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

Amitraz Solid Formulation

Version 5.3  
Revision Date: 27.08.2021  
SDS Number: 1734738-00011  
Date of last issue: 09.04.2021  
Date of first issue: 06.06.2017

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

1.1 Product identifier
   Trade name: Amitraz Solid 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
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone: 353-51-601000
   E-mail address of person responsible for the SDS: EHSDASTEWARD@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)
   Acute toxicity, Category 4 H302: Harmful if swallowed.
   Serious eye damage, Category 1 H318: Causes serious eye damage.
   Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.
   Germ cell mutagenicity, Category 2 H341: Suspected of causing genetic defects.
   Carcinogenicity, Category 1B H350: May cause cancer.
   Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Danger
   Hazard statements: H302 Harmful if swallowed.
Amitraz Solid Formulation

Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
- P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
- P391 Collect spillage.

**Hazardous components which must be listed on the label:**
- amitraz (ISO)
- Paraformaldehyde
- Sodium bis(2-ethylhexyl)sulfosuccinate

**Additional Labelling**
The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 10 %
The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 10 %
The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 10 %
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

**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.

May form explosive dust-air mixture during processing, handling or other means.
### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<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>amitraz (ISO)</td>
<td>amitraz (ISO)</td>
<td>33089-61-1 251-375-4 612-086-00-2</td>
<td>Acute Tox. 4; H302&lt;br&gt;Skin Sens. 1B; H317&lt;br&gt;STOT RE 2; H373 (Liver, Central nervous system)&lt;br&gt;Aquatic Acute 1; H400&lt;br&gt;Aquatic Chronic 1; H410&lt;br&gt;M-Factor (Acute aquatic toxicity): 10&lt;br&gt;M-Factor (Chronic aquatic toxicity): 10</td>
<td>50</td>
</tr>
<tr>
<td>Paraformaldehyde</td>
<td>Paraformaldehyde</td>
<td>30525-89-4</td>
<td>Acute Tox. 4; H302&lt;br&gt;Acute Tox. 4; H332&lt;br&gt;Skin Irrit. 2; H315&lt;br&gt;Eye Dam. 1; H318&lt;br&gt;Skin Sens. 1A; H317&lt;br&gt;Muta. 2; H341&lt;br&gt;Carc. 1B; H350&lt;br&gt;STOT SE 3; H335&lt;br&gt;specific concentration limit&lt;br&gt;Skin Sens. 1A; H317 &gt;= 0.2 %&lt;br&gt;Acute toxicity estimate&lt;br&gt;Acute oral toxicity: 592 mg/kg</td>
<td>2.55</td>
</tr>
<tr>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>577-11-7 209-406-4</td>
<td>Skin Irrit. 2; H315&lt;br&gt;Eye Dam. 1; H318</td>
<td>1</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.

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 immediately.

If swallowed: If swallowed, DO NOT induce vomiting. 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: Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. Suspected of causing genetic defects. May cause 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
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5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Silicon oxides
Metal oxides
Nitrogen oxides (NOx)
Sulphur 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: 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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis-
posal 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: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Keep away from water. Protect from moisture. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. 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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.

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. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases
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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>amitraz (ISO)</td>
<td>33089-61-1</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Occupational exposure limits of decomposition products

<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>Formaldehyde</td>
<td>50-00-0</td>
<td>TWA</td>
<td>0.3 ppm</td>
<td>2004/37/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>0.6 ppm</td>
<td>2004/37/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.74 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal sensitisation,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogens or mutagens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OELV - 8 hrs (TWA)</td>
<td></td>
<td></td>
<td>0.3 ppm</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical agents which</td>
<td></td>
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<td></td>
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<tr>
<td>following exposure may</td>
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<tr>
<td>cause sensitisation of</td>
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<tr>
<td>the respiratory tract</td>
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<tr>
<td>and lead to asthma,</td>
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<tr>
<td>rhinitis or extrinsic</td>
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<tr>
<td>allergic alveolitis,</td>
<td></td>
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<tr>
<td>Carc 1B - Substances</td>
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<tr>
<td>presumed to have</td>
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<tr>
<td>carcinogenic potential</td>
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</tr>
<tr>
<td>for humans</td>
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<td></td>
</tr>
<tr>
<td>OELV - 15 min (STEL)</td>
<td></td>
<td></td>
<td>0.6 ppm</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.738 mg/m³</td>
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<tr>
<td>Further information:</td>
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<td>Chemical agents which</td>
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<td>allergic alveolitis,</td>
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<tr>
<td>Carc 1B - Substances</td>
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<tr>
<td>presumed to have</td>
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<td></td>
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</tr>
<tr>
<td>carcinogenic potential</td>
<td></td>
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<tr>
<td>for humans</td>
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</tr>
</tbody>
</table>

