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
Kilkeel
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)

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

Multivitamin (with Sunflower Oil) Formulation

Version 1.3 Revision Date: 27.08.2021 SDS Number: 6773315-00004 Date of last issue: 09.04.2021 Date of first issue: 15.10.2020

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.</th>
<th>EC-No.</th>
<th>Index-No.</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></td>
<td></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></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></td>
<td></td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity estimate</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Multivitamin (with Sunflower Oil) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>SDS Number: 6773315-00004</th>
<th>Date of last issue: 09.04.2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>6773315-00004</td>
<td></td>
</tr>
</tbody>
</table>

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 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 firefighting: 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.

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. 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>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>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic</td>
<td>416,6 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Multivitamin (with Sunflower Oil) Formulation

<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)-a-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>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>212000 mg/kg</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
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 14387
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid
Colour : transparent
    amber
Odour : No data available
Odour Threshold : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : 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
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
    Viscosity, kinematic : No data available
Solubility(ies)
    Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Relative density : No data available
Density : 0.925 g/cm³
Relative vapour density : No data available
Particle characteristics
    Particle size : Not applicable

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

Multivitamin (with Sunflower Oil) Formulation

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.
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
Multivitamin (with Sunflower Oil) Formulation

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colecalciferol</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Rabbit</td>
<td></td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Retinyl propionate</td>
<td></td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td></td>
<td>Skin contact</td>
<td>Humans</td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td></td>
<td>Skin contact</td>
<td>Humans</td>
<td>Human repeat insult patch test (HRIPT)</td>
<td>negative</td>
</tr>
<tr>
<td>Colecalciferol</td>
<td>Maurer optimisation test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components**

**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**

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

**Components**

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

**Components**

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

**Components**

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

**Components**

**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

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
## Genotoxicity in vitro

**Colecalciferol:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 471</td>
<td>equivocal</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>OECD Test Guideline 473</td>
<td>negative</td>
</tr>
</tbody>
</table>

## Genotoxicity in vivo

**Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay):**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vivo mammalian alkaline comet assay</td>
<td>OECD Test Guideline 474</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>104 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Ingestion</td>
<td>103 weeks</td>
<td>OECD Test Guideline 451</td>
<td>negative</td>
</tr>
</tbody>
</table>
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)-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)
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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
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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

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:
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
octanol/water

**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

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

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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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Conditions of restriction for the following entries should be considered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH</td>
<td>Number on list 3</td>
</tr>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Not applicable

Other regulations:  
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable. 
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:  
DSL: not determined 
AICS: not determined 
IECSC: not determined

SECTION 16: Other information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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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.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H332 : Harmful 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
STOT RE : Specific target organ toxicity - repeated exposure

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 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;
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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

Classification of the mixture:

<table>
<thead>
<tr>
<th>Repr. 1A</th>
<th>STOT RE 2</th>
<th>Aquatic Chronic 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H360D</td>
<td>H373</td>
<td>H412</td>
</tr>
</tbody>
</table>

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.

NO / EN