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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 Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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 H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H411: Toxic to aquatic life with long lasting effects.

egory 2

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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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.

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

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

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

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% 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	>= 0.25 - < 1

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		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 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 (Kidney, Blood, Bone) Aquatic Chronic 4; H413 specific concentration limit STOT RE 1; H372 >= 3 % STOT RE 2; H373 0.3 - < 3 % Acute toxicity estimate Acute oral toxicity: 35 mg/kg Acute inhalation toxicity (dust/mist): 0.05 mg/l Acute dermal toxicity: 50 mg/kg	>= 0.1 - < 0.25
Pyridoxine hydrochloride	58-56-0 200-386-2	oo mg/kg	>= 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 ad-

vice 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

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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, 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.

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Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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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 as-

sessment

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 contami-

nated 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

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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

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Manganese sul- fate, monohydrate	10034-96-5	TWA (inhalable fraction)	0.2 mg/m3 (Manganese)	2017/164/EU	
	Further inform	Further information: Indicative			
		TWA (Respirable fraction)	0.05 mg/m3 (Manganese)	2017/164/EU	
	Further inform	nation: Indicative			
		OELV - 8 hrs (TWA) (respira- ble)	0.05 mg/m3 (Manganese)	IE OEL	
		OELV - 8 hrs (TWA) (inhalable fraction)	0.2 mg/m3 (Manganese)	IE OEL	
(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 cm ²	Internal	
Pyridoxine hydro- chloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal	

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Nicotinic acid	Workers	Inhalation	Long-term systemic effects	0.5 mg/m3
	Workers	Skin contact	Long-term systemic	0.14 mg/kg

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			effects	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 ef- fects	2068.62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443.28 mg/m3
	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 ef- fects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	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) according to Regulation (EC) No. 1907/2006

Substance name	Substance name Environmental Compartment	
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l

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1	1	1
	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,

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

Filter type

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, dis-

posable 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : yellow, orange

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : Not applicable

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Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling 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.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure 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

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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 inhala-

tion 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

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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

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

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(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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

Version Revision Date: SDS Number: Date of last issue: 25.02.2025 2.0 14.04.2025 11514380-00002 Date of first issue: 25.02.2025

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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- As-

sessment

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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 develop-

ment

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 develop-

ment

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 develop: Test Type: Embryo-foetal development

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ment 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 develop-

ment

Test Type: Embryo-foetal development

Species: Monkey

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Pyridoxine hydrochloride:

Effects on foetal develop-

ment

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Nicotinic acid:

Assessment : No significant health effects observed in animals at concentra-

tions 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 con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Citric acid:

Species : Rat

NOAEL: 4,000 mg/kgLOAEL: 8,000 mg/kgApplication Route: IngestionExposure 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:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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levels of 0.1% or higher.

Experience with human exposure

Components:

Retinyl acetate:

Ingestion : Symptoms: liver impairment

Remarks: Based on data from similar materials

Symptoms: Embryo-foetal toxicity

Remarks: Based on data from similar materials

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 tox-

icity)

1

Toxicity to fish (Chronic tox-

icity)

NOEC: 205.2 μg/l

Species: Jordanella floridae (flagfish)

Remarks: Based on data from similar materials

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) **Formulation**

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Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 415.7 µg/l

Species: Daphnia magna (Water flea)

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

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 tox-

icity)

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 (Chron-

ic 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

Exposure time: 72 h

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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 tox- : NOEC: 100 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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icity) 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 tox-

icity)

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 :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 47.4 mg/l

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 : EL50 (Daphnia magna (Water flea)): > 100 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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aquatic invertebrates 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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-

: log Pow: -1.72

octanol/water

Nicotinic acid:

Partition coefficient: n-

: log Pow: -2.34

octanol/water

Method: OECD Test Guideline 117

Remarks: The test was conducted according to guideline

Retinyl acetate:

Partition coefficient: n- : log Pow: 9.4

octanol/water Method: OECD Test Guideline 117

Menadione sodium bisulfite:

Partition coefficient: n- : log Pow: -1.56 octanol/water : Remarks: Calculation

Riboflavin 5'-(sodium hydrogen phosphate):

Partition coefficient: n- : log Pow: -0.651 ctanol/water : Remarks: Calculation

Colecalciferol:

Partition coefficient: n- : log Pow: > 6.2

octanol/water Method: OECD Test Guideline 107

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Multivitamin (with Dextrose Monohydrate) Formulation

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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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3077 ADR : UN 3077 RID : UN 3077

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hazard Identification Number : 90 Labels : 9

IMDG

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not

Not applicable

Not applicable

Not applicable

Colecalciferol

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EU) No 2024/590 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

E2 **ENVIRONMENTAL**

Quantity 1

Quantity 2

200 t 500 t

HAZARDS

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS not determined

DSL not determined

IECSC not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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
 Yery 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

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

2017/164/EU / TWA : Limit Value - eight hours

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 - Emergen-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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cy 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

compile the Safety Data Sheet

Sources of key data used to : 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

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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.

IE / EN

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