

# SAFETY DATA SHEET



## Multivitamin (with Dextrose Monohydrate) Formulation

Version  
2.0

Revision Date:  
2025/04/14

SDS Number:  
11513637-00002

Date of last issue: 2025/02/25  
Date of first issue: 2025/02/25

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Multivitamin (with Dextrose Monohydrate) Formulation

Product code : Prevensa Mivisol, Mivisol

#### Manufacturer or supplier's details

Company : MSD

Address : Lot F, Loc An Binh Son Industrial Park, Long An Commune,  
Long Thanh District,  
Dong Nai Province, Vietnam 76200

Telephone : 0251 354 5925

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS Classification

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 1A

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

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

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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.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

### Other hazards which do not result in classification

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
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Citric acid	77-92-9	>= 3 < 5
Zinc sulphate monohydrate	7446-19-7	>= 3 < 5
Sodium chloride	7647-14-5	>= 3 < 5
Manganese sulfate, monohydrate	10034-96-5	>= 2,5 < 3
Nicotinic acid	59-67-6	>= 1,5 < 2,5
Retinyl acetate	127-47-9	>= 0,5 < 1
(dl)-a-Tocopheryl acetate	7695-91-2	>= 0,1 < 0,5
Menadione sodium bisulfite	130-37-0	>= 0,25 < 0,5
Riboflavin 5'- (sodium hydrogen phosphate)	130-40-5	>= 0,1 < 0,5
Colecalciferol	67-97-0	>= 0,1 < 0,25
Pyridoxine hydrochloride	58-56-0	>= 0,1 < 0,5

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### 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.
- 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.

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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NOx) Sulphur oxides Metal oxides Chlorine compounds
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding

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certain local or national requirements.

### 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust 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 labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Manganese sulfate, monohydrate	10034-96-5	TWA	0,3 mg/m <sup>3</sup> (Manganese)	VN OEL
		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

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(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
Riboflavin 5'-(sodium hydrogen phosphate)	130-40-5	TWA	100 ug/m3 (OEB 2)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m3 (OEB 4)	Internal
		Wipe limit	50 µg/100 cm <sup>2</sup>	Internal
Pyridoxine hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal

**Engineering measures**

- : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**Personal protective equipment**

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Colour	:	yellow, orange
Odour	:	characteristic
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable

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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

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## 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.

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## 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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### Acute toxicity

Not classified based on available information.

#### Product:

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

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**Components:****Citric acid:**

- Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg
- Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Zinc sulphate monohydrate:**

- Acute oral toxicity : LD50 (Rat): > 1.000 mg/kg  
Remarks: Based on data from similar materials
- Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

**Sodium chloride:**

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

**Manganese sulfate, monohydrate:**

- Acute oral toxicity : LD50 (Rat): 2.150 mg/kg  
Remarks: Based on data from similar materials
- Acute inhalation toxicity : LC50 (Rat): > 4,45 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

**Nicotinic acid:**

- Acute oral toxicity : LD50 (Rat, female): 4.500 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted equivalent or similar to guideline
- Acute inhalation toxicity : LC50 (Rat): > 3,8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436

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Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

Acute oral toxicity : LD50 (Rat): 4.790 mg/kg

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

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 3.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Menadione sodium bisulfite:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

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

Acute oral toxicity : LD50 (Rat): > 20.000 mg/kg

**Colecalciferol:**

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg  
Acute inhalation toxicity : Acute toxicity estimate: 0,05 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgement  
Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg  
Method: Expert judgement

**Pyridoxine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 4.000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Citric acid:**

Species : Rabbit  
Method : OECD Test Guideline 404

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Result : No skin irritation

### Zinc sulphate monohydrate:

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

### Sodium chloride:

Species : Rabbit  
Result : No skin irritation

### Manganese sulfate, monohydrate:

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

### Nicotinic acid:

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

### Retinyl acetate:

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

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

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

### Menadione sodium bisulfite:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Remarks : The test was conducted according to guideline  
Based on data from similar materials

