

## Vitamin B Formulation

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
 Date of first issue: 02.10.2015

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Vitamin B Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A  
 Parque Industrial Vice Presidente José Alencar Aparecida de  
 Goiás – GO, Brazil

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use :  
 Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

#### GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards which do not result in classification

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Nicotinamide	98-92-0	Eye irritation, Category 2B	$\geq 5 < 10$
Pyridoxine Hydrochloride	58-56-0	Acute toxicity (Oral), Category 5	$\geq 1 < 5$
Thiamine hydrochloride	67-03-8	Acute toxicity (Oral), Category 5	$\geq 1 < 5$

## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.6	04.04.2023	292426-00018	Date of first issue: 02.10.2015

---

### SECTION 4. FIRST AID MEASURES

If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Chlorine compounds Oxides of phosphorus Metal oxides
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 fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

## Vitamin B Formulation

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
 Date of first issue: 02.10.2015

cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
 Clean up remaining materials from spill with suitable absorbent.  
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
 Local/Total ventilation : Use only with adequate ventilation.  
 Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Take care to prevent spills, waste and minimize release to the environment.  
 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.  
 Conditions for safe storage : Keep in properly labeled containers.  
 Store in accordance with the particular national regulations.  
 Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pyridoxine Hydrochloride	58-56-0	TWA	OEB 3 ( $\geq 10 < 100 \mu\text{g}/\text{m}^3$ )	Internal
Thiamine hydrochloride	67-03-8	TWA	OEB 1 ( $\geq 1000 \mu\text{g}/\text{m}^3$ )	Internal

Engineering measures : Ensure adequate ventilation, especially in confined areas.  
 Minimize workplace exposure concentrations.

**Vitamin B Formulation**

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
Date of first issue: 02.10.2015

---

**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

Remarks : Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety glasses

Skin and body protection : Skin should be washed after contact.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n- : No data available

**Vitamin B Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.6	04.04.2023	292426-00018	Date of first issue: 02.10.2015

---

octanol/water  
Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : No data available  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**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

**Components:****Nicotinamide:**

Acute oral toxicity : LD50 (Rat): > 2.500 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity : LC50 (Rat): > 3,8 mg/l  
Exposure time: 4 h

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**Vitamin B Formulation**

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
Date of first issue: 02.10.2015

---

Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: Based on data from similar materials

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

**Pyridoxine Hydrochloride:**

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

**Thiamine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 3.710 mg/kg  
Target Organs: Central nervous system, Lungs  
  
LD50 (Mouse): 8.224 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Nicotinamide:**

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

**Pyridoxine Hydrochloride:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Nicotinamide:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 7 days  
Method : OECD Test Guideline 405

**Pyridoxine Hydrochloride:**

Species : Rabbit  
Result : No eye irritation

**Vitamin B Formulation**

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
Date of first issue: 02.10.2015

---

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Nicotinamide:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**Pyridoxine Hydrochloride:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Nicotinamide:**

Genotoxicity in vitro : 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: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative

**Pyridoxine Hydrochloride:**

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

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Nicotinamide:**

## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.6	04.04.2023	292426-00018	Date of first issue: 02.10.2015

---

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

**Pyridoxine Hydrochloride:**

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

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Nicotinamide:**

Species : Rat  
NOAEL : 215 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days  
Method : OECD Test Guideline 407

**Aspiration toxicity**

Not classified based on available information.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Nicotinamide:**

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 1.000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l  
aquatic invertebrates Exposure time: 24 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 1.000  
plants mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l

---



**Vitamin B Formulation**

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
Date of first issue: 02.10.2015

---

Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): 4.235 mg/l  
Exposure time: 18 h  
Method: OECD Test Guideline 209

**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:****Nicotinamide:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301E

**Pyridoxine Hydrochloride:**

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

**Bioaccumulative potential****Components:****Nicotinamide:**

Partition coefficient: n-octanol/water : log Pow: -0,38

**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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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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**Vitamin B Formulation**

Version 3.6      Revision Date: 04.04.2023      SDS Number: 292426-00018      Date of last issue: 01.10.2022  
Date of first issue: 02.10.2015

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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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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION**

Revision Date : 04.04.2023  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.6	04.04.2023	292426-00018	Date of first issue: 02.10.2015

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Data Sheet cy, <http://echa.europa.eu/>

**Full text of other abbreviations**

AllC - 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; NZbC - 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.

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