according to the Hazardous Products Regulations



Multivitamin (with Dextrose Monohydrate) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 3.0 06/18/2025 11513657-00003 Date of first issue: 02/25/2025

SECTION 1. IDENTIFICATION

Product name : Multivitamin (with Dextrose Monohydrate) Formulation

Product code : Prevensa Mivisol, Mivisol

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Serious eye damage : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity : Category

- repeated exposure

Category 1 (Central nervous system, Respiratory Tract, Cardio-

vascular system)

GHS label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

H360D May damage the unborn child.

H372 Causes damage to organs (Central nervous system, Respiratory Tract, Cardio-vascular system) through prolonged or

repeated exposure.

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.

P264 Wash skin thoroughly after handling.

according to the Hazardous Products Regulations



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P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protection and 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.

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Citric acid	2- hydroxypro- pane-1,2,3- tricarboxylic acid	77-92-9	>= 1 - < 5 *
Zinc sulphate monohy- drate	Sulfuric acid, zinc salt, mono- hydrate	7446-19-7	>= 1 - < 5 *
Manganese sulfate, monohydrate	No data availa- ble	10034-96-5	>= 1 - < 5 *
Nicotinic acid	3- Pyridinecarbox- ylic acid	59-67-6	>= 1 - < 5 *
Retinyl acetate	No data availa- ble	127-47-9	>= 0.1 - < 1 *
(dl)-a-Tocopheryl ace- tate	2H-1- Benzopyran-6- ol, 3,4-dihydro- 2,5,7,8- tetramethyl-2- (4,8,12- trimethyl- tridecyl)-, 6-	7695-91-2	>= 0.1 - < 1 *

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	acetate		
Riboflavin 5'-(sodium hydrogen phosphate)	Riboflavin phosphate sodi- um	130-40-5	>= 0.1 - < 1 *
Colecalciferol	Cyclohexanol, 3-[(2E)-2- [(1R,3aS,7aR)- 1-[(1R)-1,5- dimethylhex- yl]octahydro-7a- methyl-4H- inden-4- yli- dene]ethylidene] -4-methylene-, (1S	67-97-0	>= 0.1 - < 0.3 *
Pyridoxine Hydrochlo- ride	3,4- Pyridinedi- methanol, 5- hydroxy-6- methyl-, hydro- chloride	58-56-0	>= 0.1 - < 1 *

^{*} Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

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.

Causes damage to organs through prolonged or repeated

exposure.

according to the Hazardous Products Regulations



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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

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulfur 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

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency 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

according to the Hazardous Products Regulations



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with compressed air).

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

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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

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

Wash skin thoroughly after handling.

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

assessment

Keep container tightly closed.

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

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

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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
•				

according to the Hazardous Products Regulations



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		(Form of	ters / Permissible	
		exposure)	concentration	
Manganese sulfate, monohydrate	10034-96-5	TWA	0.2 mg/m ³ (Manganese)	CA AB OEL
, ,		TWA (Respirable)	0.02 mg/m³ (Manganese)	CA BC OEL
		TWAEV (in- halable dust)	0.2 mg/m³ (Manganese)	CA QC OEL
		TWAEV (respirable aerosol frac- tion)	0.05 mg/m³ (Manganese)	CA QC OEL
		TWA (Inhal- able)	0.1 mg/m³ (Manganese)	CA BC 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 cm ²	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)

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
Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

according to the Hazardous Products Regulations



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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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : yellow, orange

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

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

handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

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Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Autoignition temperature

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

No data available Particle size

SECTION 10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

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

No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact

according to the Hazardous Products Regulations



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Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

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

Method: Calculation method

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

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

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

Method: Calculation method

Components:

Citric acid:

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

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Zinc sulphate monohydrate:

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

Remarks: Based on data from similar materials

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

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

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

Remarks: Based on data from similar materials

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

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Nicotinic acid:

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

Method: OECD Test Guideline 401

according to the Hazardous Products Regulations



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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

Riboflavin 5'-(sodium hydrogen phosphate):

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

Colecalciferol:

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 0.05 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg

Method: Expert judgment

Pyridoxine Hydrochloride:

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Citric acid:

according to the Hazardous Products Regulations



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Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Zinc sulphate monohydrate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Manganese sulfate, monohydrate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Nicotinic acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : The test was conducted equivalent or similar to guideline

Retinyl acetate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

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

according to the Hazardous Products Regulations



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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

Colecalciferol:

Species : Rabbit

Result : No eye irritation

Pyridoxine Hydrochloride:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse Result : negative

according to the Hazardous Products Regulations



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Remarks : Based on data from similar materials

