



## SAFETY DATA SHEET

### Amorolfine hydrochloride

According to the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 No. 1577, as amended.

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

##### 1.1. Product identifier

Product name	Amorolfine hydrochloride
Synonyms; trade names	(2R,6S)-rel-4-[3-[4-(1,1-Dimethylpropyl)phenyl]-2-methylpropyl]-2,6-dimethyl-morpholine hydrochloride, Ro 14-4767/002
CAS number	78613-38-4
EC number	689-236-9

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

Identified uses	Research and development.
Uses advised against	Not suitable for human consumption or veterinary purposes.

##### 1.3. Details of the supplier of the safety data sheet

Supplier	Molekula Ltd. Lingfield Way, Darlington, DL1 4XX, United Kingdom +44 (0) 3302000333 info@molekula.com
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##### 1.4. Emergency telephone number

+44 (0) 7769276927

#### SECTION 2: Hazards identification

##### 2.1. Classification of the substance or mixture

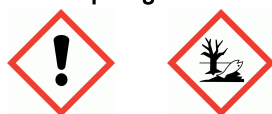
###### Classification (SI 2019 No. 720)

Physical hazards	Not Classified
Health hazards	Acute Tox. 4 - H302 Skin Irrit. 2 - H315
Environmental hazards	Aquatic Chronic 2 - H411

##### 2.2. Label elements

EC number	689-236-9
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###### Hazard pictograms



Signal word	Warning
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<b>Hazard statements</b>	<p>H302 Harmful if swallowed.</p> <p>H315 Causes skin irritation.</p> <p>H411 Toxic to aquatic life with long lasting effects.</p>
<b>Precautionary statements</b>	<p>P264 Wash contaminated skin thoroughly after handling.</p> <p>P270 Do not eat, drink or smoke when using this product.</p> <p>P273 Avoid release to the environment.</p> <p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>P301+P312 IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water.</p> <p>P321 Specific treatment (see medical advice on this label).</p> <p>P330 Rinse mouth.</p> <p>P332+P313 If skin irritation occurs: Get medical advice/ attention.</p> <p>P362+P364 Take off contaminated clothing and wash it before reuse.</p> <p>P391 Collect spillage.</p> <p>P501 Dispose of contents/ container in accordance with national regulations.</p>

### 2.3. Other hazards

This substance is not classified as PBT or vPvB according to current UK criteria.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

<b>Product name</b>	Amorolfine hydrochloride
<b>CAS number</b>	78613-38-4
<b>EC number</b>	689-236-9
<b>Chemical formula</b>	C <sub>21</sub> H <sub>35</sub> ON · HCl

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>General information</b>	Get medical attention if any discomfort continues. Show this Safety Data Sheet to the medical personnel.
<b>Inhalation</b>	Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Loosen tight clothing such as collar, tie or belt. Get medical attention if symptoms are severe or persist.
<b>Ingestion</b>	Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.
<b>Skin contact</b>	Rinse with water.
<b>Eye contact</b>	Remove any contact lenses and open eyelids wide apart. Rinse with water. Get medical attention if any discomfort continues.
<b>Protection of first aiders</b>	First aid personnel should wear appropriate protective equipment during any rescue.

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

<b>General information</b>	The severity of the symptoms described will vary dependent on the concentration and the length of exposure.
<b>Inhalation</b>	A single exposure may cause the following adverse effects: Temporary irritation.

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Ingestion	May cause discomfort if swallowed. Stomach pain. Nausea, vomiting.
Skin contact	Redness. Irritating to skin.
Eye contact	May be slightly irritating to eyes.

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

Notes for the doctor	Treat symptomatically.
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## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

Suitable extinguishing media	Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-extinguishing media suitable for the surrounding fire.
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Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
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### **5.2. Special hazards arising from the substance or mixture**

Specific hazards	This product is toxic.
Hazardous combustion products	Thermal decomposition or combustion products may include the following substances: Toxic gases or vapours. Oxides of carbon. Oxides of nitrogen. Hydrogen chloride (HCl).

### **5.3. Advice for firefighters**

Protective actions during firefighting	Avoid breathing fire gases or vapours. Evacuate area. Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk. Cool containers exposed to flames with water until well after the fire is out. Avoid discharge to the aquatic environment. Control run-off water by containing and keeping it out of sewers and watercourses. If risk of water pollution occurs, notify appropriate authorities.
Special protective equipment for firefighters	Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing will provide a basic level of protection for chemical incidents.

## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

Personal precautions	Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material.
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### **6.2. Environmental precautions**

Environmental precautions	Avoid discharge into drains or watercourses or onto the ground. Avoid discharge to the aquatic environment.
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### **6.3. Methods and material for containment and cleaning up**

Methods for cleaning up	Wear protective clothing as described in Section 8 of this safety data sheet. Clear up spills immediately and dispose of waste safely. Provide adequate ventilation. Collect spillage with a shovel and broom, or similar and reuse, if possible. Collect and place in suitable waste disposal containers and seal securely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. Dangerous for the environment. Do not empty into drains. For waste disposal, see Section 13.
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### **6.4. Reference to other sections**

Reference to other sections	For personal protection, see Section 8. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards. For waste disposal, see Section 13.
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## Amorolfine hydrochloride

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Usage precautions** Read and follow manufacturer's recommendations. Wear protective clothing as described in Section 8 of this safety data sheet. Keep away from food, drink and animal feeding stuffs. Keep container tightly sealed when not in use. Avoid discharge to the aquatic environment. Do not handle until all safety precautions have been read and understood. Do not handle broken packages without protective equipment. Do not reuse empty containers.

**Advice on general occupational hygiene** Wash promptly if skin becomes contaminated. Take off contaminated clothing. Wash contaminated clothing before reuse.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage precautions** Store away from incompatible materials (see Section 10). Keep only in the original container. Keep container tightly closed, in a cool, well ventilated place. Keep containers upright. Protect containers from damage.

**Storage class** Miscellaneous hazardous material storage.

#### 7.3. Specific end use(s)

**Specific end use(s)** The identified uses for this product are detailed in Section 1.2.

### SECTION 8: Exposure controls/Personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### Protective equipment



**Appropriate engineering controls** Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

**Eye/face protection** Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses.

**Hand protection** Wear protective gloves. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, wear gloves that are proven to be impervious to the chemical and resist degradation. Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended.

**Other skin and body protection** Wear appropriate clothing to prevent repeated or prolonged skin contact.

**Hygiene measures** Wash after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

**Respiratory protection** Ensure all respiratory protective equipment is suitable for its intended use and is 'UKCA'-marked. Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges suitable for intended use should be used. Full face mask respirators with replaceable filter cartridges suitable for intended use should be used. Half mask and quarter mask respirators with replaceable filter cartridges suitable for intended use should be used.

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### Environmental exposure controls

Keep container tightly sealed when not in use. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance	Powder.
Colour	White/off-white.
Odour	Not known.
Odour threshold	No information available.
pH	No information available.
Melting point	203 - 208°C/397 - 406°F
Initial boiling point and range	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Solubility(ies)	No information available.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.

### 9.2. Other information

Molecular weight	353.97
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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity	See the other subsections of this section for further details.
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### 10.2. Chemical stability

Stability	Stable at normal ambient temperatures and when used as recommended. Stable under the prescribed storage conditions.
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### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	No potentially hazardous reactions known.
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### 10.4. Conditions to avoid

Conditions to avoid	Avoid heat.
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### 10.5. Incompatible materials

**Materials to avoid** Strong oxidising agents.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Does not decompose when used and stored as recommended. Thermal decomposition or combustion products may include the following substances: Toxic gases or vapours. Oxides of carbon. Oxides of nitrogen. Hydrogen chloride (HCl).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity - oral

**Summary** Harmful if swallowed.

**ATE oral (mg/kg)** 500.0

#### Acute toxicity - dermal

**Summary** Based on available data the classification criteria are not met.

#### Acute toxicity - inhalation

**Summary** Based on available data the classification criteria are not met.

#### Skin corrosion/irritation

**Summary** Causes skin irritation.

#### Serious eye damage/irritation

**Summary** Based on available data the classification criteria are not met.

#### Respiratory sensitisation

**Summary** Based on available data the classification criteria are not met.

#### Skin sensitisation

**Summary** Based on available data the classification criteria are not met.

#### Germ cell mutagenicity

**Summary** Based on available data the classification criteria are not met.

#### Carcinogenicity

**Summary** Based on available data the classification criteria are not met.

#### IARC carcinogenicity

None of the ingredients are listed or exempt.

#### Reproductive toxicity

**Summary** Based on available data the classification criteria are not met.

#### Specific target organ toxicity - single exposure

**Summary** Based on available data the classification criteria are not met.

#### Specific target organ toxicity - repeated exposure

**Summary** Based on available data the classification criteria are not met.

#### Aspiration hazard

**Summary** Not relevant. Solid.

#### General information

The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

#### Inhalation

A single exposure may cause the following adverse effects: Temporary irritation.

