

According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

## 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Product code : GP0831  
Product name : Amorolfine hydrochloride  
CAS number : 78613-38-4  
Physical form : solid, substance  
REACH : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

PC21: Laboratory chemicals.

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

Company name	: Glenthams Life Sciences Ltd	Telephone	: +44 (0) 1225 667 798
	Unit 5 Leafield Way	Fax	: +44 (0) 2033 978 909
	Corsham SN13 9SW	Email	: <a href="mailto:info@glenthams.com">info@glenthams.com</a>
	United Kingdom	Web	: <a href="http://www.glenthams.com">www.glenthams.com</a>

### 1.4 Emergency telephone number

Emergency telephone : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT) number

## 2. Hazards identification

### 2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

H302	Acute Tox. 4
H315	Skin Irr. 2
H411	Aquatic Chronic 2

### 2.2 Label elements

Label elements under CLP according to (EC) 1272/2008

#### Pictograms



#### Signal words

Warning

#### Hazard statements

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

#### Precautionary statements

P273	Avoid release to the environment.
P301+P312	IF SWALLOWED: call a POISON CENTER/doctor/... IF you feel unwell.
P302+P350	IF ON SKIN: Gently wash with plenty of soap and water.
P264	Do not breathe fume.

### 2.3 Other hazards

#### PBT

This substance is not identified as a PBT substance.

## 3.0 Composition/information on ingredients

### 3.1 Substances

Name	Identifier	%	Classification
Amorolfine hydrochloride	CAS: 78613-38-4 EC: REACH: Not applicable	99.0%	H302, Acute Tox. 4 H315, Skin Irr. 2 H411, Aquatic Chronic 2

#### 4. First aid measures

##### 4.1 Description of first aid measures

Skin contact	Consult a doctor. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water.
Eye contact	Consult a doctor. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Wash out mouth with water.
Inhalation	Consult a doctor. Remove casualty from exposure ensuring one's own safety whilst doing so.

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

Skin contact	There may be irritation and redness at the site of contact.
Eye contact	The eyes may water profusely. There may be irritation and redness.
Ingestion	Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Exposure may cause coughing or wheezing. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting.
Delayed / immediate effects	Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur.

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

###### Immediate / special treatment

Do not induce vomiting. Eye bathing equipment should be available on the premises.

#### 5. Fire-fighting measures

##### 5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

##### 5.2 Special hazards arising from the substance or mixture

###### Exposure hazards

In combustion emits toxic fumes.

##### 5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

#### 6. Accidental release measures

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

###### Personal precautions

Do not create dust. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

##### 6.2 Environmental precautions

Do not discharge into drains or rivers.

##### 6.3 Methods and material for containment and cleaning up

###### Clean-up procedures

Transfer to a closable, labelled salvage container for disposal by an appropriate method.

#### 6.4 Reference to other sections

Refer to section 8 of SDS.

### 7. Handling and storage

#### 7.1 Precautions for safe handling

##### Handling requirements

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is sufficient ventilation of the area.

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

##### Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. The floor of the storage room must be impermeable to prevent the escape of liquids. Store in cool, well ventilated area.

#### 7.3 Specific end use(s)

No data available.

### 8. Exposure controls/personal protection

#### 8.1 Control parameters

##### Workplace exposure limits

No workplace exposure limit control parameters set

#### 8.2 Exposure controls

Engineering measures	The floor of the storage room must be impermeable to prevent the escape of liquids. Ensure there is sufficient ventilation of the area.
Respiratory protection	Respiratory protective device with particle filter. Self-contained breathing apparatus must be available in case of emergency.
Hand protection	Protective gloves.
Eye protection	Ensure eye bath is to hand. Safety glasses.
Skin protection	Protective clothing.
Environmental	The floor of the storage room must be impermeable to prevent the escape of liquids.

### 9. Physical and chemical properties

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

Physical state	Solid
Colour	White
Odour	No data available.
Melting point/Freezing point	No data available.
Boiling point/initial boiling point/boiling range	No data available.
Flammability	No data available.
Lower/Upper explosion limit	No data available.
Flash Point	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
pH	No data available.
Kinematic viscosity	No data available.
Solubility	No data available.
Partition coefficient n-octanol/water	No data available.
Vapour pressure	No data available.
Density/relative density	No data available.
Relative vapour pressure	No data available.
Particle characteristics	No data available.