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : The test was conducted according to guideline  
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Result : Skin irritation

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Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Citric acid:**

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

**Zinc sulphate monohydrate:**

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

**Sodium chloride:**

Species : Rabbit  
Result : No eye irritation

**Manganese sulfate, monohydrate:**

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

**Nicotinic acid:**

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

**Retinyl acetate:**

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

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

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

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Species	:	Bovine cornea
Method	:	OECD Test Guideline 437
Remarks	:	The test was conducted according to guideline Based on data from similar materials
Species	:	Tissue Culture
Method	:	OECD Test Guideline 492
Remarks	:	The test was conducted according to guideline Based on data from similar materials
Result	:	Irritation to eyes, reversing within 21 days

**Colecalciferol:**

Species	:	Rabbit
Result	:	No eye irritation

**Pyridoxine hydrochloride:**

Species	:	Rabbit
Result	:	No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Zinc sulphate monohydrate:**

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

**Sodium chloride:**

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

**Manganese sulfate, monohydrate:**

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

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Remarks : Based on data from similar materials

**Nicotinic acid:**

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

**Retinyl acetate:**

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

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

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

**Colecalciferol:**

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

**Pyridoxine hydrochloride:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Citric acid:**

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

Test Type: in vitro micronucleus test  
Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Zinc sulphate monohydrate:**

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

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

**Sodium chloride:**

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

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

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

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

Test Type: Chromosome aberration test in vitro  
Result: positive

Test Type: Chromosome aberration test in vitro  
Result: negative

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

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)

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Species: Rat  
Application Route: Intraperitoneal injection  
Result: positive

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

**Manganese sulfate, monohydrate:**

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Nicotinic acid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: The test was conducted according to guideline

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 475  
Result: negative  
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

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Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative

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

- Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Menadione sodium bisulfite:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

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

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

**Colecalciferol:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: equivocal
- Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative
- Test Type: Chromosome aberration test in vitro

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Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative

Test Type: In vivo mammalian alkaline comet assay  
Species: Rat  
Application Route: Ingestion  
Result: positive

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

**Pyridoxine hydrochloride:**

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Zinc sulphate monohydrate:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 1 Years  
Result : negative  
Remarks : Based on data from similar materials

**Sodium chloride:**

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

**Manganese sulfate, monohydrate:**

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

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

Species : Rat

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

### Reproductive toxicity

May damage the unborn child.

#### Components:

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

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

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

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

Effects on foetal development

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

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

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

##### **Nicotinic acid:**

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

##### **Retinyl acetate:**

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

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

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

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

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

**Pyridoxine hydrochloride:**

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

**STOT - single exposure**

Not classified based on available information.

**Components:****Citric acid:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

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 concentrations of 100 mg/kg bw or less.

**Retinyl acetate:**

Exposure routes : Ingestion

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

**Colecalciferol:**

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

**Repeated dose toxicity****Components:****Citric acid:**

Species : Rat  
NOAEL : 4.000 mg/kg  
LOAEL : 8.000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

**Zinc sulphate monohydrate:**

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

**Sodium chloride:**

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

**Manganese sulfate, monohydrate:**

Species : Rat, male  
NOAEL : 1.700 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

**Nicotinic acid:**

Species : Rat  
NOAEL : 50 mg/kg  
LOAEL : 250 mg/kg  
Application Route : Ingestion

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Exposure time : 28 Days  
Method : OECD Test Guideline 407  
Remarks : The test was conducted according to guideline

**Retinyl acetate:**

Species : Rat  
NOAEL : 1,43 - 3,47 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

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

Species : Rat  
NOAEL : 500 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

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

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

**Colecalciferol:**

Species : Rat  
NOAEL : 0,06 mg/kg  
LOAEL : 0,3 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Retinyl acetate:**

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

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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

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

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.535 mg/l  
Exposure time: 24 h

