

SAFETY DATA SHEET

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



Multivitamin (with Soy Oil) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 4259335-00017 Date of last issue: 28.09.2024
Date of first issue: 06.05.2019

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

1.1 Product identifier

Trade name : Multivitamin (with Soy Oil) Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Drynam Road
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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)

Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 4

H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H413: May cause long lasting harmful effects to aquatic life.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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| | | | |
|---|---|--|--|
| Hazard statements | : | H360D H372 H413 | May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. May cause long lasting harmful effects to aquatic life. |
| Precautionary statements | : | Prevention: P201 P264 P270 P273 P280 | Obtain special instructions before use. Wash skin thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. |
| Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. | | | |

Hazardous components which must be listed on the label:

Vitamin A Palmitate

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------------|---|---|--------------------------|
| Soya oil | 8001-22-7 232-274-4 | Aquatic Chronic 4; H413 | >= 70 - < 90 |
| Vitamin A Palmitate | 79-81-2 201-228-5 | Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 4; | >= 20 - < 25 |

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| | | | |
|---------------------------|--------------------------------------|---|-----------------|
| | | H413 | |
| (dl)-a-Tocopheryl acetate | 7695-91-2 231-710-0 | | >= 1 - < 10 |
| 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 esti- mate Acute oral toxicity: 35 mg/kg Acute inhalation tox- icity (dust/mist): 0.05 mg/l Acute dermal toxicity: 50 mg/kg | >= 0.1 - < 0.25 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

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

In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.

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Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

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

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

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed.

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Hygiene measures : Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------------|-----------|-------------------------------|---------------------------|----------|
| Vitamin A Palmitate | 79-81-2 | TWA | >= 1 < 10 ug/m3 (OEB 4) | Internal |
| (dl)-a-Tocopheryl acetate | 7695-91-2 | TWA | 5000 ug/m3 (OEB 1) | Internal |
| Colecalciferol | 67-97-0 | TWA | 5 µg/m3 (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 |
|---------------------------|-----------|-----------------|----------------------------|--------------------|
| Vitamin A Palmitate | Workers | Inhalation | Long-term systemic effects | 1.6 mg/m3 |
| (dl)-a-Tocopheryl acetate | Workers | Inhalation | Long-term systemic effects | 73.5 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 416.6 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 21.7 mg/m3 |
| | 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 |
|--|-----------|-----------|----------------------------|-------------------|

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

| Substance name | Environmental Compartment | Value |
|---------------------------|---------------------------|--------------------------------|
| Vitamin A Palmitate | Fresh water | 0.1 mg/l |
| | Marine water | 0.01 mg/l |
| | Intermittent use/release | 1 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 595000 mg/kg |
| | Marine sediment | 5950000 mg/kg |
| | Soil | 2100000 mg/kg |
| (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.) |

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:
Safety glasses
Equipment should conform to I.S. EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.

Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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Filter type

Filter should conform to I.S. EN 14387

: Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|---|
| Physical state | : | Aqueous solution |
| Colour | : | yellow |
| Odour | : | characteristic |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | -5 °C |
| Initial boiling point and boiling range | : | 194 °C |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | 244 °C |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | 68.41 - 68.81 mPa.s (25 °C) Method: Brookfield |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | practically insoluble |
| Solubility in other solvents | : | Solvent: Ethanol slightly soluble |

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Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Relative density : 0.9 - 0.94
Density : No data available
Relative vapour density : No data available
Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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

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Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

| | |
|---------------------------|---|
| Acute oral toxicity | : Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |
| Acute dermal toxicity | : Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |

Components:

Vitamin A Palmitate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

(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

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:

Vitamin A Palmitate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

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(dl)-a-Tocopheryl acetate:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Vitamin A Palmitate:

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

(dl)-a-Tocopheryl acetate:

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| 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:

Vitamin A Palmitate:

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

(dl)-a-Tocopheryl acetate:

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

Colecalciferol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Vitamin A Palmitate:

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: Ingestion
Method: OECD Test Guideline 474
Result: negative

(dl)- α -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 |

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
- 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)

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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:

(dl)-a-Tocopheryl acetate:

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

Reproductive toxicity

May damage the unborn child.

