SAFETY DATA SHEET

Acetyl Methionine Formulation

Version 3.0  Revision Date: 10.10.2020  SDS Number: 5357343-00003  Date of last issue: 11.02.2020
Date of first issue: 17.12.2019

Section 1: Identification

Product name: Acetyl Methionine 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: Veterinary product

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>N-Acetyl-DL-methionine</td>
<td>1115-47-5</td>
<td>&gt;= 10 - &lt; 30</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>

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.
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Most important symptoms and effects, both acute and delayed:

Rinse mouth thoroughly with water.

Protection of first-aiders:

None known.

Notes to physician:

No special precautions are necessary for first aid responders.

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)
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.

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 spills cannot be contained.

Methods and materials for containment and cleaning up:

Soak up with inert absorbent material.

For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed 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 deter-
mine 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.

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.

**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>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:

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.

Section 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

Vapour pressure: No data available
Relative vapour density : 1.03 - 1.09
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  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 : Not applicable

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.

Product:
Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method
Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
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

**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

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

**Pyridoxine hydrochloride:**
- **Species**: Rabbit
- **Result**: No skin irritation
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Serious eye damage/eye irritation
Not classified based on available information.

Components:

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

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

Chronic toxicity
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
- Genotoxicity in vivo: Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials

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

Reproductive toxicity
Not classified based on available information.

Components:

**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

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

**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

**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

**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
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**: 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.

**National Regulations**
- **NZS 5433**: Not regulated as a dangerous good

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
- **IECSC**: not determined
Further information
Sources of key data used to compile the Safety Data Sheet:

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; 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; 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
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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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