Ampicillin sodium

A0104

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: A0104
Issue date: 27/03/2024 Revision date: 26/03/2024 Supersedes version of: 06/04/2023 Version: 2.2

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

1.1. Product identifier

Product form	:	Substance
Trade name	:	Ampicillin sodium
EC-No.	:	200-708-1
CAS-No.	:	69-52-3
Product code	:	A0104
Formula	:	$C_{16}H_{18}N_3NaO_4S$
Synonyms	:	D-(-)-α-Aminobenzylpenicillin sodium
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

Distributor
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)6-30008100 (outside office hours)

Country	Organisation/Company	Address	Emergency number	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- and EUH-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) :

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.
P280 - Wear protective clothing, eye protection, face protection.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
Ampicillin sodium	CAS-No.: 69-52-3 EC-No.: 200-708-1	≥ 91

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Seek medical attention if ill effect develops.

First-aid measures after inhalation : Seek medical attention immediately. Remove victim to fresh air.

First-aid measures after skin contact : Seek medical advice. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water.

First-aid measures after ingestion : Seek medical attention if ill effect develops.

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

Symptoms/effects : Irritating. Exposure may produce an allergic reaction.

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 : Water spray. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Under fire conditions, hazardous fumes will be present: - COx. - NOx. - SOx.

5.3. Advice for firefighters

Precautionary measures fire : Wear proper protective equipment. 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 : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

Measures in case of dust release : Use good housekeeping practices to avoid rendering dust airborne.

6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

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

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 : Minimise generation of dust.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area. Moisture sensitive.

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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Additional information : Provide local exhaust or general room ventilation

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection			
Type	**Field of application**	**Characteristics**	**Standard**
Safety glasses	Dust		EN 166

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

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

8.2.2.3. Respiratory protection

Respiratory protection			
Device	**Filter type**	**Condition**	**Standard**
Dust mask	Type P2	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Colour : White to slightly yellow.
Appearance : Powder.
Molecular mass : 371,4 g/mol
Odour : Not available

Odour threshold	:	Not available
Melting point	:	≈ 215 °C
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	100 (8 – 10) g/l
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: 50 g/l
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Oxidising agents.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes: - COx. - NOx. - SOx.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

Ampicillin sodium (69-52-3)	
LD50 oral rat	> 5314 mg/kg

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 : Exposure may produce an allergic reaction. May cause irritation to the respiratory tract. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

Other information : See actual entry in RTECS for complete information:XH8400000

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
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		

14.6. Special precautions for user

Overland transport
Not regulated

Transport by sea
Not regulated

Air transport
Not regulated

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Ensure all national/local regulations are observed.

France

Occupational diseases	
Code	Description
RG 41	Diseases caused by betalactamines (including penicillins and their salts) and cephalosporins

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

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

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

Danish National Regulations : 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			
Section	**Changed item**	**Change**	**Comments**
	Adverse health effects caused by endocrine disrupting properties	Added	
	Supersedes	Modified	

Indication of changes			
Section	**Changed item**	**Change**	**Comments**
	Revision date	Modified	
	Substance type	Added	
	Regulatory framework	Added	
1.1	Product form	Modified	
1.1	Formula	Modified	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures general	Added	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
5.2	Hazardous decomposition products in case of fire	Modified	
6.1	Protective equipment	Added	
8.2	Environmental exposure controls	Added	
10.6	Hazardous decomposition products	Modified	
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added	
16	Data sources	Modified	

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

Abbreviations and acronyms:	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

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. Manufacturer. ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:	
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU Duchefa 2023

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.