Enilconazole Liquid Formulation

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

1.1 Product identifier
   Trade name : Enilconazole Liquid 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
   Walton Manor, Walton
   MK7 7AJ Milton Keynes - United Kingdom
   Telephone : 908-740-4000
   Telefax : 908-735-1496
   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)
   - Flammable liquids, Category 3
   - Acute toxicity, Category 3
   - Acute toxicity, Category 4
   - Eye irritation, Category 2
   - Carcinogenicity, Category 2
   - Specific target organ toxicity - repeated exposure, Category 2
   - Long-term (chronic) aquatic hazard, Category 1
   - Flammable liquid and vapour. H226
   - Toxic if swallowed. H301
   - Harmful if inhaled. H332
   - Causes serious eye irritation. H319
   - Suspected of causing cancer. H351
   - May cause damage to organs through prolonged or repeated exposure. H373
   - Very toxic to aquatic life with long lasting effects. H410

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
P391 Collect spillage.

Hazardous components which must be listed on the label:
1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole
Benzyl alcohol

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>577-11-7</td>
<td>209-406-4</td>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315 Eye Dam. 1; H318</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole</td>
<td>35554-44-0</td>
<td>252-615-0</td>
<td>613-042-00-5</td>
<td></td>
<td>Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Dam. 1; H318 Carc. 2; H351 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

M-Factor (Chronic aquatic toxicity): 10
Enilconazole Liquid Formulation

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Call a physician or poison control centre immediately. 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

Symptoms: Gastrointestinal disturbance

Risks: Toxic if swallowed. Causes serious eye irritation. Harmful if inhaled. Suspected of causing cancer. May cause damage to organs through prolonged or repeated exposure.
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 medium : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Sulphur oxides
Metal 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.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.
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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- 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:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
- If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling:
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- 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. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures, which in contact with water, emit flammable gases
- Explosives
- Gases

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-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl}-1H-imidazole</td>
<td>35554-44-0</td>
<td>TWA</td>
<td>0.3 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm 1,920 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: Skin

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1416.82 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>200.89 mg/kg</td>
</tr>
</tbody>
</table>
### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium bis(2-</td>
<td>Fresh water</td>
<td>0.18 mg/l</td>
</tr>
</tbody>
</table>

### Effects of Exposure:

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>419.25 mg/m³</td>
</tr>
<tr>
<td>Consumers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>120.54 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers, Ingestion</td>
<td>Long-term systemic effects</td>
<td>13.39 mg/kg bw/day</td>
</tr>
<tr>
<td>PEG Castor oil, Workers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>16.4 mg/m³</td>
</tr>
<tr>
<td>PEG Castor oil, Workers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.9 mg/m³</td>
</tr>
<tr>
<td>PEG Castor oil, Consumers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>2.9 mg/m³</td>
</tr>
<tr>
<td>PEG Castor oil, Consumers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.67 mg/kg bw/day</td>
</tr>
<tr>
<td>PEG Castor oil, Consumers, Ingestion</td>
<td>Long-term systemic effects</td>
<td>1.67 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl Alcohol, Workers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td>Benzyl Alcohol, Workers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl Alcohol, Consumers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>5.4 mg/m³</td>
</tr>
<tr>
<td>Benzyl Alcohol, Consumers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>27 mg/m³</td>
</tr>
<tr>
<td>Benzyl Alcohol, Consumers, Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl Alcohol, Consumers, Ingestion</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td>Ethanol, Workers, Inhalation</td>
<td>Acute local effects</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Ethanol, Workers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td>Ethanol, Workers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td>Ethanol, Consumers, Inhalation</td>
<td>Acute local effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td>Ethanol, Consumers, Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td>Ethanol, Consumers, Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m³</td>
</tr>
<tr>
<td>Ethanol, Consumers, Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
</tr>
</tbody>
</table>
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.

Laboratory operations do not require special containment.

**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
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Material: Chemical-resistant gloves

Remarks: Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection: Work uniform or laboratory coat.

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 BS EN 14387 Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid

Colour: light yellow

Odour: musty

Odour Threshold: No data available

pH: 9.5

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: 45 °C

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

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: No data available

Relative density: 1.094

Solubility(ies)

Water solubility: soluble

Partition coefficient: n-octanol/water: No data available

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.

9.2 Other information
- Flammability (liquids) : Not applicable
- Molecular weight : No data available
- Particle size : No data available

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 : Flammable liquid and vapour.
  Vapours may form explosive mixture with air.
  Can react with strong oxidizing agents.

10.4 Conditions to avoid
- Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials
- Materials to avoid : Oxidizing agents
  Acids

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
- Toxic if swallowed.
- Harmful if inhaled.