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

Toxicity to fish : EC50 (Oncorhynchus mykiss (rainbow trout)): 0,384 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,192 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (fresh water algae)): 0,373 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 34,5 µg/l  
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Jordanella floridae (flagfish)): 205,2 µg/l  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 415,7 µg/l  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

#### **Sodium chloride:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4.136 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50: > 2.000 mg/l

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plants	Exposure time: 96 h
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 252 mg/l Exposure time: 33 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia pulex (Water flea)): 314 mg/l Exposure time: 21 d
Toxicity to microorganisms	: EC10: > 1.000 mg/l

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

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)) : > 10 - 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (*Desmodesmus subspicatus* (green algae)): 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

ErC50 (Desmodesmus subspicatus (green algae)): 61 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (*Oncorhynchus mykiss* (rainbow trout)): 1,69 mg/l  
Exposure time: 65 d  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic) : NOEC (*Ceriodaphnia dubia* (water flea)): > 10 - 100 mg/l  
Exposure time: 7 d

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

## **Nicotinic acid:**

Toxicity to fish : LC50 (Salmo trutta (brown trout)): 520 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 77 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted equivalent or similar to guideline

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Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 37,356 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted equivalent or similar to guideline

EC10 (Desmodesmus subspicatus (green algae)): 12,098 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted equivalent or similar to guideline

Toxicity to microorganisms

: EC10 (Pseudomonas putida): 88 mg/l

Exposure time: 16 h

Method: OECD Test Guideline 209

Remarks: The test was conducted equivalent or similar to guideline

**Retinyl acetate:**

Toxicity to daphnia and other aquatic invertebrates

: EL50 (Daphnia magna (Water flea)): 46 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms

: EC50 (activated sludge): > 1.000 mg/l

Exposure time: 180 min

Method: OECD Test Guideline 209

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

Toxicity to fish

: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-)

: NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l

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icity) Exposure time: 28 d

Toxicity to microorganisms : EC50: > 927 mg/l  
Exposure time: 30 min  
Method: ISO 8192

### Menadione sodium bisulfite:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0,1 - 1 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0,1 - 1 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): >0,01 - 0,1  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): >0,001 - 0,01  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

M-Factor (Chronic aquatic toxicity) : 1

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

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 64,3 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 47,4 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

### Colecalciferol:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

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Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EL50 (Scenedesmus capricornutum (fresh water algae)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

**Pyridoxine hydrochloride:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h

**Persistence and degradability****Components:****Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Nicotinic acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 100 %  
Exposure time: 14 d  
Method: OECD Test Guideline 301E  
Remarks: The test was conducted according to guideline

**Retinyl acetate:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 15 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

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

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 21,7 - 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

**Menadione sodium bisulfite:**

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**Biodegradability** : Result: Not readily biodegradable.  
Method: OECD Test Guideline 302C  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

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

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

### **Colecalciferol:**

**Biodegradability** : Result: Not readily biodegradable.  
Biodegradation: <= 7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

### **Pyridoxine hydrochloride:**

**Biodegradability** : Result: Readily biodegradable.  
Biodegradation: 94 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301E

### **Bioaccumulative potential**

### **Components:**

#### **Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1,72

#### **Nicotinic acid:**

Partition coefficient: n-octanol/water : log Pow: -2,34  
Method: OECD Test Guideline 117  
Remarks: The test was conducted according to guideline

#### **Retinyl acetate:**

Partition coefficient: n-octanol/water : log Pow: 9,4  
Method: OECD Test Guideline 117

#### **Menadione sodium bisulfite:**

Partition coefficient: n-octanol/water : log Pow: -1,56  
Remarks: Calculation

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

Partition coefficient: n-octanol/water : log Pow: -0,651  
Remarks: Calculation

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### 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

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## 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.

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## 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

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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
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

### Special precautions for user

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

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## 15. REGULATORY INFORMATION

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

Law on Chemicals No. 06/2007/QH12

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

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

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## 16. OTHER INFORMATION

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### Further information

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

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
VN OEL	:	Vietnam. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average

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VN OEL / TWA : Time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

VN / EN