

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Betaine / Multivitamin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.03.2025
3.0	14.04.2025	11513721-00004	Date of first issue: 24.02.2025

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Betaine / Multivitamin Formulation

Product code : Supastock

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

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

Additional Labelling

EUH210 Safety data sheet available on request.

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

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allergic reaction.

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 %

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.

Ecological information: 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.

Toxicological information: 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.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
3,7-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
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
(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		$< 0,1$
Betaine hydrochloride	590-46-5 209-683-1	Eye Dam. 1; H318	$< 0,1$
Benzyl alcohol	100-51-6	Acute Tox. 4; H302	$< 0,1$

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	202-859-9 603-057-00-5	Eye Irrit. 2; H319 Skin Sens. 1B; H317 Acute toxicity estimate Acute oral toxicity: 1.200 mg/kg	
Pyridoxine hydrochloride	58-56-0 200-386-2		< 0,1
Colecalciferol	67-97-0 200-673-2 603-180-00-4	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 2; H310 STOT RE 1; H372 (Kidney, Blood, Bone) Aquatic Chronic 4; H413 specific concentration limit STOT RE 1; H372 >= 3 % STOT RE 2; H373 0,3 - < 3 % Acute toxicity estimate Acute oral toxicity: 35 mg/kg Acute inhalation toxicity (dust/mist): 0,05 mg/l Acute dermal toxicity: 50 mg/kg	<= 0,0002

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,

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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 | : | 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 (CO ₂)
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
Nitrogen oxides (NO _x) |

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Chlorine compounds
Metal oxides
Oxides of phosphorus

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.

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.

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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.
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 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.
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 |

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

- | | |
|------|---|
| Dust | 5 mg/m ³
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358 |
|------|---|

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10 mg/m³

Value type (Form of exposure): TWA (total dust)

Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m ³ (OEB 1)	Internal
Betaine hydrochloride	590-46-5	TWA	>= 100 < 1000 µg/m ³ (OEB2)	Internal
Pyridoxine hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m ³)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m ³ (OEB 4)	Internal
		Wipe limit	50 µg/100 cm ²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
L-Lysine hydrochloride	Workers	Inhalation	Long-term systemic effects	67,1 mg/m ³
	Workers	Skin contact	Long-term systemic effects	381 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	19,9 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	22,9 mg/kg bw/day
3,7-Dimethyl 2,6-octadienal	Workers	Inhalation	Long-term systemic effects	9 mg/m ³
	Workers	Skin contact	Long-term systemic effects	1,7 mg/kg bw/day
	Workers	Skin contact	Long-term local effects	0,140 mg/cm ²
	Consumers	Inhalation	Long-term systemic effects	2,7 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
(dl)-a-Tocopheryl acetate	Consumers	Skin contact	Long-term local effects	0,140 mg/cm ²
	Consumers	Ingestion	Long-term systemic effects	0,6 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	73,5 mg/m ³
	Workers	Skin contact	Long-term systemic effects	416,6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	21,7 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	250 mg/kg bw/day

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	Consumers	Ingestion	Long-term systemic effects	12,5 mg/kg bw/day
Betaine hydrochloride	Workers	Inhalation	Long-term systemic effects	177 mg/m3
	Workers	Skin contact	Long-term systemic effects	252 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	44 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12,6 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 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

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

Substance name	Environmental Compartment	Value
L-Lysine hydrochloride	Sewage treatment plant	10 mg/l

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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.)
(dl)-a-Tocopheryl acetate	Fresh water	0,27 mg/l
	Freshwater - intermittent	0,27 mg/l
	Marine water	0,027 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	212000 mg/kg dry weight (d.w.)
	Marine sediment	21200 mg/kg dry weight (d.w.)
	Soil	74800 mg/kg dry weight (d.w.)
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg
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

8.2 Exposure controls

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

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closed system, packout head with inflatable seal from 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

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.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: powder
Colour	: yellow
Odour	: characteristic
Odour Threshold	: No data available
Melting point/freezing point	: No data available
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
Upper explosion limit / Upper	: No data available

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flammability limit

Lower explosion limit / Lower
flammability limit : No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 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

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

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

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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

Acute dermal toxicity : LD50 (Rat): > 3.000 mg/kg
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.

Components:

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit

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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

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:

3,7-Dimethyl 2,6-octadienal:

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

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

(dl)-a-Tocopheryl acetate:

Species : Rabbit
Method : OECD Test Guideline 405

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Result : No eye irritation

Betaine hydrochloride:

Result : Irreversible effects on the eye

Benzyl alcohol:

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

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.

Components:

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

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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)
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:

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 mam-

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malian cells
Result: positive

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

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

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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:

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

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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

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

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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

(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
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

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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:

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.

Repeated dose toxicity

Components:

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

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Application Route : Ingestion
Exposure time : 90 Days

Betaine hydrochloride:

Species : Rat
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.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : 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 12: Ecological information

12.1 Toxicity

Components:

3,7-Dimethyl 2,6-octadienal:

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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

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

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NOEC (Pseudokirchneriella subcapitata (green algae)): $\geq$ 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

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

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:

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 : NOEC: 51 mg/l

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aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d
Species: Daphnia magna (Water flea)
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

12.2 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.

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

Benzyl alcohol:

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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

12.3 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
Remarks: The test was conducted equivalent or similar to guideline

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

12.4 Mobility in soil

No data available

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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 Endocrine disrupting properties

Product:

Assessment : 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.

12.7 Other adverse effects

No data available

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 or ID number

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

14.2 UN proper shipping name

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good

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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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.
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Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to

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	determine whether an entry is applicable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	: Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	: Not applicable

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

AICS	: not determined
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.
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Full text of H-Statements

H300	: Fatal if swallowed.
H302	: Harmful if swallowed.
H310	: Fatal 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.
H330	: Fatal if inhaled.
H372	: Causes damage to organs through prolonged or repeated exposure.
H413	: May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage

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Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 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/>

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Betaine / Multivitamin Formulation

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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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