Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/25
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Multivitamin (with Dextrose Monohydrate) Formulation

Product code : Prevensa Mivisol,Mivisol

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : powder
Colour : yellow, orange
Odour : characteristic

Causes serious eye damage. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

GHS Classification

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 2

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic : Category 2

hazard

GHS label elements

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:

P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.
P318 IF exposed or concerned, get medical advice.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes serious eye damage. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Citric acid	77-92-9	>= 1 -< 10
Zinc sulphate monohydrate	7446-19-7	>= 3 -< 10
Sodium chloride	7647-14-5	>= 1 -< 10
Manganese sulfate, monohydrate	10034-96-5	>= 2.5 -< 3
Nicotinic acid	59-67-6	>= 1 -< 2.5
Retinyl acetate	127-47-9	>= 0.3 -< 1
(dl)-a-Tocopheryl acetate	7695-91-2	>= 0.1 -< 1
Menadione sodium bisulfite	130-37-0	>= 0.25 -< 1
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	>= 0.1 -< 1
Colecalciferol	67-97-0	>= 0.1 -< 0.25
Pyridoxine hydrochloride	58-56-0	>= 0.1 -< 1

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.

5. FIREFIGHTING 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) Sulphur 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

7. HANDLING AND STORAGE

Handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	:	Oxidizing agents

Storage

Conditions for safe storage	:	Keep in properly labelled 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
Packaging material	:	Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Manganese sulfate, monohydrate	10034-96-5	PC-TWA	0.15 mg/m3 (MnO2)	CN 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

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	yellow, orange
Odour	:	characteristic
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

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.

11. TOXICOLOGICAL INFORMATION

Exposure routes	:	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 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

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

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

Sodium chloride:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	negative

Manganese sulfate, monohydrate:

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

Nicotinic acid:

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

Retinyl acetate:

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

(dl)-a-Tocopheryl acetate:

Test Type	:	Draize Test
Exposure routes	:	Skin contact

Species	:	Humans
Result	:	negative

Colecalciferol:

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

Pyridoxine hydrochloride:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Citric acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro micronucleus test Result: positive Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

Zinc sulphate monohydrate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Remarks: Based on data from similar materials

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

Zinc sulphate monohydrate:

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

Manganese sulfate, monohydrate:

Effects on fertility	:	Species: Rat Application Route: Ingestion Result: negative

Nicotinic acid:

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

Retinyl acetate:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Monkey Application Route: Ingestion Result: positive Remarks: Based on data from similar materials
Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on development from human epidemiological studies.

(dl)-a-Tocopheryl acetate:

Effects on fertility	:	Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Result: negative

Pyridoxine hydrochloride:

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

STOT - single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment	:	May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Manganese sulfate, monohydrate:

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

Nicotinic acid:

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

Retinyl acetate:

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

Colecalciferol:

Exposure routes	:	Ingestion
Target Organs	:	Kidney, Blood, Bone
Assessment	:	Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Citric acid:

Species	:	Rat
NOAEL	:	4,000 mg/kg
LOAEL	:	8,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	10 Days

Zinc sulphate monohydrate:

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

Sodium chloride:

Species	:	Rat
LOAEL	:	2,533 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 yr

Manganese sulfate, monohydrate:

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

Nicotinic acid:

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

Retinyl acetate:

Species	:	Rat
NOAEL	:	1.43 - 3.47 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

(dl)-a-Tocopheryl acetate:

Species	:	Rat
NOAEL	:	500 mg/kg

Application Route	:	Ingestion
Exposure time	:	90 Days

Riboflavin 5'-(sodium hydrogen phosphate):

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

Colecalciferol:

Species	:	Rat
NOAEL	:	0.06 mg/kg
LOAEL	:	0.3 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Retinyl acetate:

Ingestion	:	Symptoms: liver impairment Remarks: Based on data from similar materials Symptoms: Embryo-foetal toxicity Remarks: Based on data from similar materials

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 (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): > 10 - 100 mg/l Exposure time: 7 d
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

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.

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.

National Regulations

GB 6944/12268

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
Marine pollutant : yes

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.

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA	:	8-hour, time-weighted average
CN OEL / PC-TWA	:	Permissible concentration - time weighted average

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

Disclaimer

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.

CN / EN