

SAFETY DATA SHEET

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



Multivitamin (with Rice Flour) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2025
2.0	14.04.2025	11513732-00002	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 Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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

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

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

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2.2 Label elements

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

Hazard pictograms :

Signal word : Danger

Hazard statements :
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.

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. EC-No. Index-No.	Classification	Concentration (% w/w)
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	Registration number		
(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		$\geq 1 - < 10$
Nicotinic acid	59-67-6 200-441-0	Eye Irrit. 2; H319	$\geq 1 - < 10$
Retinyl acetate	127-47-9 204-844-2	Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 3; H412	$\geq 0.3 - < 1$
Menadione sodium bisulfite	130-37-0 204-987-0 607-618-00-5	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	$\geq 0.25 - < 1$
Colecalciferol	67-97-0 200-673-2 603-180-00-4	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 2; H310 STOT RE 1; H372 (Kidney, Blood, Bone) Aquatic Chronic 4; H413 specific concentra- tion limit STOT RE 1; H372 $\geq 3 \%$ STOT RE 2; H373 $0.3 - < 3 \%$	$\geq 0.3 - < 1$
Pyridoxine hydrochloride	58-56-0 200-386-2		$\geq 0.1 - < 1$
Substances with a workplace exposure limit :			
Ascorbic acid	50-81-7 200-066-2		$\geq 1 - < 10$

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

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advice.

- | | | |
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| 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 |
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potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container 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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.
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.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dust of any kind	10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40
	4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

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 cm ²	Internal
Pyridoxine hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal

Derived No Effect Level (DNEL)

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 effects	0.5 mg/m3
	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)

Substance name	Environmental Compartment	Value
(dl)-a-Tocopheryl acetate	Fresh water	0.27 mg/l

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	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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter should conform to BS EN 14387
- Filter type : Combined particulates and organic vapour type (A-P)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: powder
Colour	: White to light yellow
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: Not applicable
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
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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9.2 Other information

Molecular weight	:	No data available
Particle size	:	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. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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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
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Menadione sodium bisulfite:

Acute oral toxicity	: LD50 (Rat): > 2,000 mg/kg
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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
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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.

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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
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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.

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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.

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Components:

(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

Nicotinic acid:

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 Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative 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

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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
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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.

Pyridoxine hydrochloride:

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

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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

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	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.
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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

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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	: $\geq 8,100$ mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

Aspiration toxicity

Not classified based on available information.

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
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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

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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

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||toxicity)

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
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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
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Retinyl acetate:

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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:

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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 Other adverse effects

Product:

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

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

SECTION 14: Transport information

14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good

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IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

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The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable
UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Colecalciferol
Control of Major Accident Hazards Regulations 2015 (COMAH) : Not applicable

Other regulations:

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

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

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

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

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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
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA reference period)

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

Repr. 1A	H360D
STOT RE 2	H373

Classification procedure:

Calculation method
Calculation method

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Aquatic Chronic 3

H412

Calculation method

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GB / EN