SECTION 1. IDENTIFICATION

Product name : Acetyl Methionine Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
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>10</td>
</tr>
<tr>
<td>Nicotinamide</td>
<td>98-92-0</td>
<td>1.5</td>
</tr>
<tr>
<td>Caffeine</td>
<td>58-08-2</td>
<td>1</td>
</tr>
<tr>
<td>Pyridoxine Hydrochloride</td>
<td>58-56-0</td>
<td>0.2</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.
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Date of first issue: 12/17/2019

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)
Sulfur 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 fire-fighters: 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 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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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 vapor type

Hand protection:
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
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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: Colorless to pale yellow
Odor: characteristic
Odor 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
Vapor pressure: No data available
Relative vapor density: 1.03 - 1.09
Relative density: No data available
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Density: No data available

Solubility(ies):
  Water solubility: soluble

Partition coefficient: n-octanol/water: Not applicable

Autoignition 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

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

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
### 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:
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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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

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

Nicotinamide:

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

Caffeine:

Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
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:

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: 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
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**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

**Genotoxicity in vitro**
- **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

**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:

Nicotinamide:

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

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.

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

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

Caffeine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 90 %
Pyridoxine Hydrochloride:
Biodegrability: Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 28 d
Method: OECD Test Guideline 301A

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

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.

**Domestic regulation**

**TDG**

Not regulated as a dangerous good

### SECTION 15. REGULATORY INFORMATION

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICIC - 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
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 10/10/2020
Date format: mm/dd/yyyy

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.