyl 2,6-octadienal	5392-40-5	>= 0.1 - < 1	2-515
Dimethyl octadienol	78-70-6	>= 0.1 - < 1	2-258, 2-249
(dl)-a-Tocopheryl acetate	7695-91-2	< 0.1	9-487
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.0025 - < 0.025	3-540, 9-1805
Betaine hydrochloride	590-46-5	< 0.1	2-1291 / 1-215, 2-2709 / 1-215
Benzyl alcohol	100-51-6	< 0.1	3-1011
Pyridoxine hydrochloride	58-56-0	< 0.1	1-215 / 9-1043
Colecalciferol	67-97-0	< 0.0002	9-1054

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
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 : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

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and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing 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
Nitrogen oxides (NO_x)
Chlorine compounds
Metal oxides
Oxides of phosphorus

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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).

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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.

7. HANDLING AND STORAGE

Handling

Technical measures	<ul style="list-style-type: none">: 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	<ul style="list-style-type: none">: Use only with adequate ventilation.
Advice on safe handling	<ul style="list-style-type: none">: Do not get on skin or clothing.Avoid breathing dust.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 assessmentMinimize 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.Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	<ul style="list-style-type: none">: Oxidizing agents
Hygiene measures	<ul style="list-style-type: none">: 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.

Storage

Conditions for safe storage	<ul style="list-style-type: none">: Keep in properly labelled containers.Store in accordance with the particular national regulations.
Materials to avoid	<ul style="list-style-type: none">: Do not store with the following product types:Strong oxidizing agents

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Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
3,7-Dimethyl 2,6-octadienal	5392-40-5	TWA (Inhalable fraction and vapor)	5 ppm	ACGIH
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	8h-OEL-M	10 mg/m3	JP ISHL OEL 577-2(2)
		TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH
Betaine hydrochloride	590-46-5	TWA	>= 100 < 1000 µg/m3 (OEB2)	Internal
Benzyl alcohol	100-51-6	OEL-C	25 mg/m3	JP OEL JSOH
	Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.			
Pyridoxine hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m3 (OEB 4)	Internal
		Wipe limit	50 µg/100 cm ²	Internal

Engineering measures

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from

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stationary container, ventilated enclosure, etc.).
All engineering controls should be implemented by facility
design and operated in accordance with GMP principles to
protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.

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

Eye protection

: Consider double gloving.

: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : yellow

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

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per flammability limit

Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: Not applicable
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: Not applicable
Density and / or relative density	
Relative density	: No data available
Density	: No data available
Relative vapour density	: 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

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.

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Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 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: vapour
Acute dermal toxicity : LD50 (Rabbit): 2,250 mg/kg

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

(dl)-a-Tocopheryl acetate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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Acute dermal toxicity : LD50 (Rat): > 3,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Betaine hydrochloride:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted according to guideline
Based on data from similar materials

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 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

Pyridoxine hydrochloride:

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

Colecalciferol:

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 0.05 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg
Method: Expert judgement

Skin corrosion/irritation

Not classified based on available information.

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Components:

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit
Result : Skin irritation

Dimethyl octadienol:

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

(dl)-*a*-Tocopheryl acetate:

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

2,6-Di-tert-butyl-p-cresol:

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

Betaine hydrochloride:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : The test was conducted according to guideline

Result : No skin irritation

Benzyl alcohol:

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

Pyridoxine hydrochloride:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species : Rabbit
Result : No eye irritation

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3,7-Dimethyl 2,6-octadienal:

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

Dimethyl octadienol:

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

(dl)-a-Tocopheryl acetate:

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

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Betaine hydrochloride:

Result : Irreversible effects on the eye

Benzyl alcohol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Pyridoxine hydrochloride:

Species : Rabbit
Result : No eye irritation

Colecalciferol:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:

Starch:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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

Dimethyl octadienol:

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

(dl)-a-Tocopheryl acetate:

Test Type : Draize Test
Exposure routes : Skin contact
Species : Humans
Result : negative

