

Amorolfine

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 7/29/2019 Version: 1.0

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

1.1. Product identifier

| | |
|----------------|--|
| Product form | : Substance |
| Substance name | : Amorolfine |
| IUPAC name | : (2S,6R)-2,6-dimethyl-4-[2-methyl-3-[4-(2-methylbutan-2-yl)phenyl]propyl]morpholine |
| CAS-No. | : 78613-35-1 |
| Product code | : 21542673 |
| Formula | : C ₂₁ H ₃₅ NO |
| Product group | : Raw material |

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

| | |
|----------------------------------|---|
| Main use category | : Laboratory use, Industrial use, Professional use |
| Industrial/Professional use spec | : For professional use only |
| Use of the substance/mixture | : For analytical purposes Scientific research and development Not for human consumption or veterinary purposes. |

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Safell Organics
Molekula Ltd
Lingfield Way
Darlington - England
T +44 (0) 1949 823777 / +44 (0) 7590 545705
info@molekula.com / kbowen@molekula.com - www.molekula.com

1.4. Emergency telephone number

Emergency number : +44 (0) 7590 545705

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

| | |
|---|------|
| Acute toxicity (oral), Category 4 | H302 |
| Skin corrosion/irritation, Category 2 | H315 |
| Hazardous to the aquatic environment — Chronic Hazard, Category 2 | H411 |
| Full text of H statements : see section 16 | |

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

GHS09

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P264 - Wash hands, forearms and face thoroughly after handling.
P273 - Avoid release to the environment.
P280 - Wear protective clothing, eye protection, face protection, protective gloves.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P501 - Dispose of contents and container to a hazardous or special waste collection point.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % |
|------------|----------------------|-----|
| Amorolfine | (CAS-No.) 78613-35-1 | 100 |

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : If possible show this sheet, if not available show packaging or label. Never give anything by mouth to an unconscious person. Do not leave affected person unattended. |
| First-aid measures after inhalation | : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Give oxygen or artificial respiration if necessary. If breathing difficulties persist : Get medical advice/attention. |
| First-aid measures after skin contact | : After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Do not remove clothing if it sticks to the skin. If irritation persists, consult a doctor. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. |
| First-aid measures after ingestion | : Rinse mouth out with water. Do not induce vomiting. Get medical advice/attention. |

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

| | |
|-------------------------------------|--|
| Symptoms/effects after inhalation | : Inhalation may cause irritation (cough, short breathing, difficulty in breathing). Headache. |
| Symptoms/effects after skin contact | : May cause moderate irritation, including burning sensation, tearing, redness or swelling. Itching. |
| Symptoms/effects after eye contact | : May cause eye irritation. redness, itching, tears. stinging. |
| Symptoms/effects after ingestion | : Harmful if swallowed. Swallowing this material may result in health hazard. Symptoms of ingestion include drowsiness, weakness, headache, dizziness, nausea, vomiting. |

4.3. Indication of any immediate medical attention and special treatment needed

Get immediate medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--------------------------------|--|
| Suitable extinguishing media | : Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| Hazardous decomposition products in case of fire | : Carbon oxides (CO, CO ₂). Hydrogen chloride gas. Nitrogen oxides. |
|--|---|

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Precautionary measures fire | : Keep container tightly closed and away from heat, sparks and flame. Keep away from combustible materials. |
| Firefighting instructions | : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |
| Other information | : Warn all persons of toxic hazard. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------------------------|--|
| General measures | : Isolate from fire, if possible, without unnecessary risk. Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition. |
| 6.1.1. For non-emergency personnel | |
| Protective equipment | : Wear recommended personal protective equipment. |
| Emergency procedures | : Evacuate unnecessary personnel. Mark out the contaminated area with signs and prevent access to unauthorized personnel. Do not touch or walk on the spilled product. Avoid contact with skin, eyes and clothing. |
| Measures in case of dust release | : Keep upwind. Avoid creating or spreading dust. Ventilate the area thoroughly, especially low lying areas (basements, workpits etc). |

6.1.2. For emergency responders

| | |
|----------------------|---|
| Protective equipment | : Equip cleanup crew with proper protection. Use self-contained breathing apparatus and chemically protective clothing. |
| Emergency procedures | : Ventilate area. |

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Shovel or sweep up and put in a closed container for disposal.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid creating or spreading dust. Provide local exhaust or general room ventilation.
Hygiene measures : Take off immediately all contaminated clothing and wash it before reuse. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Ensure adequate ventilation, especially in confined areas.
Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Heat sources, Direct sunlight. Keep container closed when not in use.
Incompatible products : Strong oxidizing agents.
Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.
Heat and ignition sources : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Storage area : Store below 20 °C. Store in a dry place. Store in a closed container.