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<b>Ingestion</b>	May cause discomfort if swallowed. Stomach pain. Nausea, vomiting.
<b>Skin contact</b>	Redness. Irritating to skin.
<b>Eye contact</b>	May be slightly irritating to eyes.
<b>Route of exposure</b>	Ingestion Inhalation Skin and/or eye contact
<b>Target organs</b>	No specific target organs known.

### SECTION 12: Ecological information

#### 12.1. Toxicity

##### Acute aquatic toxicity

**Summary** Based on available data the classification criteria are not met.

**Acute toxicity - fish** LC<sub>50</sub>, 96 hours: 2.6 mg/l, Oncorhynchus mykiss (Rainbow trout)

##### Chronic aquatic toxicity

**Summary** Toxic to aquatic life with long lasting effects.

#### 12.2. Persistence and degradability

**Persistence and degradability** The degradability of the product is not known.

**Biodegradation** Not readily biodegradable.

#### 12.3. Bioaccumulative potential

**Bioaccumulative potential** No data available on bioaccumulation.

**Partition coefficient** No information available.

#### 12.4. Mobility in soil

**Mobility** No data available.

#### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment** This product does not contain any substances classified as PBT or vPvB.

#### 12.6. Other adverse effects

**Other adverse effects** None known.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**General information** The generation of waste should be minimised or avoided wherever possible. Reuse or recycle products wherever possible. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered. Care should be taken when handling emptied containers that have not been thoroughly cleaned or rinsed out. Empty containers or liners may retain some product residues and hence be potentially hazardous.

**Disposal methods** Do not empty into drains. Dispose of surplus products and those that cannot be recycled via a licensed waste disposal contractor. Waste, residues, empty containers, discarded work clothes and contaminated cleaning materials should be collected in designated containers, labelled with their contents. Incineration or landfill should only be considered when recycling is not feasible.

### SECTION 14: Transport information

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**General** For limited quantity packaging/limited load information, consult the relevant modal documentation using the data shown in this section.

### 14.1. UN number

UN No. (ADR/RID)	3077
UN No. (IMDG)	3077
UN No. (ICAO)	3077
UN No. (ADN)	3077

### 14.2. UN proper shipping name

Proper shipping name (ADR/RID)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine hydrochloride)
Proper shipping name (IMDG)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine hydrochloride)
Proper shipping name (ICAO)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine hydrochloride)
Proper shipping name (ADN)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amorolfine hydrochloride)

### 14.3. Transport hazard class(es)

ADR/RID class	9
ADR/RID classification code	M7
ADR/RID label	9
IMDG class	9
ICAO class/division	9
ADN class	9

Transport labels



### 14.4. Packing group

ADR/RID packing group	III
IMDG packing group	III
ICAO packing group	III
ADN packing group	III

### 14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant



### 14.6. Special precautions for user



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Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**EmS** F-A, S-F

**ADR transport category** 3

**Emergency Action Code** 2Z

**Hazard Identification Number (ADR/RID)** 90

**Tunnel restriction code** (-)

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

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78  
and the IBC Code

## SECTION 15: Regulatory information

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

**National regulations** Health and Safety at Work etc. Act 1974 (as amended).  
The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].  
EH40/2005 Workplace exposure limits.

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

### Inventories

#### **EU - EINECS/ELINCS**

None of the ingredients are listed or exempt.

## SECTION 16: Other information

**Abbreviations and acronyms used in the safety data sheet**

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.  
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.  
RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.  
IATA: International Air Transport Association.  
ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air.  
IMDG: International Maritime Dangerous Goods.  
CAS: Chemical Abstracts Service.  
ATE: Acute Toxicity Estimate.  
LC50: Lethal Concentration to 50 % of a test population.  
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose).  
EC<sub>50</sub>: 50% of maximal Effective Concentration.  
PBT: Persistent, Bioaccumulative and Toxic substance.  
vPvB: Very Persistent and Very Bioaccumulative.

**Classification abbreviations and acronyms**

Acute Tox. = Acute toxicity  
Skin Irrit. = Skin irritation  
Aquatic Chronic = Hazardous to the aquatic environment (chronic)

**Classification procedures according to SI 2019 No. 720**

Acute Tox. 4 - H302: Skin Irrit. 2 - H315: : Expert judgement. Aquatic Chronic 2 - H411: : Expert judgement.

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<b>Training advice</b>	Only trained personnel should use this material.
<b>Revision date</b>	25/08/2022
<b>Revision</b>	1
<b>SDS number</b>	1388
<b>Hazard statements in full</b>	H302 Harmful if swallowed. H315 Causes skin irritation. H411 Toxic to aquatic life with long lasting effects.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.