

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Multivitamin (with Sunflower Oil) Formulation

Version 1.2      Revision Date: 09.04.2021      SDS Number: 6773328-00003      Date of last issue: 21.12.2020  
Date of first issue: 15.10.2020

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### 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 Sub-stance/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

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### SECTION 2: Hazards identification


#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

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.

#### 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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Retinyl propionate	7069-42-3 230-363-2	Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 4; H413	>= 2.5 - < 10
(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 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 1 - < 10
2,6-Di-tert-butyl-p-cresol	128-37-0 204-881-4	Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0.25 - < 1

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		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Colecalciferol	67-97-0 200-673-2 603-180-00-4	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 2; H310 STOT RE 1; H372 (Kidney, Blood, Bone) Aquatic Chronic 4; H413  specific concentration limit STOT RE 1; H372 >= 3 % STOT RE 2; H373 0.3 - < 3 %  Acute toxicity estimate  Acute inhalation toxicity: 0.05 mg/l Acute dermal toxicity: 50 mg/kg	>= 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.  
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.

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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.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

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

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

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

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

#### 6.3 Methods and material for containment and cleaning up

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

#### 6.4 Reference to other sections

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

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### 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.

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Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
: 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

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	OELV - 8 hrs (TWA)	2 mg/m3	IE OEL
Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used				
Colecalciferol	67-97-0	TWA	5 µg/m3 (OEB 4)	Internal
		Wipe limit	50 µg/100 cm <sup>2</sup>	Internal

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

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

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	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/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	110 mg/m <sup>3</sup>
	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/m <sup>3</sup>
	Consumers	Inhalation	Acute systemic effects	27 mg/m <sup>3</sup>
	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/m <sup>3</sup>
	Workers	Dermal	Long-term systemic effects	0.5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.86 mg/m <sup>3</sup>
	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) according to Regulation (EC) No. 1907/2006:

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 weight (d.w.)
	(dl)-a-Tocopheryl acetate	Fresh water
Marine water		0.027 mg/l
Intermittent use/release		0.27 mg/l
Sewage treatment plant		100 mg/l
Fresh water sediment		212000 mg/kg
Marine sediment		21200 mg/kg
Soil		74800 mg/kg
Benzyl alcohol	Fresh water	1 mg/l

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	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

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 I.S. EN 14387

Filter type : Organic vapour type (A)



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### 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	
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/cm <sup>3</sup>
Relative vapour density	: No data available
Particle characteristics	
Particle size	: Not applicable

#### 9.2 Other information

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

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### 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 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

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### 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 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 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

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### **(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

#### **Colecalciferol:**

Species : Rabbit  
Result : No eye irritation

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### 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

##### 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

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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 cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

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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

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

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

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### 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



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### 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)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

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

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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 mg/l  
Exposure time: 180 min  
Method: OECD Test Guideline 209

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### **(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 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

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- 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:**
- 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

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### 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- : log Pow: 5.1

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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

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## 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.

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## 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)	:	Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	:	Not applicable

#### 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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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
- 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; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European



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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

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

### Classification of the mixture:

Repr. 1A	H360D
STOT RE 2	H373
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method
Calculation method
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.

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