

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Multivitamin (with Sunflower Oil) Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 14.04.2025 | SDS Number: 9374518-00010 | Date of last issue: 04.12.2024 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

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

1.1 Product identifier

Trade name : Multivitamin (with Sunflower 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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Reproductive toxicity, Category 1A H360D: May damage the unborn child.

Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms



Signal word

: Danger

Hazard statements

: H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Retinyl propionate
Benzyl alcohol

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|--------------------|---|-----------------|--------------------------|
| Retinyl propionate | 7069-42-3 | Repr. 1A; H360D | >= 2.5 - < 10 |

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| | | | |
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| | 230-363-2 | STOT RE 1; H372 (Liver) Aquatic Chronic 4; H413 | |
| (dl)-a-Tocopheryl acetate | 7695-91-2 231-710-0 | | >= 1 - < 10 |
| Benzyl alcohol | 100-51-6 202-859-9 603-057-00-5 | Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 | >= 1 - < 10 |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 204-881-4 | Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | >= 0.25 - < 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 % | >= 0.025 - < 0.1 |

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.

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Get medical attention.

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 : 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 cause an allergic skin reaction.
May damage the unborn child.
May cause 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 cir-

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| | |
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| ods | cumstances 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060). |
|---------------------------|---|

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. |

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

7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Requirements for storage areas and containers | <p>:</p> <p>Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.</p> |
| Advice on common storage | <p>:</p> <p>Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases</p> |

7.3 Specific end use(s)

| | |
|-----------------|-----------------------------------|
| Specific use(s) | <p>:</p> <p>No data available</p> |
|-----------------|-----------------------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|----------------------------|-----------|-------------------------------|---------------------------|----------|
| (dl)-a-Tocopheryl acetate | 7695-91-2 | TWA | 5000 ug/m3 (OEB 1) | Internal |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 | TWA | 10 mg/m3 | GB EH40 |
| Colecalciferol | 67-97-0 | TWA | 5 µg/m3 (OEB 4) | Internal |
| | | Wipe limit | 50 µg/100 cm ² | Internal |

Derived No Effect Level (DNEL)

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| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------------------|-----------|-----------------|----------------------------|--------------------|
| (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 |
| | Consumers | Ingestion | Long-term systemic effects | 12.5 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 |
| 2,6-Di-tert-butyl-p-cresol | Workers | Inhalation | Long-term systemic effects | 3.5 mg/m3 |
| | Workers | Dermal | Long-term systemic effects | 0.5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 0.86 mg/m3 |
| | Consumers | Dermal | Long-term systemic effects | 0.25 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0.25 mg/kg bw/day |

Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment | Value |
|--------------------|---------------------------|------------------------------|
| Retinyl propionate | Fresh water | 0.1 mg/l |
| | Freshwater - intermittent | 1 mg/l |
| | Marine water | 0.01 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 2080 mg/kg dry weight (d.w.) |
| | Soil | 735 mg/kg dry |

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| | | 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 |
| 2,6-Di-tert-butyl-p-cresol | Fresh water | 0.199 µg/l |
| | Intermittent use/release | 0.02 µg/l |
| | Marine water | 0.02 µg/l |
| | Sewage treatment plant | 0.17 mg/l |
| | Fresh water sediment | 0.0996 mg/kg dry weight (d.w.) |
| | Marine sediment | 0.00996 mg/kg dry weight (d.w.) |
| | Soil | 0.04769 mg/kg dry weight (d.w.) |
| | Oral (Secondary Poisoning) | 8.33 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.

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.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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.

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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. Filter should conform to BS EN 14387 |
| Filter type | : Organic vapour type (A) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|------------------------|
| Appearance | : liquid |
| Colour | : transparent amber |
| Odour | : No data available |
| Odour Threshold | : No data available |
| pH | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flash point | : No data available |
| Evaporation rate | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density | : No data available |

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Relative density : No data available
Density : 0.925 g/cm³
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight : No data available
Particle size : Not applicable

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.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

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

Components:

Retinyl propionate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

(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

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

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

Colecalciferol:

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| 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:

Retinyl propionate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritation

(dl)- α -Tocopheryl acetate:

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

Benzyl alcohol:

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 |

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Retinyl propionate:

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

(dl)- α -Tocopheryl acetate:

Species : Rabbit
Method : OECD Test Guideline 405

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||Result : No eye irritation

Benzyl alcohol:

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

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

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

Colecalciferol:

||Species : Rabbit
||Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Retinyl propionate:

||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

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

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

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

Retinyl propionate:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: 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 Remarks: Based on data from similar materials |
|----------------------|---|--|

(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 |
|----------------------|---|--|

Benzyl alcohol:

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

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| | |
|------------------------------------|---|
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection 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 |
| Genotoxicity in vivo | : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat 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) 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. |

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Carcinogenicity

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

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

Benzyl alcohol:

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

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

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

Reproductive toxicity

May damage the unborn child.

Components:

Retinyl propionate:

| | | |
|------------------------------------|---|--|
| Effects on foetal development | : | Test Type: Embryo-foetal development Species: Monkey Application Route: Ingestion Result: positive Remarks: Based on data from similar materials |
| 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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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 |

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 |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Retinyl propionate:

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

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:

Retinyl propionate:

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

(dl)- α -Tocopheryl acetate:

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

Benzyl alcohol:

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

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

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

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.

Experience with human exposure

Components:

Retinyl propionate:

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

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Retinyl propionate:

| | | |
|----------------------------|---|--|
| Toxicity to fish | : | LL50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l Exposure time: 96 h Method: DIN 38412 |
| Toxicity to microorganisms | : | EC50 (activated sludge): > 1,000 mg/l Exposure time: 180 min Method: OECD Test Guideline 209 |

(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 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) |

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 | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 |

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| | |
|--|--|
| plants | 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: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 |
| 2,6-Di-tert-butyl-p-cresol: | |
| Toxicity to fish | : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l Exposure time: 96 h 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 microorganisms | : EC50 : > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : NOEC: 0.053 mg/l Exposure time: 30 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 0.316 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) |
| M-Factor (Chronic aquatic toxicity) | : 1 |

Colecalciferol:

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| | | |
|---|---|--|
| 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:

Retinyl propionate:

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

(dl)- α -Tocopheryl acetate:

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

Benzyl alcohol:

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

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

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

Colecalciferol:

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

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12.3 Bioaccumulative potential

Components:

Retinyl propionate:

Partition coefficient: n-octanol/water : log Pow: 9.12
Remarks: Calculation

Benzyl alcohol:

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

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

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 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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.

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Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

| | | |
|-------------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.2 UN proper shipping name

| | | |
|-------------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.3 Transport hazard class(es)

| | | |
|-------------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.4 Packing group

| | | |
|-------------------------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA (Cargo) | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | Not regulated as a dangerous good |

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

| | |
|---|---|
| UK REACH List of restrictions (Annex 17) | : Conditions of restriction for the following entries should be considered: Number on list 3 |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | 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. |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : Not applicable |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV) | : Not applicable |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : Not applicable |
| Control of Major Accident Hazards Regulations 2015 (COMAH) | |
| | Not applicable |

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

| | |
|-------|------------------|
| DSL | : not determined |
| AICS | : not determined |
| IECSC | : not determined |

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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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.
H302 : Harmful if swallowed.
H310 : Fatal in contact with skin.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

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; 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

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

of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

| | |
|-------------------|-------|
| Skin Sens. 1 | H317 |
| Repr. 1A | H360D |
| STOT RE 2 | H373 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

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

GB / EN