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>Calcium carbonate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6.36 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Acute systemic effects</td>
<td>6.1 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>1.06 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Long-term systemic effects</td>
<td>6.1 mg/kg bw/day</td>
</tr>
<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>Workers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic effects</td>
<td>200.89 mg/kg bw/day</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Consumers</th>
<th>Inhalation</th>
<th>Long-term systemic effects</th>
<th>419.25 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>120.54 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>13.39 mg/kg bw/day</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>Calcium carbonate</td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>Fresh water</td>
<td>0.18 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.152 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.018 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>12.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>17.789 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.779 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.04 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Processing may form hazardous compounds (see section 10).
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Eye protection : Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield
Equipment should conform to I.S. EN 166

Hand protection
Material : Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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 14387

Filter type: Combined particulates and inorganic gas/vapour type (B-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>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</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>May form explosive dust-air mixture during processing, handling or other means.</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>Not applicable</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>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Relative vapour density : No data available
Particle characteristics
  Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : Not applicable

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 : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.
Hazardous decomposition products will be formed upon contact with water or humid air.

10.4 Conditions to avoid
Conditions to avoid : Exposure to moisture
  Heat, flames and sparks.
  Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents
  Water

10.6 Hazardous decomposition products
Contact with water or humid air : Formaldehyde

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
Harmful if swallowed.

Product:
Acute oral toxicity : Acute toxicity estimate: 958.7 mg/kg
                 Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
                           Exposure time: 4 h
                           Test atmosphere: dust/mist
                           Method: Calculation method

Components:
amitraz (ISO):
Acute oral toxicity : LD50 (Rat): > 400 mg/kg
                     LD50 (Mouse): > 1,085 mg/kg
                     LD50 (Guinea pig): > 400 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 1,600 mg/kg

Paraformaldehyde:
Acute oral toxicity : LD50 (Rat, male): 592 mg/kg
                     Acute toxicity estimate: 592 mg/kg
                     Method: Calculation method

Acute inhalation toxicity : LC50 (Rat): 1.07 mg/l
                          Exposure time: 4 h
                          Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 10,000 mg/kg

Sodium bis(2-ethylhexyl)sulfosuccinate:
Acute oral toxicity : LD50 (Rat): 3,080 mg/kg

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

Skin corrosion/irritation
Not classified based on available information.

Components:
amitraz (ISO):
Species : Rabbit
Result : No skin irritation
Paraformaldehyde:
Species: Rabbit
Result: Skin irritation

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

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**
amitraz (ISO):
Species: Rabbit
Result: No eye irritation

Paraformaldehyde:
Species: Rabbit
Result: Irreversible effects on the eye

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

**Respiratory or skin sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

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

**Components:**
amitraz (ISO):
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Sensitiser

Paraformaldehyde:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: positive
Remarks: Based on data from similar materials
Assessment: Probability or evidence of high skin sensitisation rate in hu-
Sodium bis(2-ethylhexyl)sulfosuccinate:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Paraformaldehyde:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: positive
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Result: positive
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test
Result: positive
Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive
Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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- **Species:** Rat  
- **Application Route:** inhalation (vapour)  
- **Result:** positive  
- **Remarks:** Based on data from similar materials

**Germ cell mutagenicity assessment:**
- Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

**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

### Carcinogenicity
May cause cancer.

#### Components:

**Amitraz (ISO):**
- **Species:** Rat  
- **Application Route:** Oral  
- **Exposure time:** 2 Years  
- **NOAEL:** > 10.18 mg/kg body weight  
- **Result:** negative

- **Species:** Mouse  
- **Exposure time:** 2 Years  
- **LOAEL:** 2.3 mg/kg body weight  
- **Result:** positive  
- **Target Organs:** Liver, Stomach

**Paraformaldehyde:**
- **Species:** Rat  
- **Application Route:** Ingestion  
- **Exposure time:** 105 weeks  
- **Result:** negative
Species: Rat
Application Route: Inhalation
Exposure time: 28 Months
Result: positive
Remarks: Based on data from similar materials

Carcinogenicity - Assessment:
Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity:
Not classified based on available information.