7.3. Specific end use(s)

For analytical purposes. Scientific research and development. Not for human consumption or veterinary purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Handle in accordance with good industrial hygiene and safety procedures.

Personal protective equipment:

Avoid all unnecessary exposure.

| | | | | | |
|--|----------------------|-------------------|---|--------------------|-----------------|
| Materials for protective clothing: | | | | | |
| Wear suitable protective clothing, gloves and eye/face protection | | | | | |
| Hand protection: | | | | | |
| The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard EN 374 | | | | | |
| Type | Material | Permeation | Thickness (mm) | Penetration | Standard |
| Disposable gloves | Nitrile rubber (NBR) | 6 (> 480 minutes) | 0.11 | | EN 374 |
| Eye protection: | | | | | |
| Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure. Use eye protection according to EN 166, designed to protect against powders and dusts. | | | | | |
| Type | Use | | Characteristics | Standard | |
| Safety goggles | Fine dust, Dust | | tightly fitting safety goggles, With side shields | EN 166 | |
| Skin and body protection: | | | | | |
| Emergency safety showers should be available in the immediate vicinity of any potential exposure. Keep suitable chemically resistant protective clothing readily available for emergency use | | | | | |
| Type | | | Standard | | |
| Protective clothing (with elasticated cuffs and closed neck) | | | EN ISO 13982 | | |
| Respiratory protection: | | | | | |
| Keep self contained breathing apparatus readily available for emergency use. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended | | | | | |
| Device | Filter type | | Condition | Standard | |
| Respiratory protective device with a particle filter | Type P1, Type P2 | | Dust protection | EN 14387 | |

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Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|----------------------|
| Physical state | : Solid |
| Appearance | : Powder. |
| Molecular mass | : 317.51 g/mol |
| Colour | : white. |
| Odour | : No data available. |
| Odour threshold | : No data available |
| pH | : 3.5 - 4 |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : 206 - 208 °C |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Non flammable. |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Log Pow | : 5.772 |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Protect from sunlight. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. Thermal decomposition generates : Carbon oxides (CO, CO₂). hydrogen chloride. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|-------------------------------|
| Acute toxicity (oral) | : Oral: Harmful if swallowed. |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

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| | |
|---------------------------|--|
| LD50 oral rat | > 2000 mg/kg |
| Skin corrosion/irritation | : Causes skin irritation. pH: 3.5 - 4 |
| Additional information | : Based on available data, the classification criteria are not met |

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| | |
|---|---|
| Serious eye damage/irritation | : Not classified |
| | pH: 3.5 - 4 |
| Additional information | : Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Carcinogenicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Reproductive toxicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| STOT-single exposure | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| STOT-repeated exposure | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Aspiration hazard | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Potential adverse human health effects and symptoms | : Based on available data, the classification criteria are not met. |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|--|
| Acute aquatic toxicity | : Not classified |
| Chronic aquatic toxicity | : Toxic to aquatic life with long lasting effects. |

Amorolfine (78613-35-1)

| | |
|-------------|---|
| LC50 fish 1 | 2.6 mg/l Oncorhynchus mykiss (rainbow trout) 96hr |
|-------------|---|

12.2. Persistence and degradability

Amorolfine (78613-35-1)

| | |
|-------------------------------|--------------------|
| Persistence and degradability | No data available. |
|-------------------------------|--------------------|

12.3. Bioaccumulative potential

Amorolfine (78613-35-1)

| | |
|---------------------------|--------------------|
| Log Pow | 5.772 |
| Bioaccumulative potential | No data available. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Amorolfine (78613-35-1)

| |
|--|
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |

12.6. Other adverse effects

| | |
|------------------------|-------------------------------------|
| Additional information | : Avoid release to the environment. |
|------------------------|-------------------------------------|

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--|---|
| Product/Packaging disposal recommendations | : Dispose in a safe manner in accordance with local/national regulations. |
| Ecology - waste materials | : Avoid release to the environment. |

SECTION 14: Transport information






In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IMDG | IATA | ADN | RID |
|------------------------|------|------|------|------|
| 14.1. UN number | | | | |
| 3077 | 3077 | 3077 | 3077 | 3077 |