#### 9.2 Other information

No data available.

## 10. Stability and reactivity

### 10.1 Reactivity

Stable under recommended transport or storage conditions.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

#### Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

### 10.4 Conditions to avoid

Heat.

### 10.5 Incompatible materials

#### Materials to avoid

Strong acids. Strong oxidising agents.

## 11. Toxicological information

### 11.1 Information on toxicological effects

#### a) Acute toxicity

No data available.

#### b) Skin corrosion/irritation

Skin corrosion/irritation (Category 2)

#### c) Serious eye damage/irritation

No data available.

#### d) Respiratory or skin sensitisation

No data available.

#### e) Germ cell mutagenicity

No data available.

#### f) Carcinogenicity

No data available.

#### g) Reproductive toxicity

No data available.

#### h) STOT-single exposure

No data available.

#### i) STOT-repeated exposure

No data available.

#### j) Aspiration hazard

No data available.

#### Symptoms / routes of exposure

Skin contact	There may be irritation and redness at the site of contact.
Eye contact	The eyes may water profusely. There may be irritation and redness.
Ingestion	Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Exposure may cause coughing or wheezing. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting.
Delayed / immediate effects	Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur.

Other information No data available.

## 11.2 Information on other hazards

### 11.2.1 Endocrine disrupting properties

This product does not contain known or suspected endocrine disruptors according to REACH or relevant EU Regulations.

### 11.2.2 Other information

No additional information

## 12. Ecological information

### 12.1 Toxicity

No data available.

### 12.2 Persistence and degradability

Not biodegradable.

### 12.3 Bioaccumulative potential

Bioaccumulation potential.

### 12.4 Mobility in soil

Readily absorbed into soil.

### 12.5 Results of PBT and vPvB assessment

This substance is not identified as a PBT substance.

### 12.6 Endocrine disrupting properties

This substance is not identified as having endocrine disrupting properties

### 12.7 Other adverse effects

No data available.

## 13. Disposal considerations

### 13.1 Waste treatment methods

#### Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

#### NB

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

## 14. Transport information

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
UN3077	UN3077	UN3077	UN3077	UN3077
<b>14.2. UN proper shipping name</b>				
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.
<b>Transport document description</b>				
UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOROLFINE HYDROCHLORIDE), 9, III	UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOROLFINE HYDROCHLORIDE), 9, III	UN3077 Environmentally hazardous substance, solid, n.o.s. (Amorolfine hydrochloride), 9, III	UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOROLFINE HYDROCHLORIDE), 9, III	UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMOROLFINE HYDROCHLORIDE), 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



Dangerous for the Environment: yes



Dangerous for the Environment: yes



Dangerous for the Environment: yes

## 15. Regulatory information

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

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/878.

#### Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation: No data available.

Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances: No data available.

Regulation (EC) 1005/2009 on substances that deplete the ozone layer: No data available.

Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No 2019/1021: No data available.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

## 16. Other information

### H-Statement Full Texts

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

### Abbreviations Full Texts

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  
ALARP As low as is reasonably practicable  
CAS Chemical Abstracts Service  
CLP Classification, Labelling and Packaging Regulations  
COSHH Control of Substances Hazardous to Health  
EC Number European Community Number  
EC50 Effective Concentration 50%  
EILINCS European List of Notified Chemical Substances  
EINECS European Inventory of Existing Commercial Chemical Substances  
GHS Globally Harmonised System  
HSE Health & Safety Executive UK  
IATA International Air Transport Association  
IM Intramuscular  
IMDG The International Maritime Dangerous Goods Code  
IP Intraperitoneal  
IV Intravascular

LD50	Lethal Dose 50%
LOEC	Lowest Observable Effective Concentration
LTEL	Long Term Exposure Limit
NOEC	No Observable Effective Concentration
OECD	Organisation for Economic Cooperations and Development
PBT	Persistent Bioaccumulative Toxic
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulations Concerning the International Carriage of Dangerous Goods by Rail
SC	Subcutaneous
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STOT	Specific Target Organ Toxicity
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
WEL	Workplace Exposure Limits

**This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/878.**

Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.

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