# Multivitamin (with Rice Flour) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 24.02.2025 |
|---|---|---|---|
| 2.0 | 14.04.2025 | 11513708-00002 | Date of first issue: 24.02.2025 |

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

### 1.1 Product identifier

Trade name : Multivitamin (with Rice Flour) Formulation

Product code : Growmix Shrimp

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD
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 | 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:**

P201 Obtain special instructions before use.
P260 Do not breathe dust.
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 acetate
Colecalciferol

### 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.

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| (dl)-a-Tocopheryl acetate | 7695-91-2<br>231-710-0 | | >= 1 - < 10 |
| Nicotinic acid | 59-67-6<br>200-441-0 | Eye Irrit. 2; H319 | >= 1 - < 10 |
| Retinyl acetate | 127-47-9<br>204-844-2 | Repr. 1A; H360D<br>STOT RE 1; H372 (Liver)<br>Aquatic Chronic 3; H412 | >= 0,3 - < 1 |
| Menadione sodium bisulfite | 130-37-0<br>204-987-0<br>607-618-00-5 | Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br>_____<br>M-Factor (Acute aquatic toxicity): 1<br>M-Factor (Chronic aquatic toxicity): 1 | >= 0,25 - < 1 |
| Colecalciferol | 67-97-0<br>200-673-2<br>603-180-00-4 | Acute Tox. 2; H300<br>Acute Tox. 2; H330<br>Acute Tox. 2; H310<br>STOT RE 1; H372 (Kidney, Blood, Bone)<br>Aquatic Chronic 4; H413<br>_____<br>specific concentration limit<br>STOT RE 1; H372<br>>= 3 %<br>STOT RE 2; H373<br>0,3 - < 3 %<br><br>_____<br>Acute toxicity estimate<br><br>Acute oral toxicity: 35 mg/kg<br>Acute inhalation toxicity (dust/mist): 0,05 mg/l<br>Acute dermal toxicity: 50 mg/kg | >= 0,3 - < 1 |
| Pyridoxine hydrochloride | 58-56-0<br>200-386-2 | | >= 0,1 - < 1 |
| Substances with a workplace exposure limit : | | | |

| | | | |
|---|---|---|---|
| Ascorbic acid | 50-81-7<br>200-066-2 | | >= 1 - < 10 |

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 : If in eyes, rinse well with water.
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 : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Metal 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.
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 : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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 | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

**Occupational Exposure Limits**

Dust
5 mg/m3
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m3
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Ascorbic acid | 50-81-7 | TWA | 5000 µg/m3 (OEB 1) | Internal |
| (dl)-a-Tocopheryl acetate | 7695-91-2 | TWA | 5000 ug/m3 (OEB 1) | Internal |
| Colecalciferol | 67-97-0 | TWA | 5 µg/m3 (OEB 4) | Internal |
| | | Wipe limit | 50 µg/100 cm² | Internal |
| Pyridoxine hydro-chloride | 58-56-0 | TWA | OEB 3 (>= 10 < 100 µg/m3) | 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 |
| | Consumers | Skin contact | Long-term systemic effects | 250 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 12,5 mg/kg bw/day |
| Nicotinic acid | Workers | Inhalation | Long-term systemic | 0,5 mg/m3 |

| | | | | |
|---|---|---|---|---|
| | | | effects | |
| | Workers | Skin contact | Long-term systemic effects | 0,14 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 0,25 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 0,14 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,14 mg/kg bw/day |

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

| Substance name | Environmental Compartment | Value |
|---|---|---|
| (dl)-a-Tocopheryl acetate | Fresh water | 0,27 mg/l |
| | Freshwater - intermittent | 0,27 mg/l |
| | Marine water | 0,027 mg/l |
| | Sewage treatment plant | 100 mg/l |
| | Fresh water sediment | 212000 mg/kg dry weight (d.w.) |
| | Marine sediment | 21200 mg/kg dry weight (d.w.) |
| | Soil | 74800 mg/kg dry weight (d.w.) |
| Nicotinic acid | Fresh water | 0,077 mg/l |
| | Freshwater - intermittent | 0,77 mg/l |
| | Marine water | 0,008 mg/l |
| | Sewage treatment plant | 8,8 mg/l |
| | Fresh water sediment | 0,122 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,012 mg/kg dry weight (d.w.) |
| | Soil | 0,043 mg/kg dry weight (d.w.) |

