SAFETY DATA SHEET

Vitamin B Formulation

Section 1: Identification

Product name : Vitamin B Formulation

Manufacturer or supplier's details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

Section 2: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotinamide</td>
<td>98-92-0</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Pyridoxine hydrochloride</td>
<td>58-56-0</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Thiamine hydrochloride</td>
<td>67-03-8</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.

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 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

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

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 cannot be contained.

Methods and materials for containment and 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.

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 labelled containers. Store in accordance with the particular national regulations.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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>

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

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.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
Molecular weight : No data available
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**
  - Can react with strong oxidizing agents.

- **Conditions to avoid**
  - None known.

- **Incompatible materials**
  - Oxidizing agents

- **Hazardous decomposition products**
  - No hazardous decomposition products are known.

**Section 11: Toxicological information**

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

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
SAFETY DATA SHEET
Vitamin B Formulation

Result : negative

Chronic toxicity

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:
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:**

<table>
<thead>
<tr>
<th>nicotinamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
</tr>
<tr>
<td><strong>NOAEL</strong></td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

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Section 12: Ecological information

**Ecotoxicity**

**Components:**

<table>
<thead>
<tr>
<th>nicotinamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
</tbody>
</table>

**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: \( \log{\text{Pow}} = -0.38 \)

- **Pyridoxine hydrochloride:**
  - Partition coefficient: n-octanol/water: \( \log{\text{Pow}} = 4.32 \)

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

Section 14: Transport information

**International Regulations**

**UNRTDG**
- **UN number:** Not applicable
- **Proper shipping name:** Not applicable
- **Class:** Not applicable
- **Subsidiary risk:** Not applicable
- **Packing group:** Not applicable
- **Labels:** Not applicable

**IATA-DGR**

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Page 9 of 12
Section 15: Regulatory information

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

HSNO Approval Number
Not applicable

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined
SAFETY DATA SHEET

Vitamin B Formulation

Section 16: Other information

Further information

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

Date format: dd.mm/yyyy

Full text of other abbreviations

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; ICS0 - 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 mate-
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.

NZ / EN