2,6-Di-tert-butyl-p-cresol:

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

Betaine hydrochloride:

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 according to guideline

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

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Exposure routes : Skin contact
Species : Humans
Result : positive

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

Pyridoxine hydrochloride:

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

Colecalciferol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Starch:

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

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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

(dl)-a-Tocopheryl acetate:

Genotoxicity in vitro

: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo

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

2,6-Di-tert-butyl-p-cresol:

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

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Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Betaine hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: Directive 67/548/EEC, Annex, B.13/14
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

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: Directive 67/548/EEC, Annex V, B.10.
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

Benzyl alcohol:

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

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

Pyridoxine hydrochloride:

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

Colecalciferol:

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Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: equivocal
	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative
	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
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
	Test Type: In vivo mammalian alkaline comet assay Species: Rat Application Route: Ingestion Result: positive
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

3,7-Dimethyl 2,6-octadienal:

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

(dl)-a-Tocopheryl acetate:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

2,6-Di-tert-butyl-p-cresol:

Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

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Betaine hydrochloride:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	104 weeks
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	The test was conducted equivalent or similar to guideline Based on data from similar materials

Benzyl alcohol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:**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

Dimethyl octadienol:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: No test guideline followed
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(dl)-a-Tocopheryl acetate:

Effects on fertility	:	Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rabbit

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Application Route: Ingestion
Result: negative

2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Pyridoxine hydrochloride:

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

Not classified based on available information.

Components:

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Colecalciferol:

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Bone

Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

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Repeated dose toxicity

Components:

Starch:

Species : Rat
NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days
Method : OECD Test Guideline 410

3,7-Dimethyl 2,6-octadienal:

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

(dl)-a-Tocopheryl acetate:

Species : Rat
NOAEL : 500 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

Betaine hydrochloride:

Species : Rat

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LOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408
Remarks : The test was conducted according to guideline
Based on data from similar materials

Benzyl alcohol:

Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Colecalciferol:

Species : Rat
NOAEL : 0.06 mg/kg
LOAEL : 0.3 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408

Aspiration toxicity

Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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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

(dl)-a-Tocopheryl acetate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l
Exposure time: 28 d

Toxicity to microorganisms : EC50: > 927 mg/l
Exposure time: 30 min
Method: ISO 8192

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
Exposure time: 96 h

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Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Betaine hydrochloride:

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: The test was conducted according to guideline Based on data from similar materials
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline Based on data from similar materials
		EC10 (Desmodesmus subspicatus (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline Based on data from similar materials

Benzyl alcohol:

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Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Pyridoxine hydrochloride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Colecalciferol:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EL50 (Scenedesmus capricornutum (fresh water algae)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Persistence and degradability

Components:

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.

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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

(dl)-a-Tocopheryl acetate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 21.7 - 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Pyridoxine hydrochloride:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 28 d
Method: OECD Test Guideline 301E

Colecalciferol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: <= 7 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-octanol/water : log Pow: 2.76

Dimethyl octadienol:

Partition coefficient: n-octanol/water : log Pow: 2.84
Method: OECD Test Guideline 107

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Remarks: The test was conducted equivalent or similar to guideline

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

Betaine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: -4.93
Remarks: Calculation

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Pyridoxine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 4.32

Colecalciferol:

Partition coefficient: n-octanol/water : log Pow: > 6.2
Method: OECD Test Guideline 107

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable

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Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
2,6-Di-tert-butyl-4-methylphenol	64

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

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Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
citral	>=0.1 - <1	From April 1st, 2025
3,7-Dimethyl-1,6-octadien-3-ol	>=0.1 - <1	From April 1st, 2025

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

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Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP ISHL OEL 577-2(2) : Concentration standard (Value set by the Minister of Health, Labour and Welfare stipulated under the Ministerial Ordinance Article 577-2(2))

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

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ACGIH / TWA	: 8-hour, time-weighted average
JP ISHL OEL 577-2(2) / 8h- OEL-M	: 8-hour Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C	: Occupational Exposure Limit-Ceiling

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.

JP / EN