### 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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**Personal protective equipment**

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>Filter should conform to NS EN 14387 |
| Filter type | : | Combined particulates and organic vapour type (A-P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | powder |
| Colour | : | White to light yellow |
| 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) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |

| | | |
|---|---|---|
| Viscosity, kinematic | : | Not applicable |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | Not applicable |
| Particle characteristics | | |
| Particle size | : | No data available |

**9.2 Other information**

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | Not applicable |
| 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 | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |

**10.4 Conditions to avoid**

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |

**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

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

**Components:**

**(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

**Nicotinic acid:**

Acute oral toxicity : LD50 (Rat, female): 4.500 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Rat): > 3,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Remarks: The test was conducted according to guideline

**Retinyl acetate:**

Acute oral toxicity : LD50 (Rat): 4.790 mg/kg

**Menadione sodium bisulfite:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

**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

**Pyridoxine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 4.000 mg/kg

**Ascorbic acid:**

Acute oral toxicity : LD50 (Rat): 11.900 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**(dl)-a-Tocopheryl acetate:**

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

**Nicotinic acid:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : The test was conducted equivalent or similar to guideline

**Retinyl acetate:**

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

**Menadione sodium bisulfite:**

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Remarks : The test was conducted according to guideline
Based on data from similar materials

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : The test was conducted according to guideline
Based on data from similar materials

Result : Skin irritation

**Pyridoxine hydrochloride:**

Species : Rabbit
Result : No skin irritation

**Ascorbic acid:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**(dl)-a-Tocopheryl acetate:**

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

**Nicotinic acid:**

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days
Remarks : The test was conducted according to guideline

**Retinyl acetate:**

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

**Menadione sodium bisulfite:**

Species : Bovine cornea
Method : OECD Test Guideline 437
Remarks : The test was conducted according to guideline
Based on data from similar materials

Species : Tissue Culture

Method : OECD Test Guideline 492
Remarks : The test was conducted according to guideline
Based on data from similar materials

Result : Irritation to eyes, reversing within 21 days

**Colecalciferol:**

Species : Rabbit
Result : No eye irritation

**Pyridoxine hydrochloride:**

Species : Rabbit
Result : No eye irritation

**Ascorbic acid:**

Species : Rabbit
Method : OECD Test Guideline 405
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:**

**(dl)-a-Tocopheryl acetate:**

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

**Nicotinic acid:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : The test was conducted equivalent or similar to guideline

**Retinyl acetate:**

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

**Colecalciferol:**

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

**Pyridoxine hydrochloride:**

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

**Ascorbic acid:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**(dl)-a-Tocopheryl acetate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Nicotinic acid:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative<br>Remarks: The test was conducted according to guideline<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br>Remarks: The test was conducted according to guideline |

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: The test was conducted according to guideline

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

**Menadione sodium bisulfite:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

**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.

**Pyridoxine hydrochloride:**

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

**Ascorbic acid:**

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: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:**

**(dl)-a-Tocopheryl acetate:**

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

**Ascorbic acid:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Ingestion |
| Exposure time | : | 2 Years |
| Result | : | negative |

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**(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

**Nicotinic acid:**

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

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.

**Pyridoxine hydrochloride:**

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

**Ascorbic acid:**

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:**

**Nicotinic acid:**

| | | |
|---|---|---|
| Assessment | : | No significant health effects observed in animals at concentrations of 100 mg/kg bw or less. |

**Retinyl acetate:**

| | | |
|---|---|---|
| Exposure routes | : | Ingestion |
| Target Organs | : | Liver |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |

**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:**

**(dl)-a-Tocopheryl acetate:**

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

**Nicotinic acid:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 50 mg/kg |
| LOAEL | : | 250 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 28 Days |
| Method | : | OECD Test Guideline 407 |
| Remarks | : | The test was conducted according to guideline |

**Retinyl acetate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 1,43 - 3,47 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**Colecalciferol:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 0,06 mg/kg |
| LOAEL | : | 0,3 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

Method : OECD Test Guideline 408

**Ascorbic acid:**

Species : Rat, male
NOAEL : >= 8.100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

**Aspiration toxicity**

Not classified based on available information.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

Not classified based on available information.