Product:
- Acute oral toxicity : LD50 (Rat): 192 - 309 mg/kg
Acute inhalation toxicity: LC50 (Rat): 3.1 mg/l
    Exposure time: 4 h
    Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 900 mg/kg

**Components:**

**Sodium bis(2-ethylhexyl)sulfosuccinate:**

Acute oral toxicity: LD50 (Rat): 3,080 mg/kg

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

**1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:**

Acute oral toxicity: LD50 (Rat): 227 mg/kg
    Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
    LD50 (Mouse): 390 - 620 mg/kg
    LD50 (Dog): > 640 mg/kg

Acute inhalation toxicity: LC50 (Rat): 1.84 - 2.88 mg/l
    Exposure time: 4 h
    Test atmosphere: dust/mist
    Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Acute dermal toxicity: LD50 (Rat): 4,200 - 4,800 mg/kg
    LD50 (Rabbit): 4,200 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 155 mg/kg
    Application Route: Intraperitoneal

**Benzyl alcohol:**

Acute oral toxicity: LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
    Exposure time: 4 h
    Test atmosphere: dust/mist
    Method: OECD Test Guideline 403

**Ethanol:**

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
    Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
    Exposure time: 4 h
    Test atmosphere: vapour
Skin corrosion/irritation
Not classified based on available information.

Product:
Species: Rabbit
Result: Mild skin irritation

Components:
Sodium bis(2-ethylhexyl)sulfosuccinate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Skin irritation

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Species: Rabbit
Result: Mild skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Product:
Species: Rabbit
Result: Moderate eye irritation

Components:
Sodium bis(2-ethylhexyl)sulfosuccinate:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irreversible effects on the eye

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Species: Rabbit
Result: Irreversible effects on the eye
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
Result: Moderate eye irritation
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

**Benzyl alcohol:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

**Ethanol:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Product:**
Species: Guinea pig
Result: Not a skin sensitizer.

**Components:**

**Sodium bis(2-ethylhexyl)sulfosuccinate:**
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
Result: negative

**1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:**
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: equivocal

Exposure routes: Dermal
Species: Humans
Result: Not a skin sensitizer.

**Benzyl alcohol:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Version 5.3 Revision Date: 23.03.2020 SDS Number: 906837-00011 Date of last issue: 13.09.2019
Date of first issue: 22.09.2016

Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Sodium bis(2-ethylhexyl)sulfosuccinate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: equivocal

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Test Type: gene mutation test
Test system: Chinese hamster fibroblasts
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative
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Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Result: negative

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Ethanol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Carcinogenicity
Suspected of causing cancer.

Components:

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 40 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
LOAEL: 33 mg/kg body weight
Result: positive
Target Organs: Liver

Species: Mouse
Application Route: oral (feed)
Exposure time: 23 Months
NOAEL: 8 mg/kg body weight
LOAEL: 105 mg/kg body weight
Result: positive
Target Organs: Liver
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Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development:
Species: Rat
Application Route: Ingestion
Result: negative

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Effects on fertility: Test Type: Multi-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 20 mg/kg body weight
Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.
Remarks: Not classified due to data which are conclusive although insufficient for classification.

Effects on foetal development:
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 80 mg/kg body weight
Result: Reduced foetal weight, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Maternal toxicity observed., No teratogenic effects, Postimplantation loss.
Remarks: The effects were seen only at maternally toxic doses.

**Benzyl alcohol:**
Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

**Ethanol:**
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**Components:**
1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Target Organs : Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Product:**
Species : Rabbit
NOAEL : 1 mg/kg
Application Route : Dermal
Exposure time : 21 d
Symptoms : No adverse effects

**Components:**
Sodium bis(2-ethylhexyl)sulfosuccinate:
Species : Rat
NOAEL : 750 mg/kg
Application Route : Ingestion
Enilconazole Liquid Formulation

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Species: Rat  
NOAEL: 5 mg/kg  
LOAEL: 20 mg/kg  
Application Route: Oral  
Exposure time: 3 - 24 Months  
Target Organs: Liver  
Symptoms: decrease in appetite

Species: Dog  
NOAEL: 2.5 mg/kg  
LOAEL: 20 mg/kg  
Application Route: Oral  
Exposure time: 12 Months  
Symptoms: Salivation, Vomiting

Species: Mouse  
NOAEL: 12 mg/kg  
LOAEL: 140 mg/kg  
Application Route: Oral  
Exposure time: 3 Months  
Target Organs: Liver

Benzyl alcohol:

Species: Rat  
NOAEL: 1.072 mg/l  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 28 Days  
Method: OECD Test Guideline 412

Ethanol:

Species: Rat  
NOAEL: 1,280 mg/kg  
LOAEL: 3,156 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Product:

Inhalation: Remarks: May cause respiratory tract irritation.  
Skin contact: Remarks: May irritate skin.  
Eye contact: Remarks: May irritate eyes.  
Ingestion: Symptoms: Gastrointestinal disturbance, central nervous system effects
Enilconazole Liquid Formulation

Components:
1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Skin contact: Symptoms: pruritis, skin rash, Skin irritation
Eye contact: Symptoms: Eye irritation
Ingestion: Symptoms: Nausea

