SAFETY DATA SHEET

Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 25.02.2025
2.0	14.04.2025	11513656-00002	Date of first issue: 25.02.2025

SECTION 1. IDENTIFICATION

Product identifier : Multivitamin (with Dextrose Monohydrate) Formulation

Product code : Prevensa Mivisol,Mivisol

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Serious eye damage : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 2 (Central nervous system, Respiratory Tract, Cardio-vascular system)

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

H360D May damage the unborn child.
H373 May cause damage to organs (Central nervous system, Respiratory Tract, Cardio-vascular system) 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Citric acid	77-92-9	Eye Irrit., 2A STOT SE, 3	>= 1 -< 5
Zinc sulphate monohydrate	7446-19-7	Acute Tox. (Oral), 4 Eye Dam., 1 Aquatic Acute, 1 Aquatic Chronic, 1	>= 3 -< 5
Sodium chloride	7647-14-5	Acute Tox. (Oral), 5	>= 1 -< 5
Manganese sulfate, monohydrate	10034-96-5	Acute Tox. (Oral), 5 Eye Dam., 1 STOT RE, (Central nervous system, Respiratory Tract, Cardio-vascular system) , 1 Aquatic Acute, 2 Aquatic Chronic, 2	>= 2,5 -< 3

Nicotinic acid	59-67-6	Acute Tox. (Oral), 5 Eye Irrit., 2A Aquatic Acute, 3	>= 1 -< 2,5
Retinyl acetate	127-47-9	Acute Tox. (Oral), 5 Skin Irrit., 3 Repr., 1A STOT RE, (Liver) , 1 Aquatic Acute, 3 Aquatic Chronic, 3	>= 0,3 -< 1
(dl)-a-Tocopheryl acetate	7695-91-2		>= 0,1 -< 1
Menadione sodium bisulfite	130-37-0	Skin Irrit., 2 Eye Irrit., 2A Aquatic Acute, 1 Aquatic Chronic, 1	>= 0,25 -< 1
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5		>= 0,1 -< 1
Colecalciferol	67-97-0	Acute Tox. (Oral), 2 Acute Tox. (Inhalation), 2 Acute Tox. (Dermal), 2 STOT RE, (Kidney, Blood, Bone) , 1 Aquatic Chronic, 4	>= 0,1 -< 0,25
Pyridoxine Hydrochloride	58-56-0	Acute Tox. (Oral), 5	>= 0,1 -< 1

SECTION 4. 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.

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.

Most important symptoms and effects, both acute and delayed	:	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.
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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
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) Sulfur oxides Metal oxides Chlorine compounds
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Methods and materials for containment and 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.

SECTION 7. HANDLING AND STORAGE

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.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Manganese sulfate, monohydrate	10034-96-5	LT (Dust)	5 mg/m³ (Manganese)	BR OEL
		LT (Fumes)	1 mg/m³ (Manganese)	BR OEL
		TWA (Inhalable particulate matter)	0,1 mg/m³ (Manganese)	ACGIH
		TWA (Respirable particulate matter)	0,02 mg/m³ (Manganese)	ACGIH
(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

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Color	:	yellow, orange
Odor	:	characteristic
Odor 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
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition 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.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5.000 mg/kg Method: Calculation method

Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5.000 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

Sodium chloride:

Acute oral toxicity	:	LD50 (Rat): 3.550 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 42 mg/l Exposure time: 1 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 5.000 mg/kg

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 judgment

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg
Method: Expert judgment

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

Sodium chloride:

Species	:	Rabbit
Result	:	No skin irritation

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

Zinc sulphate monohydrate:

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

Sodium chloride:

Species	:	Rabbit
Result	:	No eye irritation

Manganese sulfate, monohydrate:

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

Nicotinic acid:

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

Retinyl acetate:

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

(dl)-a-Tocopheryl acetate:

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

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

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

Sodium chloride:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

Manganese sulfate, monohydrate:

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

Nicotinic acid:

Test Type	:	Maximization Test
Routes of exposure	:	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	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

(dl)-a-Tocopheryl acetate:

Test Type	:	Draize Test
Routes of exposure	:	Skin contact
Species	:	Humans
Result	:	negative

Colecalciferol:

Test Type	:	Maurer optimisation test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Pyridoxine Hydrochloride:

Test Type	:	Maximization Test
Routes of exposure	:	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

Sodium chloride:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: positive

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

Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive

Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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

Sodium chloride:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

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 fetal 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 fetal development	:	Test Type: Embryo-fetal 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 fetal development	:	Test Type: Embryo-fetal 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 fetal development	:	Test Type: Embryo-fetal 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 fetal development	:	Test Type: Embryo-fetal development Species: Rabbit Application Route: Ingestion Result: negative

Pyridoxine Hydrochloride:

Effects on fetal development	:	Test Type: Embryo-fetal 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 (Central nervous system, Respiratory Tract, Cardio-vascular system) 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:

Routes of exposure : Ingestion
Target Organs : Liver
Assessment : Causes damage to organs through prolonged or repeated exposure.

Colecalciferol:

Routes of exposure : 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

Sodium chloride:

Species	:	Rat
LOAEL	:	2.533 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 y

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-fetal toxicity. Remarks: Based on data from similar materials

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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 (Jordanella floridae (flagfish)): 205,2 µg/l Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 415,7 µg/l Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	1

Sodium chloride:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 4.136 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50: > 2.000 mg/l Exposure time: 96 h
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 252 mg/l Exposure time: 33 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia pulex (Water flea)): 314 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10: > 1.000 mg/l

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 fish (Chronic toxicity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 1,69 mg/l Exposure time: 65 d Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chron-	:	NOEC (Ceriodaphnia dubia (water flea)): > 10 - 100 mg/l Exposure time: 7 d

ic toxicity)

Toxicity to microorganisms	:	NOEC: 560 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

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 fish (Chronic toxicity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l Exposure time: 28 d
Toxicity to microorganisms	:	EC50: > 927 mg/l Exposure time: 30 min Method: ISO 8192

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 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 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

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

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
Class	:	9
Packing group	:	III

Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc sulphate monohydrate, Menadione sodium bisulfite)
Class	:	9
Packing group	:	III
Labels	:	9
Hazard Identification Number	:	90

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.

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
Brazil. List of chemicals controlled by the Federal Police	:	Not applicable

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

AICS	:	not determined
DSL	:	not determined

IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	:	14.04.2025
Date format	:	dd.mm.yyyy

Further information

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

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 other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
BR OEL	:	Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA	:	8-hour, time-weighted average
BR OEL / LT	:	Up to 48 hours /week

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

BR / Z8