

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### SECTION 1. IDENTIFICATION

Product name : Multivitamin (with Dextrose Monohydrate) Formulation  
Product code : Prevensa Mivisol, Mivisol

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
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 OSHA Hazard Communication Standard (29 CFR 1910.1200)



Combustible dust

Serious eye damage : Category 1  
Reproductive toxicity : Category 1A  
Specific target organ toxicity : Category 1 (Central nervous system, Respiratory Tract, Cardio-vascular system)  
- repeated exposure

#### Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

#### GHS label elements

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
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.

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Version 3.0      Revision Date: 06/18/2025      SDS Number: 11513638-00003      Date of last issue: 04/14/2025  
Date of first issue: 02/25/2025

Supplemental Hazard Statements : Corrosive to the respiratory tract.

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.  
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.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Citric acid	77-92-9*	>= 1 - <= 5	TSC
Zinc sulphate monohydrate	7446-19-7*	>= 1 - <= 5	TSC
Manganese sulfate, monohydrate	10034-96-5*	>= 1 - <= 5	TSC
Nicotinic acid	59-67-6*	>= 1 - <= 5	TSC
Retinyl acetate	127-47-9*	>= 0.5 - <= 1.5	TSC
(dl)-a-Tocopheryl acetate	7695-91-2*	>= 0.1 - <= 1	TSC
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5*	>= 0.1 - <= 1	TSC
Colecalciferol	67-97-0*	>= 0.1 - <= 1	TSC

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

Pyridoxine Hydrochloride	58-56-0*	>= 0.1 - <= 1	TSC
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\* Indicates that the identifier is a CAS No.

TSC- the 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 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. Causes damage to organs through prolonged or repeated exposure. Corrosive to the respiratory tract.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

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according to the OSHA Hazard Communication Standard



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Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

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|--|---|
| Hazardous combustion products                  | : Carbon oxides<br>Nitrogen oxides (NOx)<br>Sulfur oxides<br>Metal oxides<br>Chlorine compounds   |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |  |
|---|--|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : If sufficient ventilation is unavailable, use with local exhaust   |

# SAFETY DATA SHEET

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## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

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|-----------------------------|--|
| Advice on safe handling     | :<br>ventilation.<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | :<br>Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | :<br>Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases  |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

- |                                      |  |
|--------------------------------------|--|
| inert or nuisance dust               | 50 Million particles per cubic foot<br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3          |
|                                      | 15 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3                         |
|                                      | 5 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3                 |
|                                      | 15 Million particles per cubic foot<br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3 |
| Dust, nuisance dust and particulates | 10 mg/m <sup>3</sup><br>Value type (Form of exposure): PEL (Total dust)<br>Basis: CAL PEL                          |

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0      Revision Date: 06/18/2025      SDS Number: 11513638-00003      Date of last issue: 04/14/2025  
Date of first issue: 02/25/2025

5 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Manganese sulfate, monohydrate	10034-96-5	C	5 mg/m <sup>3</sup> (Manganese)	OSHA Z-1
		TWA (Inhalable particulate matter)	0.1 mg/m <sup>3</sup> (Manganese)	ACGIH
		TWA (Respirable particulate matter)	0.02 mg/m <sup>3</sup> (Manganese)	ACGIH
		TWA	1 mg/m <sup>3</sup> (Manganese)	NIOSH REL
		ST	3 mg/m <sup>3</sup> (Manganese)	NIOSH REL
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m <sup>3</sup> (OEB 1)	Internal
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	TWA	100 ug/m <sup>3</sup> (OEB 2)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	50 µg/100 cm <sup>2</sup>	Internal
Pyridoxine Hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m <sup>3</sup> )	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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

### Hand protection

Material : Chemical-resistant gloves

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

Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

### SECTION 10. STABILITY AND REACTIVITY

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



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Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 31.26 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

##### **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-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0      Revision Date: 06/18/2025      SDS Number: 11513638-00003      Date of last issue: 04/14/2025  
Date of first issue: 02/25/2025

	tion toxicity
	<b>Nicotinic acid:</b>
	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
	<b>Retinyl acetate:</b>
	Acute oral toxicity : LD50 (Rat): 4,790 mg/kg
	<b>(dl)-a-Tocopheryl acetate:</b>
	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
	<b>Riboflavin 5'-(sodium hydrogen phosphate):</b>
	Acute oral toxicity : LD50 (Rat): > 20,000 mg/kg
	<b>Colecalciferol:</b>
	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
	<b>Pyridoxine Hydrochloride:</b>
	Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Citric acid:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

#### Zinc sulphate monohydrate:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
Remarks	: Based on data from similar materials

#### Manganese sulfate, monohydrate:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

#### Nicotinic acid:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
Remarks	: The test was conducted equivalent or similar to guideline

#### Retinyl acetate:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: Mild skin irritation

#### (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
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

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

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### Components:

#### **Zinc sulphate monohydrate:**

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

#### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### 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
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
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

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

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### 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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### Nicotinic acid:

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

### Retinyl acetate:

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Monkey  
Application Route: Ingestion  
Result: positive  
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

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

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

### Pyridoxine Hydrochloride:

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

### STOT-single exposure

Corrosive to the respiratory tract.

