

Creation Date 24-Feb-2014 Revision Date 24-Feb-2014 Revision Number 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: Amoxicillin

Cat No. : 455140000; 455140010; 455140050; 455140250

CAS-No 26787-78-0 **EC-No.** 248-003-8 **Molecular Formula** C16 H19 N3 O5 S

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

Recommended Use Laboratory chemicals
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Acros Organics BVBA

Janssen Pharmaceuticalaan 3a

2440 Geel, Belgium

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Respiratory Sensitization Category 1
Skin Sensitization Category 1

Environmental hazards

Based on available data, the classification criteria are not met

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Symbol(s) Xn - Harmful

R-phrase(s)

R42/43 - May cause sensitization by inhalation and skin contact

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

2.2. Label elements

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Signal Word Danger

Hazard Statements

H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements

P280 - Wear protective gloves/ protective clothing

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/ attention

P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician

2.3. Other hazards

No information available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008	DSD Classification - 67/548/EEC
4-Thia-1-azobicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-, [2S-[2.alpha.,5.alpha.,6.beta.(S)]]-	26787-78-0	EEC No. 248-003-8	>95	Skin Sens. 1 (H317) Resp. Sens. 1 (H334)	Xn; R42 Xi; R43

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Inhalation Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention.

Protection of First-aiders Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination

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

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May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin reaction... Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing.

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

Notes to Physician Treat symptomatically

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO2), Nitrogen oxides (NOx), Sulfur oxides.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation.

6.2. Environmental precautions

Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Keep refrigerated. Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

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Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL) No information available.

Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral				
Dermal				
Inhalation				

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source.

Personal protective equipment

Eye Protection Safety glasses with side-shields (European standard - EN 166)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Natural rubber Nitrile rubber Neoprene PVC	See manufacturers recommendations	-	EN 374	(minimum requirement)

Skin and body protection Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion. Remove gloves with care avoiding skin contamination.

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When workers are facing concentrations above the exposure limit they must use appropriate

Solid

Solid

certified respirators

To protect the wearer, respiratory protective equipment must be the correct fit and be used and

maintained properly.

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are

exceeded or if irritation or other symptoms are experienced..

Recommended Filter type: Particulates filter conforming to EN 143.

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance

Amoxicillin

Respiratory Protection

Physical State Solid.
Odor odorless

Odor Threshold No data available

pH No information available.

Melting Point/Range330°C / 626°FSoftening PointNo data availableBoiling Point/RangeNo information available.

Flash Point No information available. Method - No information available.

Evaporation Rate Not applicable Solid

Flammability (solid,gas) No information available.

Explosion Limits No data available.

Vapor PressureNo data availableVapor DensityNot applicable

Specific Gravity / Density

Bulk Density

No data available

No data available

Water Solubility

Solubility in other solvents

No information available.

No information available.

Partition Coefficient (n- Component log Pow octanol/water) 4-Thia-1-azobicyclo[3.2.0]heptane-2- 0.97

carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino]-3,3-

dimethyl-7-oxo-, [2S-

[2.alpha.,5.alpha.,6.beta.(S)]]-

Autoignition Temperature Not applicable

Decomposition temperature No data available

Viscosity Not applicable

Explosive PropertiesNo information available. **Oxidizing Properties**No information available.

9.2. Other information

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Molecular Formula C16 H19 N3 O5 S

Molecular Weight 365.4

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available.

10.2. Chemical stability

Amoxicillin

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization No information available Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Incompatible products, Excess heat, Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NOx), Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Product Information

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met

DermalNo data availableInhalationNo data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
4-Thia-1-azobicyclo[3.2.0]heptane-2-	>15 g/kg (Rat)		
carboxylic acid, 6-[[amino(4-			
hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-			
oxo- [2S-[2 alpha 5 alpha 6 beta (S)]]-			

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory Category 1 **Skin** Category 1

No information available.

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

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(g) reproductive toxicity;No data available(h) STOT-single exposure;No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; Not applicable

Solid

Other Adverse Effects See actual entry in RTECS for complete information The toxicological properties have not been

fully investigated.

Symptoms / effects, both acute and delayed

Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of

the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Amoxicillin

Ecotoxicity effectsContains no substances known to be hazardous to the environment or that are not degradable

in waste water treatment plants

12.2. Persistence and degradability

Persistence

No information available Persistence is unlikely.

12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
4-Thia-1-azobicyclo[3.2.0]heptane-2-	0.97	No data available
carboxylic acid, 6-[[amino(4-		
hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-		
oxo-, [2S-[2.alpha.,5.alpha.,6.beta.(S)]]-		

12.4. Mobility in soilNo information available.

12.5. Results of PBT and vPvB

assessment

No data available for assessment

12.6. Other adverse effects

Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues / Unused

Products

Waste is classified as hazardous. Dispose of in accordance with the European Directives on

waste and hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point..

European Waste Catalogue (EWC) According to the European Waste Catalogue, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO Not regulated

14.1. UN number

ACR45514

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14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

Amoxicillin

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

IATA Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazardsNo hazards identified

14.6. Special precautions for user No special precautions required

14.7. Transport in bulk according to

Annex II of MARPOL73/78 and the

Not applicable, packaged goods

IBC Code

SECTION 15: REGULATORY INFORMATION

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

International Inventories X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
4-Thia-1-	248-003-8	-		-	Χ	-	Х	-	-	Х	Χ
azobicyclo[3.2.0]heptane-2-											
carboxylic acid, 6-[[amino(4-											
hydroxyphenyl)acetyl]amino]-3,3-											
dimethyl-7-oxo-, [2S-											
[2.alpha.,5.alpha.,6.beta.(S)]]-											

National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

R42/43 - May cause sensitization by inhalation and skin contact

Full text of H-Statements referred to under sections 2 and 3

H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Legend

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Amoxicillin

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Existing and Evaluated Chemical Substances

WEL - Workplace Exposure Limit

ACGIH - American Conference of Industrial Hygiene

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration
PBT - Persistent, Bioaccumulative, Toxic

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Key literature references and sources for data

Suppliers safety data sheet,

Chemadvisor - LOLI,

Merck index,

RTECS

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japan Existing and New Chemical Substances **AICS** - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% **POW** - Partition coefficient Octanol:Water **vPvB** - very Persistent, very Bioaccumulative

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Shins

ATE - Acute Toxicity Estimate
VOC - Volatile Organic Compounds

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date24-Feb-2014Revision Date24-Feb-2014Revision SummaryNot applicable

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet
