SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Acefylline Heptaminol Formulation

Version: 1.4
Revision Date: 27.08.2021
SDS Number: 5478732-00005
Date of last issue: 09.04.2021
Date of first issue: 04.03.2020

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

1.1 Product identifier
Trade name: Acefylline Heptaminol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Kilsheean
Clonmel Tipperary, IE
Telephone: 353-51-601000
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)
Specific target organ toxicity - single exposure, Category 2
H371: May cause damage to organs.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Warning
Hazard statements: H371 May cause damage to organs.
Precautionary statements:
Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P308 + P311 IF exposed or concerned: Call a POISON CENTER/doctor.
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Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1)

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.

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients

3.2 Mixtures
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1)</td>
<td>10075-18-0 233-205-0</td>
<td>Acute Tox. 4; H302 STOT SE 2; H371</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute oral toxicity: 900 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
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 unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause damage to organs.

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

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. 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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. 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 spills 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:
- Do not breathe mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Do not eat, drink or smoke when using this product.
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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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. 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>1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1)</td>
<td>10075-18-0</td>
<td>TWA</td>
<td>50 μg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Wipe limit | 500 μg/cm² | Internal |

8.2 Exposure controls

**Engineering measures**
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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**
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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Colour</td>
<td>Colorless to pale yellow</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>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>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>Flash point</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>pH</td>
<td>5.0 - 6.0</td>
</tr>
</tbody>
</table>
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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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Components:
1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1):

Acute oral toxicity: LD50 (Rat): 900 mg/kg
- Target Organs: Gastrointestinal tract, Lungs
- LD50 (Mouse): 2,733 mg/kg
- Acute toxicity estimate: 900 mg/kg
- Method: Calculation method

Acute toxicity (other routes of administration):
LD50 (Mouse): > 500 mg/kg
- Application Route: Intravenous

LD50 (Cat): 300 mg/kg
- Application Route: Intravenous

LD50 (Dog): 350 mg/kg
- Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.
Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
May cause damage to organs.

Components:

1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1):

Exposure routes : Oral
Assessment : Shown to produce significant health effects in animals at concentrations of >300 to 2000 mg/kg bw.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment : 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.

Experience with human exposure

Components:

1,2,3,6-Tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetic acid, compound with 6-amino-2-methylheptan-2-ol (1:1):
Ingestion : Target Organs: Gastro-intestinal system
Symptoms: Nausea, Vomiting, Pain, Diarrhoea, bleeding
Target Organs: Heart
Symptoms: Palpitation, tachycardia, hypotension
Target Organs: Hair
Symptoms: hair loss
Target Organs: Central nervous system
Symptoms: muscle twitching, Irritability, insomnia, nervousness, Headache

SECTION 12: Ecological information

12.1 Toxicity
No data available
12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

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 Endocrine disrupting properties

**Product:**
**Assessment:** 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.

12.7 Other adverse effects
No data available

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 or ID 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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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 Maritime transport in bulk according to IMO instruments
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):

Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59):
Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:
Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast):
Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:
Not applicable

REACH - List of substances subject to authorisation (Annex XIV):
Not applicable

Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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
Full text of H-Statements

H302 : Harmful if swallowed.
H371 : May cause damage to organs if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity
STOT SE : Specific target organ toxicity - single exposure

Further information


Classification of the mixture: Classification procedure:

STOT SE 2 H371 Calculation method
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.