SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Multivitamin (with Sunflower Oil) Formulation

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

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)

Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 3

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :
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:
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P201  Obtain special instructions before use.
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.

Storage:
P405  Store locked up.

Hazardous components which must be listed on the label:
Retinyl propionate

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinyl propionate</td>
<td>7069-42-3 230-363-2</td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 4; H413</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>7695-91-2 231-710-0</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6 202-859-9 603-057-00-5</td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity estimate Acute oral toxicity:</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>
## 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).

### For explanation of abbreviations see section 16.

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
<th>Aquatic Acute</th>
<th>Aquatic Chronic</th>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>Specific Concentration Limit</th>
<th>Acute Oral Toxicity</th>
<th>Acute Inhalation Toxicity</th>
<th>Acute Dermal Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0 204-881-4</td>
<td>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colecaciferol</td>
<td>67-97-0 200-673-2 603-180-00-4</td>
<td>Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 2; H310 STOT RE 1; H372 (Kidney, Blood, Bone) Aquatic Chronic 4; H413</td>
<td>Specific Concentration Limit STOT RE 1; H372 &gt;= 3 % STOT RE 2; H373 0.3 - &lt; 3 %</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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If inhaled : If inhaled, remove to fresh air.
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 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 method : Use extinguishing measures that are appropriate to local cir-
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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.
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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.

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.
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 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
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>7695-91-2</td>
<td>TWA</td>
<td>5000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>2 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Colecalciferol</td>
<td>67-97-0</td>
<td>TWA</td>
<td>5 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>73.5 mg/m³</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
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<tbody>
<tr>
<td>1.3</td>
<td>27.08.2021</td>
<td>6773328-00004</td>
<td>09.04.2021</td>
<td>15.10.2020</td>
</tr>
</tbody>
</table>

**Workers**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Workers</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Workers</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Workers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
</tr>
</tbody>
</table>

---

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinyl propionate</td>
<td>Fresh water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.01 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2080 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>735 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>(dl)-Tocopheryl acetate</td>
<td>Fresh water</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.027 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
</tbody>
</table>

---

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Fresh water sediment</th>
<th>Marine sediment</th>
<th>Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>1 mg/l</td>
<td>0.1 mg/l</td>
<td>0.456 mg/kg</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>0.199 µg/l</td>
<td>0.02 µg/l</td>
<td>0.17 mg/l</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
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 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

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.
9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>transparent amber</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.925 g/cm³</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>Particle size</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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
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
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): 1,620 mg/kg
Acute toxicity estimate: 1,620 mg/kg
Method: Calculation method

Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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:
Acute oral toxicity: LD50 (Rat, male): 35 mg/kg
Acute toxicity estimate: 35 mg/kg
Method: Calculation method

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

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

Skin corrosion/irritation
Not classified based on available information.
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Components:

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

(dl)-a-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)-a-Tocopheryl acetate:
Species : Rabbit
Method : OECD Test Guideline 405
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
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**Colesteryl:**
- **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:**

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

**2,6-Di-tert-butyl-p-cresol:**
- **Test Type:** Human repeat insult patch test (HRIPT)
- **Exposure routes:** Skin contact
- **Species:** Humans
- **Result:** negative

**Colesteryl:**
- **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

- Genotoxicity in vitro
  - 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

- 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
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**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.

**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
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**Date of last issue**: 09.04.2021  
**Date of first issue**: 15.10.2020

### 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

#### 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.

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)-a-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)
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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.

11.2 Information on other hazards

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.

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

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): $> 1,000 \text{ mg/l}$  
Exposure time: 180 min  
Method: OECD Test Guideline 209

(dl)-a-Tocopheryl acetate:
Toxicity to fish:  
LC50 (Oncorhynchus mykiss (rainbow trout)): $> 100 \text{ mg/l}$  
Exposure time: 96 h  
Method: OECD Test Guideline 203

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

Toxicity to algae/aquatic plants:  
ErC50 (Pseudokirchneriella subcapitata (green algae)): $> 100 \text{ mg/l}$  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
NOEC (Pseudokirchneriella subcapitata (green algae)): $\geq 100 \text{ mg/l}$  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms:  
EC50: $> 927 \text{ mg/l}$  
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 plants:  
EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: 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

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:
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)-a-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

12.3 Bioaccumulative potential

**Components:**

**Retinyl propionate:**
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
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12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Method: OECD Test Guideline 107

12.6 Endocrine disrupting properties

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.

12.7 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.
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
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good
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14.4 Packing group
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, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
REACH - List of substances subject to authorisation (Annex XIV)

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:

DSL: not determined
AICS: 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
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<table>
<thead>
<tr>
<th>Version</th>
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</thead>
<tbody>
<tr>
<td>1.3</td>
<td>27.08.2021</td>
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</tbody>
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are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

<table>
<thead>
<tr>
<th>H300</th>
<th>Fatal if swallowed.</th>
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</thead>
<tbody>
<tr>
<td>H302</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>H310</td>
<td>Fatal in contact with skin.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H330</td>
<td>Fatal if inhaled.</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled.</td>
</tr>
<tr>
<td>H360D</td>
<td>May damage the unborn child.</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H413</td>
<td>May cause long lasting harmful effects to aquatic life.</td>
</tr>
</tbody>
</table>

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 |
| STOT RE | : Specific target organ toxicity - repeated exposure |
| IE OEL | : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1 |
| IE OEL / OELV - 8 hrs (TWA) | : Occupational exposure limit value (8-hour reference period) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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 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
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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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
- Repr. 1A: H360D
- STOT RE 2: H373
- Aquatic Chronic 3: H412

Classification procedure:
- Calculation method

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.

IE / EN