Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 25.02.2025
2.0	14.04.2025	11514378-00002	Date of first issue: 25.02.2025

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

1.1 Product identifier

Trade name	:	Multivitamin (with Dextrose Monohydrate) Formulation
Product code	:	Prevensa Mivisol,Mivisol

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 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)

Serious eye damage, Category 1	H318: Causes serious eye damage.
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 2	H411: Toxic to aquatic life with long lasting effects.

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 :

H318	Causes serious eye damage.
H360D	May damage the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	Toxic 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:

P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P391	Collect spillage.

Hazardous components which must be listed on the label:

Zinc sulphate monohydrate
Manganese sulfate, monohydrate
Retinyl acetate

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.
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.	Classification	Concentration

	EC-No. Index-No. Registration number		(% w/w)
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10
Zinc sulphate monohydrate	7446-19-7 030-006-00-9	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——————— M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 3 - < 10
Manganese sulfate, monohydrate	10034-96-5	Eye Dam. 1; H318 STOT RE 1; H372 (Central nervous system, Respiratory Tract, Cardio-vascular system) Aquatic Chronic 2; H411	>= 2.5 - < 3
Nicotinic acid	59-67-6 200-441-0	Eye Irrit. 2; H319	>= 1 - < 10
Retinyl acetate	127-47-9 204-844-2	Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 3; H412	>= 0.3 - < 1
(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		>= 0.1 - < 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	>= 0.25 - < 1
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5 204-988-6		>= 0.1 - < 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	>= 0.1 - < 0.25

		(Kidney, Blood, Bone) Aquatic Chronic 4; H413 ——————— specific concentration limit STOT RE 1; H372 >= 3 % STOT RE 2; H373 0.3 - < 3 %	
Pyridoxine hydrochloride	58-56-0 200-386-2		>= 0.1 - < 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.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

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. Causes serious eye damage. 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) Sulphur oxides Metal oxides Chlorine compounds

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.

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.
Do not get in 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.
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
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 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

Manganese sulfate, monohydrate	10034-96-5	TWA (Inhalable)	0.2 mg/m3 (Manganese)	GB EH40
		TWA (Respirable fraction)	0.05 mg/m3 (Manganese)	GB EH40
		TWA (inhalable fraction)	0.2 mg/m3 (Manganese)	2017/164/EU
	Further information: Indicative			
		TWA (Respirable fraction)	0.05 mg/m3 (Manganese)	2017/164/EU
	Further information: Indicative			
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	TWA	100 ug/m3 (OEB 2)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m3 (OEB 4)	Internal
		Wipe limit	50 µg/100 cm²	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
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
Manganese sulfate, monohydrate	Workers	Inhalation	Long-term systemic effects	0.2 mg/m3
	Workers	Skin contact	Long-term systemic effects	0.00414 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.043 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.0021 mg/kg bw/day
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m3
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic	443.28 mg/m3

			effects	
	Consumers	Inhalation	Acute systemic effects	443.28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126.65 mg/kg bw/day
(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

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)
	Soil	33.1 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.)
Manganese sulfate, monohydrate	Fresh water	0.0128 mg/l
	Marine water	0.0004 mg/l
	Intermittent use/release	0.03 mg/l
	Sewage treatment plant	56 mg/l
	Fresh water sediment	0.0114 mg/kg
	Marine sediment	0.00114 mg/kg
	Soil	25.1 mg/kg

Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry weight (d.w.)
(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.)

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.
Equipment should conform to BS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	yellow, orange
Odour	:	characteristic
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.

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.

10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. 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 toxicological effects

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:

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Zinc sulphate monohydrate:

Acute oral toxicity : LD50 (Rat): > 1,000 mg/kg
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

Acute oral toxicity : LD50 (Rat): 2,150 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 4.45 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation 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

(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

Menadione sodium bisulfite:

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

Riboflavin 5'-(sodium hydrogen phosphate):

Acute oral toxicity	:	LD50 (Rat): > 20,000 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

Skin corrosion/irritation

Not classified based on available information.

Components:

Citric acid:

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

Zinc sulphate monohydrate:

Species	:	Rabbit
Method	:	OECD Test Guideline 404

Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Manganese sulfate, monohydrate:

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

(dl)-a-Tocopheryl acetate:

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

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Citric acid:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days

Zinc sulphate monohydrate:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irreversible effects on the eye
Remarks	:	Based on data from similar materials

Manganese sulfate, monohydrate:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irreversible effects on the eye

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

(dl)-a-Tocopheryl 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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	negative
Remarks	:	Based on data from similar materials

Manganese sulfate, monohydrate:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative
Remarks	:	Based on data from similar materials

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

(dl)-a-Tocopheryl acetate:

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Citric acid:

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

Test Type: in vitro micronucleus test
Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Zinc sulphate monohydrate:

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
Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

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 Remarks: Based on data from similar materials

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

(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

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

Riboflavin 5'-(sodium hydrogen phosphate):

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: 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

Carcinogenicity

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	1 Years
Result	:	negative
Remarks	:	Based on data from similar materials

Manganese sulfate, monohydrate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative

(dl)-a-Tocopheryl acetate:

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

Reproductive toxicity

May damage the unborn child.