Manganese sulfate, monohydrate:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact Result : negative

Remarks : Based on data from similar materials

Nicotinic acid:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : The test was conducted equivalent or similar to guideline

Retinyl acetate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

(dl)-a-Tocopheryl acetate:

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

Colecalciferol:

Test Type : Maurer optimisation test

Routes of exposure : Skin contact Species : Guinea pig Result : negative

Pyridoxine Hydrochloride:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Citric acid:

according to the Hazardous Products Regulations



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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Zinc sulphate monohydrate:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Nicotinic acid:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro

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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

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:

according to the Hazardous Products Regulations



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

Method: OECD Test Guideline 471

Result: equivocal

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

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

cytogenetic assay)

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Test Type: In vivo mammalian alkaline comet assay

Species: Rat

Application Route: Ingestion

Result: positive

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Pyridoxine Hydrochloride:

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

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Zinc sulphate monohydrate:

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

Remarks : Based on data from similar materials

Manganese sulfate, monohydrate:

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

according to the Hazardous Products Regulations



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(dl)-a-Tocopheryl acetate:

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

Reproductive toxicity

May damage the unborn child.

Components:

Citric acid:

Effects on fetal development : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Zinc sulphate monohydrate:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Manganese sulfate, monohydrate:

Effects on fertility : Species: Rat

Application Route: Ingestion

Result: negative

Nicotinic acid:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: The test was conducted according to guideline

Retinyl acetate:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Monkey

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

according to the Hazardous Products Regulations



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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 fetal development : Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Pyridoxine Hydrochloride:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT-single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Causes 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:

Routes of exposure : Ingestion
Target Organs : Liver

according to the Hazardous Products Regulations



Multivitamin (with Dextrose Monohydrate) Formulation

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Assessment : Causes damage to organs through prolonged or repeated

exposure.

Colecalciferol:

Routes of exposure : Ingestion

Target Organs : Kidney, Blood, Bone

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

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Citric acid:

Species : Rat

NOAEL: 4,000 mg/kgLOAEL: 8,000 mg/kgApplication Route: IngestionExposure time: 10 Days

Zinc sulphate monohydrate:

Species: RatNOAEL: 234 mg/kgApplication Route: IngestionExposure 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

according to the Hazardous Products Regulations



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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/kgApplication 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 Davs

Method **OECD Test Guideline 408**

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Retinyl acetate:

Ingestion Symptoms: liver impairment

Remarks: Based on data from similar materials

Symptoms: Embryo-fetal toxicity.

Remarks: Based on data from similar materials

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Citric acid:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

according to the Hazardous Products Regulations



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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

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

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

according to the Hazardous Products Regulations



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Nicotinic acid:

Toxicity to fish LC50 (Salmo trutta (brown trout)): 520 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: The test was conducted according to guideline

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 77 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: The test was conducted equivalent or similar to

guideline

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 37.356

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted equivalent or similar to

quideline

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

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:

aquatic invertebrates

Toxicity to daphnia and other : 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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

according to the Hazardous Products Regulations



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plants mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

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

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

aquatic invertebrates

Toxicity to daphnia and other : 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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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Bioaccumulative potential

Components:

Citric acid:

Partition coefficient: n-

: log Pow: -1.72

octanol/water

Nicotinic acid:

Partition coefficient: n- : log Pow: -2.34

octanol/water Method: OECD Test Guideline 117

Remarks: The test was conducted according to guideline

Retinyl acetate:

Partition coefficient: n-

log Pow: 9.4

octanol/water

Method: OECD Test Guideline 117

Riboflavin 5'-(sodium hydrogen phosphate):

Partition coefficient: n- : log Pow: -0.651

octanol/water Remarks: Calculation

Colecalciferol:

Partition coefficient: n- : log Pow: > 6.2

octanol/water Method: OECD Test Guideline 107

Pyridoxine Hydrochloride:

Partition coefficient: n-

octanol/water

log Pow: 4.32

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

according to the Hazardous Products Regulations



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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 : 956

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Zinc sulphate monohydrate, Menadione sodium bisulfite)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation

TDG

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
ERG Code : 171

Marine pollutant : yes(Zinc sulphate monohydrate, Menadione sodium bisulfite)

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.

according to the Hazardous Products Regulations



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SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

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 Tempera-

according to the Hazardous Products Regulations



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ture; 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

Sources of key data used to

compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 06/18/2025 Date format : mm/dd/yyyy

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8