

# Multivitamin (with Dextrose Monohydrate) Formulation

Version Revision Date: SDS Number: Date of last issue: 2025/02/25 2.0 2025/04/14 11513661-00002 Date of first issue: 2025/02/25

#### 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 : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

#### 2. HAZARDS IDENTIFICATION

**GHS Classification** 

Serious eye damage/eye irri-

tation

Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - :

repeated exposure

Category 2 (Central nervous system, Respiratory Tract, Cardio-

vascular system)

Long-term (chronic) aquatic

hazard

Category 2

**GHS** label elements

Hazard pictograms



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.



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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.

P202 Do not handle until all safety precautions have been read and understood.

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.

#### Disposal:

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

#### 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	< 10
Zinc sulphate monohydrate	7446-19-7	>= 3 -< 10
Manganese sulfate, monohydrate	10034-96-5	>= 2.5 -< 3
Nicotinic acid	59-67-6	< 10
Retinyl acetate	127-47-9	>= 0.3 -< 1
(dl)-a-Tocopheryl acetate	7695-91-2	< 10
Menadione sodium bisulfite	130-37-0	>= 0.25 -< 2.5
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	< 10
Colecalciferol	67-97-0	>= 0.025 -< 0.25



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Pyridoxine hydrochloride 58-56-0 < 10

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn. Get medical attention immediately.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes serious eye damage.

May damage the unborn child.

May cause damage to organs through prolonged or repeated

Contact with dust can cause mechanical irritation or drying of

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).

Treat symptomatically and supportively. Notes to physician

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 prod: : Carbon oxides



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ucts Nitrogen oxides (NOx)

Sulphur oxides Metal oxides

Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

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, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer for disposal.

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

with compressed air).

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

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 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



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ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

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

#### 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, monohy- drate	10034-96-5	NAB (Res- pirable par-	0.02 mg/m3 (Manganese)	ID OEL	
urate		ticulate mat-	(Manganese)		
		ter)			
	Further information: Not classified as carcinogenic to humans. Not				
	enough data to classify these materials as carcinogenic to hu-				
	mans or anima				
		NAB (Inhala-	0.1 mg/m3	ID OEL	
		ble particu-	(Manganese)		
		late matter)			
	Further information: Not classified as carcinogenic to humans. Not				
	enough data to classify these materials as carcinogenic to hu-				
	mans or animals				
		TWA (Inhal-	0.1 mg/m3	ACGIH	
		able particu-	(Manganese)		
		late matter)			
		TWA (Res-	0.02 mg/m3	ACGIH	
		pirable par-	(Manganese)		
		ticulate mat-			



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II		ter)		
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	TWA	100 ug/m3 (OEB 2)	Internal
Colecalciferol	67-97-0	TWA	5 μg/m3 (OEB 4)	Internal
		Wipe limit	50 μg/100 cm <sup>2</sup>	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 con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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



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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, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

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



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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 reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.
Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

### 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: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method



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### Components:

Citric acid:

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

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Zinc sulphate monohydrate:

Acute oral toxicity : LD50 (Rat): > 1,000 mg/kg

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

Acute oral toxicity : LD50 (Rat): 2,150 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 4.45 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Nicotinic acid:

Acute oral toxicity : LD50 (Rat, female): 4,500 mg/kg

Method: OECD Test Guideline 401

Remarks: The test was conducted equivalent or similar to

guideline

Acute inhalation toxicity : LC50 (Rat): > 3.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 436

Remarks: The test was conducted according to guideline

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: The test was conducted according to guideline

Retinyl acetate:



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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



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### 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



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Zinc sulphate monohydrate:

Species : Rabbit

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

Remarks : Based on data from similar materials

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



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## Pyridoxine hydrochloride:

Species : Rabbit

Result : No eye irritation

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

#### Zinc sulphate monohydrate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Remarks : Based on data from similar materials

#### Manganese sulfate, monohydrate:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : negative

Remarks : Based on data from similar materials

#### Nicotinic acid:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : The test was conducted equivalent or similar to guideline

#### Retinyl acetate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

### (dl)-a-Tocopheryl acetate:

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



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**Colecalciferol:** 

Test Type : Maurer optimisation test

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Pyridoxine hydrochloride:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Zinc sulphate monohydrate:

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

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

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

Result: negative



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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



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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



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Species: Rat

Application Route: Ingestion

Result: positive

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Pyridoxine hydrochloride:

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

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Zinc sulphate monohydrate:

Species : Mouse
Application Route : Ingestion
Exposure time : 1 Years
Result : negative

Remarks : Based on data from similar materials

Manganese sulfate, monohydrate:

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

(dl)-a-Tocopheryl acetate:

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

Reproductive toxicity

May damage the unborn child.

