SAFETY DATA SHEET

Vitamin B Formulation

Version: 4.2
Revision Date: 09.04.2021
SDS Number: 292443-00016
Date of last issue: 10.10.2020
Date of first issue: 02.10.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Vitamin B Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: MSD
117 16th Road
1685 Halfway house, Midrand, South Africa

Telephone: +27 11 655 3000

E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

Additional Labelling
EUH210 Safety data sheet available on request.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders: No special precautions are necessary for first aid responders.

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.

4.2 Most important symptoms and effects, both acute and delayed
None known.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:

- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:

- Carbon oxides
- Nitrogen oxides (NOx)
- Chlorine compounds
- Oxides of phosphorus
- Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters:

- Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:

- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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 cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:

- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyridoxine hydrochloride</td>
<td>58-56-0</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Thiamine hydrochloride</td>
<td>67-03-8</td>
<td>TWA</td>
<td>OEB 1 (&gt;= 1000 µg/m3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>nicotinamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>43.75 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>12.5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>21.88 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>12.5 mg/kg</td>
</tr>
</tbody>
</table>
Exposure controls

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

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

Remarks : Wash hands before breaks and at the end of workday.
Skin and body protection : Skin should be washed after contact.
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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : No data available
Odour : No data available
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 : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
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Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)
  Water solubility: No data available

Partition coefficient: n-octanol/water: No data available

Auto-ignition 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.

9.2 Other information

Flammability (liquids): No data available

Molecular weight: No data available

Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

**Information on likely routes of exposure**
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

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

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:
nicotinamide:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
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:
nicotinamide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
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<td>02.10.2015</td>
</tr>
</tbody>
</table>

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:**
- **Effects on foetal development**:
  - **Test Type**: Embryo-foetal development
  - **Species**: Rabbit
  - **Application Route**: Ingestion
  - **Method**: OECD Test Guideline 414
  - **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.

**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.
SECTION 12: Ecological information

12.1 Toxicity

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

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

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

12.2 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
12.3 Bioaccumulative potential

**Components:**

- **nicotinamide:**
  Partition coefficient: n-octanol/water : log Pow: -0.38

- **Pyridoxine hydrochloride:**
  Partition coefficient: n-octanol/water : log Pow: 4.32

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**

**Assessment** : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**

**Endocrine disrupting potential** : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product** : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good
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SECTION 14: Transport information

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Organiza-
Further information


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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