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0      Revision Date: 06/18/2025      SDS Number: 11513638-00003      Date of last issue: 04/14/2025  
Date of first issue: 02/25/2025

### Components:

#### **Manganese sulfate, monohydrate:**

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

#### **Nicotinic acid:**

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

#### **Retinyl acetate:**

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

#### **Colecalciferol:**

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

### **Repeated dose toxicity**

### Components:

#### **Citric acid:**

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

#### **Zinc sulphate monohydrate:**

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

#### **Manganese sulfate, monohydrate:**

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---



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

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Citric acid:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h

##### **Zinc sulphate monohydrate:**

Toxicity to fish	: EC50 (Oncorhynchus mykiss (rainbow trout)): 0.384 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.192 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: EC50 (Selenastrum capricornutum (fresh water algae)): 0.373 mg/l Exposure time: 96 h Remarks: Based on data from similar materials  NOEC (Pseudokirchneriella subcapitata (green algae)): 34.5 µg/l Remarks: Based on data from similar materials
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

##### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

	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
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

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

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

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

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

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

##### Colecalciferol:

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: <= 7 %

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0	Revision Date: 06/18/2025	SDS Number: 11513638-00003	Date of last issue: 04/14/2025 Date of first issue: 02/25/2025
----------------	------------------------------	-------------------------------	---

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

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

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

##### Colecalciferol:

Partition coefficient: n-octanol/water : log Pow: > 6.2  
Method: OECD Test Guideline 107

##### Pyridoxine Hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 4.32

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

Contaminated packaging : Do not dispose of waste into sewer.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

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

##### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Zinc sulphate monohydrate, Menadione sodium bisulfite)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

##### IMDG-Code

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

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

UN/ID/NA number : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Zinc sulphate monohydrate, Menadione sodium bisulfite)  
Class : 9  
Packing group : III

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version 3.0      Revision Date: 06/18/2025      SDS Number: 11513638-00003      Date of last issue: 04/14/2025  
Date of first issue: 02/25/2025

Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Zinc sulphate monohydrate, Menadione sodium bisulfite)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Zinc sulphate monohydrate	7446-19-7	1000	29753

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : The following components are subject to reporting levels established by SARA Title III, Section 313:

Zinc sulphate monohydrate	7446-19-7	>= 1 - < 5 %
Manganese sulfate, monohydrate	10034-96-5	>= 1 - < 5 %

### US State Regulations

#### Pennsylvania Right To Know

α-D-Glucopyranose, hydrate (1:1)	14431-43-7
Citric acid	77-92-9
Zinc sulphate monohydrate	7446-19-7
Sodium chloride	7647-14-5
Manganese sulfate, monohydrate	10034-96-5

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

### California Prop. 65

WARNING: This product can expose you to chemicals including Retinyl acetate, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California List of Hazardous Substances

Zinc sulphate monohydrate	7446-19-7
Manganese sulfate, monohydrate	10034-96-5

### California Permissible Exposure Limits for Chemical Contaminants

Manganese sulfate, monohydrate	10034-96-5
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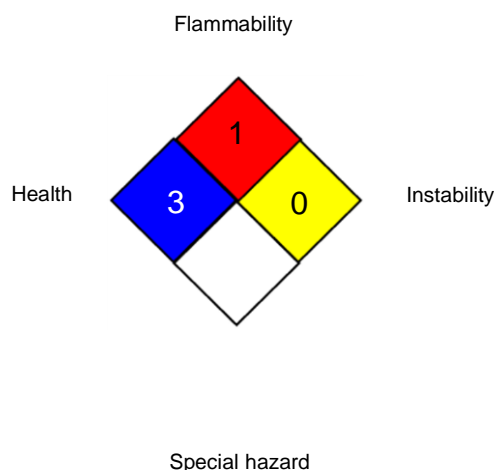
### The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / C	:	Ceiling
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - 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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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Revision Date	:	06/18/2025
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Multivitamin (with Dextrose Monohydrate) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11513638-00003	Date of first issue: 02/25/2025

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

US / Z8