Components:

Vitamin A Palmitate:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Monkey
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

(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

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STOT - single exposure

|| Not classified based on available information.

STOT - repeated exposure

|| Causes damage to organs through prolonged or repeated exposure.

Components:

Vitamin A Palmitate:

| | | |
|-----------------|---|---|
| Exposure routes | : | Ingestion |
| Target Organs | : | Liver |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |
| Remarks | : | Based on data from similar materials |

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:

Soya oil:

| | | |
|-------------------|---|-------------|
| Species | : | Rat |
| NOAEL | : | 4,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 h |

Vitamin A Palmitate:

| | | |
|-------------------|---|--------------------------------------|
| Species | : | Rat |
| LOAEL | : | > 1 - 10 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 3 Months |
| Remarks | : | Based on data from similar materials |

(dl)-a-Tocopheryl acetate:

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

Colecalciferol:

| | | |
|-------------------|---|------------|
| Species | : | Rat |
| NOAEL | : | 0.06 mg/kg |
| LOAEL | : | 0.3 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

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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.

Experience with human exposure

Components:

Vitamin A Palmitate:

Ingestion : Symptoms: liver impairment
Remarks: Based on data from similar materials
Symptoms: Embryo-foetal toxicity
Remarks: Based on data from similar materials

SECTION 12: Ecological information

12.1 Toxicity

Components:

Vitamin A Palmitate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 96 h
Method: DIN 38412
Remarks: Based on data from similar materials

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

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 152.94 mg/l
Exposure time: 72 h

(dl)-a-Tocopheryl acetate:

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

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| 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 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) |

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:

Vitamin A Palmitate:

| | |
|------------------|--|
| Biodegradability | : Result: Not readily biodegradable. Biodegradation: 40 - 50 % Exposure time: 28 d Method: OECD Test Guideline 301F |
|------------------|--|

(dl)-a-Tocopheryl acetate:

| | |
|------------------|--|
| Biodegradability | : Result: Not readily biodegradable. Biodegradation: 21.7 - 31 % Exposure time: 28 d |
|------------------|--|

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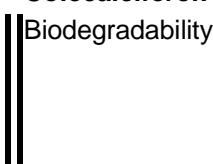
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Method: OECD Test Guideline 301C

Colecalciferol:



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

12.3 Bioaccumulative potential

Components:

Soya oil:



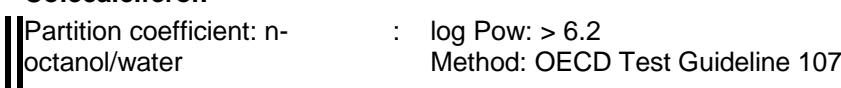
Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Calculation

Vitamin A Palmitate:



Partition coefficient: n-octanol/water : log Pow: > 6.2

Colecalciferol:



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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 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

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

| | |
|------------------------|---|
| Product | <p>: Dispose of in accordance with local regulations.</p> <p>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</p> <p>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</p> <p>Do not dispose of waste into sewer.</p> |
| Contaminated packaging | <p>: Empty containers should be taken to an approved waste handling site for recycling or disposal.</p> <p>If not otherwise specified: Dispose of as unused product.</p> |

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 |
| 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 |

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

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 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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 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

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

: Colecalciferol

REACH - List of substances subject to authorisation (Annex XIV)

: 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

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Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where 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.

Full text of H-Statements

H300 : Fatal if swallowed.
H310 : Fatal in contact with skin.
H330 : Fatal if inhaled.
H360D : May damage the unborn child.
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
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air 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;

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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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

| | |
|-------------------|-------|
| Repr. 1A | H360D |
| STOT RE 1 | H372 |
| Aquatic Chronic 4 | H413 |

Classification procedure:

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

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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