

[13C,2H3]-AZITHROMYCIN - C1768

ALSACHIM

a Shimadzu Group Company

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name : [13C,2H3]-AZITHROMYCIN

Product code : C1768.

N° CAS : 83905-01-5 unlabeled

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

Identified uses : Laboratory chemicals, Manufacture of substances

1.3. Details of the supplier of the safety data sheet

Registered company name : Alsachim.

Address : 160 rue Tobias Stimmer.67400.Illkirch Graffenstaden.France.

Telephone : +33 (0) 390 402 200. Fax : +33 (0) 390 402 199 .

E-mail : contact@alsachim.com

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Respiratory sensitisation, Category 1 (Resp. Sens. 1, H334).

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

Specific target organ toxicity (repeated exposure), Category 1 (STOT RE 1, H372).

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).

This substance does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS08



GHS09

Signal Word :

DANGER

Product identifiers :

EC 617-500-5

2R,3R,4R,5R,8R,10R,11R,13S,14R)-11-[(2S,3R,4S,6R)-4-DIMETHYLAMINO-3-HYDROXY-6-METHY
L-OXAN-2-YL]OXY-2-ETHYL-3,4,10-TRIHYDROXY-13-[(2S,4R,5S,6S)-5-HYDROXY-4-METHOXY-
4,6-DIMETHYL-OXAN-2-YL]OXY-3,5,6,8,10,12,14-HEPTAMETHYL-1-OXA-6-AZACYCLOPENTAD
ECAN-15-ONE

Hazard statements :

H317

May cause an allergic skin reaction.

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H372

Causes damage to organs through prolonged or repeated exposure .

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P260

Do not breathe dust/fume/gas/mist/vapours/spray.

P264

Wash hands thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

P273

Avoid release to the environment.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

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Precautionary statements - Response :

P302 + P352	IF ON SKIN: Wash with plenty of water.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P314	Get medical advice/attention if you feel unwell.
P321	Specific treatment (see information on this label).
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P391	Collect spillage.

Precautionary statements - Disposal :

P501	Dispose of contents/container to an approved waste disposal facility.
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2.3. Other hazards

The substance does not fulfil the PBT or vPvP criteria in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Synonyms	Azithromycin-13C-D3
N° CAS	83905-01-5 unlabeled
Molecular weight	753 g/mol

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation :

In the event of massive inhalation of dust, remove the person exposed to fresh air. Keep warm and at rest.

If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor.

In the event of an allergic reaction, seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

In the event of an allergic reaction, seek medical attention.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Seek medical attention immediately, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

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5.3. Advice for firefighters

No data available.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

Avoid inhaling dust.

If a large quantity has been spilt, evacuate all personnel and only allow intervention by trained operators equipped with safety apparatus.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming).

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the substance is handled.

Individuals with a history of skin sensitisation should not, under any circumstance, handle this substance.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention :

Handle in well-ventilated areas.

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Do not breathe in dust.

Also provide breathing apparatus for certain short tasks of an exceptional nature and for emergency interventions.

In all cases, recover emissions at source.

Avoid exposure - obtain special instructions before use.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the substance is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep the container tightly closed in a dry, well-ventilated place.

For a prolonged period, keep at -20°C (±5°C) in a closed container, away from light and moisture.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

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Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Recommended properties :

- Impervious gloves in accordance with standard EN374

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing dust.

If the ventilation is insufficient, wear appropriate breathing apparatus.

When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149.

Category :

- FFP1

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387 :

- A1 (Brown)

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :

Solid.

Molecular formula :

C38H72N2O12 - C3713CH69D3N2O12

Color

White to off white

Important health, safety and environmental information

pH :

Not relevant.

Boiling point/boiling range :

Not relevant.

Flash point interval :

Not relevant.

Vapour pressure (50°C) :

Below 110 kPa (1.10 bar).

Density :

= 1

Method for determining the density :

Solubility

Ethanol, Methanol, Acetonitril

Water solubility :

Insoluble.

Melting point/melting range :

Not relevant.

Self-ignition temperature :

Not relevant.

Decomposition point/decomposition range :

Not relevant.

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9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This substance is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- formation of dusts

Dusts can form an explosive mixture with air.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause hypersensitivity of the respiratory tracts with effects taking the form of asthma, rhinitis/conjunctivitis or alveolitis.

May cause an allergic reaction by skin contact.

Causes severe damage to organs in the event of repeated or prolonged exposure.

11.1.1. Substances

No toxicological data available for the substances.

SECTION 12 : ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the substance and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

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Soiled packaging :

Empty container completely. Keep label(s) on container.
Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2017 - IMDG 2016 - ICAO/IATA 2017).

14.1. UN number

3077

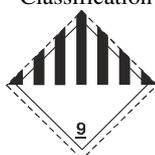
14.2. UN proper shipping name

UN3077=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(2r,3r,4r,5r,8r,10r,11r,13s,14r)-11-[(2s,3r,4s,6r)-4-dimethylamino-3-hydroxy-6-methyl-oxan-2-yl]oxy-2-ethyl-3,4,10-trihydroxy-13-[(2s,4r,5s,6s)-5-hydroxy-4-methoxy-4,6-dimethyl-oxan-2-yl]oxy-3,5,6,8,10,12,14-heptamethyl-1-oxa-6-azacyclopentadecan-15-one)

14.3. Transport hazard class(es)

- Classification :



9

14.4. Packing group

III

14.5. Environmental hazards

- Environmentally hazardous material :



14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M7	III	9	90	5 kg	274 335 375 601	E1	3	-

Not subject to this regulation if Q ≤ 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	9	-	III	5 kg	F-A,S-F	274 335 969	E1

Not subject to this regulation if Q ≤ 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	956	400 kg	956	400 kg	A97 A158 A179 A197	E1
	9	-	III	Y956	30 kg G	-	-	A97 A158 A179 A197	E1

Not subject to this regulation if Q ≤ 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

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

No data available.

SECTION 15 : REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2018/1480 (ATP 13)

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- Container information:

The substance is packed in an interior packaging, not exceeding 10 ml, the required labelling elements appear on the outer packaging.

- Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the substance and not as a guarantee of the properties thereof.

Abbreviations :

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS08 : Health hazard

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.