

Amoxicillin sodium / Potassium Clavulanate Mixed in ratio 5:1

Safety Data Sheet

A0189

according to Regulation (EU) 2015/830

Version: 2.0

Date of issue: 03/08/2011 Revision date 06/07/2018

Supersedes 02/07/2014

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

1.1. Product identifier

Product form : Mixture
 Trade name : Amoxicillin sodium / Potassium Clavulanate
 Mixed in ratio 5:1
 Product code : A0189
 Formula : C₁₆H₁₉N₃O₅S (Amoxicillin sodium) / C₈H₈N₂O₅K (Potassium clavulanate)
 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 : Professional use
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Biochemie B.V.
 A. Hofmanweg 71
 2031 BH Haarlem - The Netherlands
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Respiratory sensitisation, Category 1 H334
 Skin sensitisation, Category 1 H317

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

Hazard pictograms (CLP)



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements (CLP)

: P261 - Avoid breathing dust, fume, gas, mist, spray, vapours.
P280 - Wear Protective clothing, protective gloves, face shield, eye protection.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor
P302+P352 - IF ON SKIN: Wash with plenty of water.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Amoxicillin trihydrate	(CAS-No.) 61336-70-7 (EC-No.) 248-003-8	83,3	Resp. Sens. 1, H334 Skin Sens. 1, H317
Potassium clavulanate	(CAS-No.) 61177-45-5 (EC-No.) 262-640-9	16,7	Flam. Sol. 1, H228

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Seek medical attention if ill effect or irritation develops.
First-aid measures after inhalation : Assure fresh air breathing
If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact : Wash skin with plenty of water and soap
Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact : Rinse with water.
First-aid measures after ingestion : Rinse mouth.

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

Symptoms/effects : Exposure may produce an allergic reaction.
Symptoms/effects after inhalation : Difficulty in breathing.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Alcohol resistant foam.
Dry chemical powder.
Carbon dioxide (CO₂).
Water spray.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : When heated to decomposition, emits toxic fumes:
- CO_x
- NO_x
- SO_x.

5.3. Advice for firefighters

Firefighting instructions : Avoid (reject) fire-fighting water to enter environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing.
Measures in case of dust release : Use good housekeeping practices to avoid rendering dust airborne.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed and dry
Store in dry, cool, well-ventilated area.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear approved mask. Filter type P2 (EN 143)

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Powder.
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 252,6 °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)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available

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Solubility	: Water: 222 g/l
Log Pow	: < 3
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

Bulk density : 1200 kg/m³

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions of storage, handling and use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Moisture.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

May liberate toxic gases:

- CO_x
- NO_x
- SO_x.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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SECTION 12: Ecological information**12.1. Toxicity**

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EC50 Daphnia 1	> 1000 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Amoxicillin sodium / Potassium Clavulanate Mixed in ratio 5:1	
Log Pow	< 3

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment. Prevent entry to sewers and public waters

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
14.1. UN number		
Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

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14.6. Special precautions for user**. Overland transport**

Not regulated

- Transport by sea

Not regulated

- Air transport

Not regulated

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**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Ensure all national/local regulations are observed.

Germany

Reference to AwSV

: Water hazard class (WGK) 3, severe hazard to waters (Classification according to AwSV, Annex 1)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen

: None of the components are listed

SZW-lijst van mutagene stoffen

: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen –

: None of the components are listed

Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: None of the components are listed

Denmark

Recommendations Danish Regulation

: Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency number	Modified	
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8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
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Abbreviations and acronyms:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources : Manufacturer. ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:

Flam. Sol. 1	Flammable solids, Category 1
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H228	Flammable solid.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SDS Biochemicals version 2018

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