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| 14.2. UN proper shipping name | | | | |
|--|---|---|--|---|
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Transport document description | | | | |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine), 9, III, (-) | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine), 9, III, MARINE POLLUTANT | UN 3077 Environmentally hazardous substance, solid, n.o.s. (Amorolfine), 9, III | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine), 9, III | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine), 9, III |
| 14.3. Transport hazard class(es) | | | | |
| 9 | 9 | 9 | 9 | 9 |
|  |  |  |  |  |
| 14.4. Packing group | | | | |
| III | III | III | III | III |
| 14.5. Environmental hazards | | | | |
| Dangerous for the environment : Yes | Dangerous for the environment : Yes Marine pollutant : Yes | Dangerous for the environment : Yes | Dangerous for the environment : Yes | Dangerous for the environment : Yes |
| No supplementary information available | | | | |
| 14.6. Special precautions for user | | | | |

Overland transport

| | |
|---|---|
| Classification code (ADR) | : M7 |
| Special provisions (ADR) | : 274, 335, 375, 601 |
| Limited quantities (ADR) | : 5kg |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |
| Special packing provisions (ADR) | : PP12, B3 |
| Mixed packing provisions (ADR) | : MP10 |
| Portable tank and bulk container instructions (ADR) | : T1, BK1, BK2, BK3 |
| Portable tank and bulk container special provisions (ADR) | : TP33 |
| Tank code (ADR) | : SGAV, LGBV |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 3 |
| Special provisions for carriage - Packages (ADR) | : V13 |
| Special provisions for carriage - Bulk (ADR) | : VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13 |
| Hazard identification number (Kemler No.) | : 90 |
| Orange plates | :  |

Tunnel restriction code (ADR) : -

Transport by sea

| | |
|-----------------------------------|---------------------------|
| Special provisions (IMDG) | : 274, 335, 966, 967, 969 |
| Limited quantities (IMDG) | : 5 kg |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP02, P002 |
| Special packing provisions (IMDG) | : PP12 |

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| | |
|---------------------------------|---------------------|
| IBC packing instructions (IMDG) | : IBC08 |
| IBC special provisions (IMDG) | : B3 |
| Tank instructions (IMDG) | : BK1, BK2, BK3, T1 |
| Tank special provisions (IMDG) | : TP33 |
| EmS-No. (Fire) | : F-A |
| EmS-No. (Spillage) | : S-F |
| Stowage category (IMDG) | : A |
| Stowage and handling (IMDG) | : SW23 |

Air transport

| | |
|--|-------------------------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y956 |
| PCA limited quantity max net quantity (IATA) | : 30kgG |
| PCA packing instructions (IATA) | : 956 |
| PCA max net quantity (IATA) | : 400kg |
| CAO packing instructions (IATA) | : 956 |
| CAO max net quantity (IATA) | : 400kg |
| Special provisions (IATA) | : A97, A158, A179, A197 |
| ERG code (IATA) | : 9L |

Inland waterway transport

| | |
|---------------------------------------|--|
| Classification code (ADN) | : M7 |
| Special provisions (ADN) | : 274, 335, 375, 601 |
| Limited quantities (ADN) | : 5 kg |
| Excepted quantities (ADN) | : E1 |
| Carriage permitted (ADN) | : T* B** |
| Equipment required (ADN) | : PP, A |
| Number of blue cones/lights (ADN) | : 0 |
| Additional requirements/Remarks (ADN) | : * Only in the molten state. ** For carriage in bulk see also 7.1.4.1. *** Only in the case of transport in bulk. |

Rail transport

| | |
|---|---------------------------|
| Classification code (RID) | : M7 |
| Special provisions (RID) | : 274, 335, 375, 601 |
| Excepted quantities (RID) | : E1 |
| Packing instructions (RID) | : P002, IBC08, LP02, R001 |
| Special packing provisions (RID) | : PP12, B3 |
| Mixed packing provisions (RID) | : MP10 |
| Portable tank and bulk container instructions (RID) | : T1, BK1, BK2, BK3 |
| Portable tank and bulk container special provisions (RID) | : TP33 |
| Tank codes for RID tanks (RID) | : SGAV, LGBV |
| Transport category (RID) | : 3 |
| Special provisions for carriage – Packages (RID) | : W13 |
| Special provisions for carriage – Bulk (RID) | : VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (RID) | : CW13, CW31 |
| Colis express (express parcels) (RID) | : CE11 |
| Hazard identification number (RID) | : 90 |

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

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions
Amorolfine is not on the REACH Candidate List
Directive 2012/18/EU (SEVESO III)

15.1.2. National regulations

No additional information available

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Chronic 2 | Hazardous to the aquatic environment — Chronic Hazard, Category 2 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| H302 | Harmful if swallowed. |
| H315 | Causes skin irritation. |
| H411 | Toxic to aquatic life with long lasting effects. |

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.