SAFETY DATA SHEET

Acetyl Methionine Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Acetyl Methionine Formulation

Manufacturer or supplier's details

Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 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 : Veterinary product

2. HAZARDS 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.

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>N-Acetyl-DL-methionine</td>
<td>1115-47-5</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>nicotinamide</td>
<td>98-92-0</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Caffeine</td>
<td>58-08-2</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Pyridoxine hydrochloride</td>
<td>58-56-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.
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- **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.

## 5. FIREFIGHTING 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), Sulphur 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**: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

## 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.

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.

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.

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>N-Acetyl-DL-methionine</td>
<td>1115-47-5</td>
<td>TWA</td>
<td>2000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<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>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). 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: Combined particulates and organic vapour type

Hand protection: Chemical-resistant gloves
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Colour : Colorless to pale yellow
Odour : characteristic
Odour Threshold : No data available
pH : 3.30 - 4.30
Melting point/freezing point : No data available
Initial boiling point and boiling range : 99 °C
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
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.

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: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Components:

**N-Acetyl-DL-methionine:**
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity**: LC50 (Rat): > 5.25 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403
  - Remarks: Based on data from similar materials

**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

**Caffeine:**
- **Acute oral toxicity**: LD50 (Rat): 367.7 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): 4.94 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403
- **Acute dermal toxicity**: LD50 (Rat): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**Pyridoxine hydrochloride:**
- **Acute oral toxicity**: LD50 (Rat): 4,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

N-Acetyl-DL-methionine:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

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

Caffeine:
- 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

Caffeine:
- Species: Rabbit
- Result: No eye irritation
- 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:

**N-Acetyl-DL-methionine:**
- **Test Type**: Buehler Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative
- **Remarks**: Based on data from similar materials

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

**Caffeine:**
- **Test Type**: Local lymph node assay (LLNA)
- **Exposure routes**: Skin contact
- **Species**: Mouse
- **Method**: OECD Test Guideline 429
- **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:

**N-Acetyl-DL-methionine:**
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Based on data from similar materials
  - Test Type: In vitro mammalian cell gene mutation test
    - Result: negative
    - Remarks: Based on data from similar materials

- **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
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

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

  Test Type: Chromosome aberration test in vitro
  Result: positive

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

  Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Ingestion
  Result: equivocal

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:
Caffeine:
  Species: Rat
  Application Route: Ingestion
  Exposure time: 104 weeks
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

Caffeine:
Effects on fertility: Test Type: Fertility
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
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.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

N-Acetyl-DL-methionine:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

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

Caffeine:
Species: Mouse
NOAEL: >= 167.4 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Acetyl-DL-methionine:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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

Caffeine:

Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): 87 mg/l
Exposure time: 96 h
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 182 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to algae/aquatic plants: EC50 (Scenedesmus subspicatus): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Scenedesmus subspicatus): 6.25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC50 (Pseudomonas putida): 3,490 mg/l
Exposure time: 17 h
Method: DIN 38 412 Part 8

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:

N-Acetyl-DL-methionine:

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

nicotinamide:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301E
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### Caffeine:
- Biodegradability: Result: Readily biodegradable.  
  Biodegradation: > 90 \%  
  Exposure time: 28 d  
  Method: OECD Test Guideline 301A

### Pyridoxine hydrochloride:
- Biodegradability: Result: Readily biodegradable.  
  Biodegradation: 94 \%  
  Exposure time: 28 d  
  Method: OECD Test Guideline 301E

### Bioaccumulative potential

#### Components:

- **N-Acetyl-DL-methionine**:
  - Partition coefficient: n-octanol/water  
    
  - log Pow: -0.313  
    Remarks: Calculation

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

- **Caffeine**:
  - Partition coefficient: n-octanol/water  
    
  - log Pow: -0.091

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

### Mobility in soil
- No data available

### Other adverse effects
- No data available

## 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.

## 14. TRANSPORT INFORMATION

### International Regulations

**UNRTDG**
- Not regulated as a dangerous good

**IATA-DGR**
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Version 3.0  Revision Date: 2020/10/10  SDS Number: 5357338-00003  Date of last issue: 2020/02/11

Date of first issue: 2019/12/17

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

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.
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.