**Components:** 

Citric acid:

Effects on foetal develop: Test Type: One-generation reproduction toxicity study

ment Species: Rat

Application Route: Ingestion

Result: negative

Zinc sulphate monohydrate:



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Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

Effects on fertility : Species: Rat

**Application Route: Ingestion** 

Result: negative

Nicotinic acid:

ment

Effects on foetal develop-

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 develop-

ment

Test Type: Embryo-foetal development

Species: Monkey

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

(dl)-a-Tocopheryl acetate:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: negative



## Multivitamin (with Dextrose Monohydrate) Formulation

Version Revision Date: SDS Number: Date of last issue: 2025/02/25 2.0 2025/04/14 11513661-00002 Date of first issue: 2025/02/25

Pyridoxine hydrochloride:

Effects on foetal develop- : Test Type: Embryo-foetal development

ment 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 concentra-

tions of 100 mg/kg bw or less.

Retinyl acetate:

Exposure routes : Ingestion Target Organs : Liver

Assessment : Causes damage to organs through prolonged or repeated

exposure.

**Colecalciferol:** 

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Bone

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

**Components:** 

Citric acid:



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Species : Rat

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

### Zinc sulphate monohydrate:

Species : Rat

NOAEL : 234 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

#### Manganese sulfate, monohydrate:

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

#### Nicotinic acid:

Species : Rat

NOAEL : 50 mg/kg

LOAEL : 250 mg/kg

Application Route : Ingestion

Exposure time : 28 Days

Method : OECD Test Guideline 407

Remarks : The test was conducted according to guideline

### Retinyl acetate:

Species : Rat

NOAEL : 1.43 - 3.47 mg/kg

Application Route : Ingestion Exposure time : 90 Days

### (dl)-a-Tocopheryl acetate:

Species : Rat

NOAEL : 500 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

### Riboflavin 5'-(sodium hydrogen phosphate):

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion



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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



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Exposure time: 96 h

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 34.5

µg/l

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-

icity)

NOEC (Jordanella floridae (flagfish)): 205.2 µg/l

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 415.7 µg/l Remarks: Based on data from similar materials

M-Factor (Chronic aquatic :

toxicity)

Manganese sulfate, monohydrate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

NOEC (Desmodesmus subspicatus (green algae)): 1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

ErC50 (Desmodesmus subspicatus (green algae)): 61 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

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-

ic 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



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aquatic invertebrates

Toxicity to daphnia and other : 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

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted equivalent or similar to

guideline

EC10 (Pseudomonas putida): 88 mg/l Toxicity to microorganisms

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

EC50 (activated sludge): > 1,000 mg/l Toxicity to microorganisms

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



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NOEC (Pseudokirchneriella subcapitata (green algae)): >=

100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

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 tox- : 1

city)

M-Factor (Chronic aquatic

1

toxicity)

Riboflavin 5'-(sodium hydrogen phosphate):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 64.3 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 47.4 mg/l



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aquatic invertebrates Exposure time: 48 h

Remarks: Based on data from similar materials

Colecalciferol:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EL50 (Scenedesmus capricornutum (fresh water algae)): >

100 ma/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



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(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- :

: log Pow: -1.72

l octanol/water
Nicotinic acid:

Partition coefficient: n- : log Pow: -2.34

octanol/water Method: OECD Test Guideline 117

Remarks: The test was conducted according to guideline

Retinyl acetate:

Partition coefficient: n- : log Pow: 9.4

octanol/water Method: OECD Test Guideline 117

Menadione sodium bisulfite:



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Partition coefficient: n- : log Pow: -1.56

octanol/water Remarks: Calculation

Riboflavin 5'-(sodium hydrogen phosphate):

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

Partition coefficient: n- : log Pow: > 6.2

octanol/water Method: OECD Test Guideline 107

Pyridoxine hydrochloride:

Partition coefficient: n- : log Pow: 4.32

octanol/water

Colecalciferol:

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 han-

dling 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



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Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

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.

#### 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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable Prohibited substances : Not applicable Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I



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Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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 Agen-

cy, 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)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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



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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

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.

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