Components:

Citric acid:

Effects on foetal development	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative

Zinc sulphate monohydrate:

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

Effects on fertility	:	Species: Rat 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.

(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

Pyridoxine hydrochloride:

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.

Components:

Citric acid:

Assessment	:	May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Manganese sulfate, monohydrate:

Target Organs	:	Central nervous system, Respiratory Tract, Cardio-vascular system
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

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:

Citric acid:

Species	:	Rat
NOAEL	:	4,000 mg/kg

LOAEL	:	8,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	10 Days

Zinc sulphate monohydrate:

Species	:	Rat
NOAEL	:	234 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks
Method	:	OECD Test Guideline 408
Remarks	:	Based on data from similar materials

Manganese sulfate, monohydrate:

Species	:	Rat, male
NOAEL	:	1,700 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks

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

(dl)-a-Tocopheryl acetate:

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

Riboflavin 5'-(sodium hydrogen phosphate):

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks
Method	:	OECD Test Guideline 408
Remarks	:	Based on data from similar materials

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.

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:

Citric acid:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h

Zinc sulphate monohydrate:

Toxicity to fish	:	EC50 (Oncorhynchus mykiss (rainbow trout)): 0.384 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)): 0.192 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Selenastrum capricornutum (fresh water algae)): 0.373 mg/l Exposure time: 96 h Remarks: Based on data from similar materials NOEC (Pseudokirchneriella subcapitata (green algae)): 34.5

		µg/l Remarks: Based on data from similar materials
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC: 205.2 µg/l Species: Jordanella floridae (flagfish) Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 415.7 µg/l Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	1

Manganese sulfate, monohydrate:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	NOEC (Desmodesmus subspicatus (green algae)): 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 ErC50 (Desmodesmus subspicatus (green algae)): 61 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC : 560 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	:	NOEC: 1.69 mg/l Exposure time: 65 d Species: Oncorhynchus mykiss (rainbow trout) Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 10 - 100 mg/l Exposure time: 7 d Species: Ceriodaphnia dubia (water flea)

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

(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)

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

Riboflavin 5'-(sodium hydrogen phosphate):

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 64.3 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 47.4 mg/l

aquatic invertebrates		Exposure time: 48 h Remarks: Based on data from similar materials

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

12.2 Persistence and degradability

Components:

Citric acid:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B

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

(dl)-a-Tocopheryl acetate:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 21.7 - 31 % Exposure time: 28 d Method: OECD Test Guideline 301C

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

Riboflavin 5'-(sodium hydrogen phosphate):

Biodegradability	:	Result: Readily biodegradable. Remarks: 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

12.3 Bioaccumulative potential

Components:

Citric acid:

Partition coefficient: n-octanol/water	:	log Pow: -1.72

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

Riboflavin 5'-(sodium hydrogen phosphate):

Partition coefficient: n-octanol/water	:	log Pow: -0.651 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

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	:	UN 3077
ADR	:	UN 3077
RID	:	UN 3077
IMDG	:	UN 3077
IATA	:	UN 3077

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (Zinc sulphate monohydrate, Menadione sodium bisulfite)

14.3 Transport hazard class(es)

		Class	Subsidiary risks
ADN	:	9	
ADR	:	9	
RID	:	9	
IMDG	:	9	
IATA	:	9	

14.4 Packing group

ADN

Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9

ADR

Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)

RID

Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9

IMDG

Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous	:	yes

ADR

Environmentally hazardous	:	yes

RID

Environmentally hazardous	:	yes

IMDG

Marine pollutant	:	yes

IATA (Passenger)

Environmentally hazardous	:	yes

IATA (Cargo)

Environmentally hazardous	:	yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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
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)

		Quantity 1	Quantity 2
E2	ENVIRONMENTAL HAZARDS	200 t	500 t

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.
H302	:	Harmful if swallowed.
H310	:	Fatal in contact with skin.
H315	:	Causes skin irritation.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H330	:	Fatal if inhaled.
H335	:	May cause respiratory irritation.
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.
H411	:	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 Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Irrit.	:	Skin irritation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
2017/164/EU	:	Europe. Commission Directive 2017/164/EU establishing a fourth list of indicative occupational exposure limit values
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
2017/164/EU / TWA	:	Limit Value - eight hours
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 - Interna-

tional 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:**
Eye Dam. 1	H318	Calculation method
Repr. 1A	H360D	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 2	H411	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.

GB / EN