Components:

amitraz (ISO):
Effects on fertility:
Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: > 4.8 mg/kg body weight
Result: No significant adverse effects were reported

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3 mg/kg body weight
Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight
Result: Effects on foetal development

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:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

Components:

Paraformaldehyde:
Assessment: May cause respiratory irritation.
STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:
amitraz (ISO):
Target Organs : Liver, Central nervous system
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity
Components:
amitraz (ISO):
Species : Mouse
NOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver

Species : Dog
NOAEL : 0.25 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system, Liver

Paraformaldehyde:
Species : Rat, male
NOAEL : 15 mg/kg
Application Route : Ingestion
Exposure time : 105 Weeks
Remarks : Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Species : Rat
NOAEL : 750 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

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
Experience with human exposure

**Components:**

amitraz (ISO):

- **Ingestion:**
  - **Target Organs:** Central nervous system

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

amitraz (ISO):

- **Toxicity to fish:**
  - LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.45 mg/l
  - Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): 0.035 mg/l
  - Exposure time: 48 h

- **Toxicity to algae/aquatic plants:**
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0.04 mg/l
  - Exposure time: 91 h

  **M-Factor (Acute aquatic toxicity):** 10

- **Toxicity to fish (Chronic toxicity):**
  - NOEC: 0.00148 mg/l
  - Exposure time: 32 d
  - Species: Pimephales promelas (fathead minnow)

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
  - NOEC: 0.0011 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)

  **M-Factor (Chronic aquatic toxicity):** 10

**Paraformaldehyde:**

- **Toxicity to fish:**
  - LC50: > 1 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia pulex (Water flea)): > 1 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: Based on data from similar materials

- **Toxicity to algae/aquatic plants:**
  - ErC50 (Desmodesmus subspicatus (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
### Toxicity to microorganisms

**EC50**: > 10 mg/l  
**Exposure time**: 3 h  
**Method**: OECD Test Guideline 209  
**Remarks**: Based on data from similar materials

### Toxicity to fish (Chronic toxicity)

**NOEC**: > 1 mg/l  
**Exposure time**: 28 d  
**Species**: Oryzias latipes (Orange-red killifish)  
**Remarks**: Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**NOEC**: > 1 mg/l  
**Exposure time**: 21 d  
**Species**: Daphnia magna (Water flea)  
**Method**: OECD Test Guideline 211  
**Remarks**: Based on data from similar materials

### 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

### 12.2 Persistence and degradability

**Components**:

**Paraformaldehyde**:

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

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

**Biodegradability**: Result: Readily biodegradable.  
**Biodegradation**: 91.2 %  
**Exposure time**: 28 d
12.3 Bioaccumulative potential

**Components:**

**amitraz (ISO):**
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): 1,333
- Partition coefficient: n-octanol/water: log Pow: 5.5

**Paraformaldehyde:**
- Partition coefficient: n-octanol/water: log Pow: -1.40
  - Remarks: Calculation

**Sodium bis(2-ethylhexyl)sulfosuccinate:**
- Partition coefficient: n-octanol/water: log Pow: 1.998
  - Remarks: Calculation

12.4 Mobility in soil

**Components:**

**amitraz (ISO):**
- Distribution among environmental compartments: log Koc: 3.3

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

Amitraz Solid Formulation

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

- **ADN**: UN 3077
- **ADR**: UN 3077
- **RID**: UN 3077
- **IMDG**: UN 3077
- **IATA**: UN 3077

14.2 UN proper shipping name

- **ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
- **ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
- **RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
- **IMDG**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
- **IATA**: Environmentally hazardous substance, solid, n.o.s. (amitraz (ISO))

14.3 Transport hazard class(es)

- **ADN**: 9
- **ADR**: 9
- **RID**: 9
- **IMDG**: 9
- **IATA**: 9

14.4 Packing group

- **ADN**
  - Packing group: III
  - Classification Code: M7
  - Hazard Identification Number: 90
Amitraz Solid Formulation

14.5 Environmental hazards

AND
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : 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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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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): Not applicable
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

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

Full text of H-Statements
H302: Harmful if swallowed.
H315: Causes skin irritation.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Amitraz Solid Formulation

H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H332 : Harmful if inhaled.
H335 : May cause respiratory irritation.
H341 : Suspected of causing genetic defects.
H350 : May cause 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
Muta. : Germ cell mutagenicity
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2004/37/EC / STEL : Short term exposure limit
2004/37/EC / TWA : Long term exposure limit
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute 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; AIIC - Australian Inventory of Industrial Chemicals; 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); 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 Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Air Transport Association; 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
# Amitraz Solid Formulation

**Version** 5.3  
**Revision Date:** 27.08.2021  
**SDS Number:** 1734738-00011  
**Date of last issue:** 09.04.2021  
**Date of first issue:** 06.06.2017

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; TECI - Thailand Existing Chemicals 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

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

## Classification of the mixture:

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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.

IE / EN