SECTION 12: Ecological information

12.1 Toxicity

Components:
Sodium bis(2-ethylhexyl)sulfosuccinate:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): 49 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 6.6 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 82.5 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): 22 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC50 (Pseudomonas putida): 164 mg/l
Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): EC10: 9 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 1.48 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
LC50 (Lepomis macrochirus (Bluegill sunfish)): 3.99 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 3.54 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (PseudoKirchneriella subcapitata (green algae)): 1.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
# Enilconazole Liquid Formulation

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## Ecotoxicology Assessment

**Acute aquatic toxicity**

- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.457 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201
- NOEC: < 0.007 mg/l  
  Exposure time: 21 d  
  Species: Daphnia magna (Water flea)  
  Method: OECD Test Guideline 211

**M-Factor (Chronic aquatic toxicity)**

- 10

**Benzyl alcohol:**

- **Toxicity to fish**
  - LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
    Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): 230 mg/l  
    Exposure time: 48 h  
    Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants**
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l  
    Exposure time: 72 h  
    Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
    Exposure time: 72 h  
    Method: OECD Test Guideline 201

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC: 51 mg/l  
    Exposure time: 21 d  
    Species: Daphnia magna (Water flea)  
    Method: OECD Test Guideline 211

**Ethanol:**

- **Toxicity to fish**
  - LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
    Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l  
    Exposure time: 48 h

- **Toxicity to algae/aquatic plants**
  - ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
    Exposure time: 72 h  
    EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
    Exposure time: 72 h
12.2 Persistence and degradability

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 91.2%
Exposure time: 28 d

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Biodegradability: Result: not rapidly degradable
Biodegradation: 50%
Exposure time: 166 d

Benzyl alcohol:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96%
Exposure time: 14 d

Ethanol:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 84%
Exposure time: 20 d

12.3 Bioaccumulative potential

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Partition coefficient: n-octanol/water: log Pow: 1.998
Remarks: Calculation

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Partition coefficient: n-octanol/water: log Pow: 3.82

Benzyl alcohol:

Partition coefficient: n-octanol/water: log Pow: 1.05

Ethanol:

Partition coefficient: n-octanol/water: log Pow: -0.35
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Enilconazole Liquid Formulation

Version: 5.3
Revision Date: 23.03.2020
SDS Number: 906837-00011
Date of last issue: 13.09.2019
Date of first issue: 22.09.2016

12.4 Mobility in soil

Components:

1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:
Distribution among environmental compartments: log Koc: 3.82

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN: UN 1992
ADR: UN 1992
RID: UN 1992
IMDG: UN 1992
IATA: UN 1992

14.2 UN proper shipping name

ADN: FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethanol, 1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)
ADR: FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethanol, 1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)
RID: FLAMMABLE LIQUID, TOXIC, N.O.S. (Ethanol, 1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)
Enilconazole Liquid Formulation

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**IMDG**: FLAMMABLE LIQUID, TOXIC, N.O.S.  
(Ethanol, 1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

**IATA**: Flammable liquid, toxic, n.o.s.  
(Ethanol, 1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

### 14.3 Transport hazard class(es)
- **ADN**: 3
- **ADR**: 3
- **RID**: 3
- **IMDG**: 3
- **IATA**: 3

### 14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: FT1
- Hazard Identification Number: 36
- Labels: 3 (6.1)

**ADR**
- Packing group: III
- Classification Code: FT1
- Hazard Identification Number: 36
- Labels: 3 (6.1)
- Tunnel restriction code: (D/E)

**RID**
- Packing group: III
- Classification Code: FT1
- Hazard Identification Number: 36
- Labels: 3 (6.1)

**IMDG**
- Packing group: III
- Labels: 3 (6.1)
- EmS Code: F-E, S-D

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 366
- Packing instruction (LQ): Y343
- Packing group: III
- Labels: Flammable Liquids, Toxic

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 355
- Packing instruction (LQ): Y343
- Packing group: III
- Labels: Flammable Liquids, Toxic
Enilconazole Liquid Formulation

14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

**REACH - List of substances subject to authorisation (Annex XIV)**

: 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


<table>
<thead>
<tr>
<th>P5c</th>
<th>FLAMMABLE LIQUIDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>5,000 t</td>
<td>50,000 t</td>
</tr>
</tbody>
</table>

| E1  | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

**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.
Enilconazole Liquid Formulation

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 are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225: Highly flammable liquid and vapour.
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H351: Suspected of causing cancer.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Carc.: Carcinogenicity
- Eye Dam.: Serious eye damage
- Eye Irrit.: Eye irritation
- Flam. Liq.: Flammable liquids
- Skin Irrit.: Skin irritation
- STOT RE: Specific target organ toxicity - repeated exposure
- GB EH40: UK. EH40 WEL - Workplace Exposure Limits
- GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture

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<thead>
<tr>
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<th>Code</th>
<th>Procedure</th>
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<tbody>
<tr>
<td>Flam. Liq. 3</td>
<td>H226</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Acute Tox. 3</td>
<td>H301</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
<td>H332</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Carc. 2</td>
<td>H351</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

GB / EN