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**Experience with human exposure**

**Components:**

**Retinyl acetate:**

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:**

**(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)

**Nicotinic acid:**

Toxicity to fish : LC50 (Salmo trutta (brown trout)): 520 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 77 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: The test was conducted equivalent or similar to guideline

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 37,356 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted equivalent or similar to guideline

EC10 (Desmodesmus subspicatus (green algae)): 12,098 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted equivalent or similar to guideline

Toxicity to microorganisms : EC10 (Pseudomonas putida): 88 mg/l
Exposure time: 16 h
Method: OECD Test Guideline 209
Remarks: The test was conducted equivalent or similar to guideline

**Retinyl acetate:**

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): 46 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1.000 mg/l

Exposure time: 180 min
Method: OECD Test Guideline 209

**Menadione sodium bisulfite:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0,1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0,1 - 1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: The test was conducted according to guideline
Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): >0,01 - 0,1
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): >0,001 - 0,01
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

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

**Pyridoxine hydrochloride:**

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

**Ascorbic acid:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50 : 140 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

### 12.2 Persistence and degradability

**Components:**

**(dl)-a-Tocopheryl acetate:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 21,7 - 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

**Nicotinic acid:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 14 d
Method: OECD Test Guideline 301E
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 15 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

**Menadione sodium bisulfite:**

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 302C
Remarks: The test was conducted according to guideline
Based on data from similar materials

**Colecalciferol:**

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

**Pyridoxine hydrochloride:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 28 d
Method: OECD Test Guideline 301E

**Ascorbic acid:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 5 d
Method: OECD Test Guideline 302

### 12.3 Bioaccumulative potential

**Components:**

**Nicotinic acid:**

Partition coefficient: n-octanol/water : log Pow: -2,34
Method: OECD Test Guideline 117
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

Partition coefficient: n-octanol/water : log Pow: 9,4
Method: OECD Test Guideline 117

**Menadione sodium bisulfite:**

Partition coefficient: n-octanol/water : log Pow: -1,56
Remarks: Calculation

**Colecalciferol:**

Partition coefficient: n-octanol/water : log Pow: > 6,2
Method: OECD Test Guideline 107

**Pyridoxine hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: 4,32

**Ascorbic acid:**

Partition coefficient: n-octanol/water : log Pow: -1,85

### 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.
Do not dispose of waste into sewer.

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

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

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

**14.4 Packing group**

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

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Maritime transport in bulk according to IMO instruments**

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

| | | |
|---|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.<br><br>Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

| | | |
|---|---|---|
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Colecalciferol |

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:**

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

| | | |
|---|---|---|
| Other information | : | Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines. |

**Full text of H-Statements**

| | | |
|---|---|---|
| H300 | : | Fatal if swallowed. |
| H310 | : | Fatal in contact with skin. |
| H315 | : | Causes skin irritation. |
| H319 | : | Causes serious eye irritation. |
| H330 | : | Fatal if inhaled. |
| H360D | : | May damage the unborn child. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H400 | : | Very toxic to aquatic life. |
| H410 | : | Very toxic to aquatic life with long lasting effects. |
| H412 | : | Harmful to aquatic life with long lasting effects. |
| H413 | : | May cause long lasting harmful effects to aquatic life. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |

| | | |
|---|---|---|
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Irrit. | : | Eye irritation |
| Repr. | : | Reproductive toxicity |
| Skin Irrit. | : | Skin irritation |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| FOR-2011-12-06-1358 | : | Norway. Occupational Exposure limits |
| FOR-2011-12-06-1358 / TWA | : | Long term exposure limit |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

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

| **Classification of the mixture:** | | **Classification procedure:** |
|---|---|---|
| Repr. 1A | H360D | Calculation method |
| STOT RE 2 | H373 | Calculation method |
| Aquatic Chronic 3 | H412 | Calculation method |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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