

Section 1: IDENTIFICATION OF SUBSTANCE/MIXTURE AND COMPANY

1.1. Identification of the substance

Product form: Powder and solvent for suspension for injection

Product name: EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection

Active substance : Benzathine Benzylpenicillin

Chemical name : N,N'-dibenzylethane-1,2-diamine;(2S,5R,6R)-3,3-dimethyl-7-oxo-6-[(2-phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid

National Drug Code (NDC): 1,2 MUI: 81284-521-01; 2,4 MUI : 81284-522-01

Molecular formula : Benzathine Benzylpenicillin : C₄₈H₅₆N₆O₈S₂

1.2. Uses

EXTENCILLINE is indicated in adults, adolescents, children and neonates for the treatment and prophylaxis of the following infections

For the treatment of: erysipelas, syphilis: early syphilis (primary and secondary), latent syphilis (except for neurosyphilis and presence of pathological CSF findings), yaws, pinta

For the prophylaxis of: rheumatic fever (chorea, rheumatic carditis), poststreptococcal glomerulonephritis, erysipelas

Consideration should be given to official guidance on the appropriate use of antibacterial agents

For professional use only

Restrictions on use : Hypersensitivity to the active substance benzathine benzylpenicillin, to other penicillins, soy phospholipids, peanuts

1.3. Information about the security data sheet provider

Company	Distributor	Supplier
Provepharm SAS 22 Rue Marc Donadille 13013 Marseille, France Phones: 04 91 08 69 30 Website: www.provepharm.com Email: hse@provepharm.com	Provepharm Inc. 100 Springhouse drive, Suite 105, Collegetown, PA 19426, USA Phone: +1 610 601 8600	Laboratoires Delbert 49 rue Rouelle Paris, 75015 France Phone : 01 46 99 68 20 qualite@delbert.fr

1.4. Emergency telephone number:

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or the mixture

GHS US classification :

Acute toxicity (oral) Category 4, H302

Respiratory sensitization, Category 1, H334

Full text of hazard classes and H-statements: see section 16.

2.2. Label elements

Warning mention: Danger

Hazard statements:

H302 - Harmful if swallowed

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

Precautionary statements:

P233 - Keep container tightly closed

P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

P264 - Wash hands, forearms and face thoroughly after handling



P270 - Do not eat, drink or smoke when using this product

P284 - Wear respiratory protection

P301 + P317 - If swallowed: Get medical help

P304 + P340 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing

P330 - Rinse mouth

P342 + P316 : If experiencing respiratory symptoms: Get emergency medical help immediately

P403 - Store in a well-ventilated place

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.2. Other hazards

This medicine contains soybean oil. If you are allergic to peanuts or soy, do not use this medicine.

Do not use this medicine in case of hypersensitivity to benzathine benzylpenicillin or other penicillins.

Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Quantity	Classification
Benzathine Benzylpenicillin	CAS-No.: 1538-09-6	22.5 – 100 %	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334  
LECITHIN	CAS-No.: 8002-43-5	0.9 – 10 %	Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation
Water for injection	-	5 mL	Not listed

Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of hazard classes and H-statements: see section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

After inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

After skin contact: In case of contact, immediately wash skin with plenty of water and soap or mild soap for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

After eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water or normal saline solution for at least 15 minutes. Seek medical attention immediately.

After ingestion: Wash out mouth with water and administer fresh water if the person is conscious. Do not induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Use water spray, dry chemical, fog or foam.

Unsuitable extinguishing media: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Combustion Products: When heated to decomposition, it emits toxic Fumes, Carbon monoxide, Carbon dioxide.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering 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

General Measures: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE) as identified in section 8.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. Refer to section 8: Exposure controls/personal protection.

Emergency Procedures: Isolate the hazard area. Ventilate area.

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Notify authorities if liquid enters sewers or public waters.

6.3. Material for containment and cleaning up

On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

Soak up with inert absorbent material and dispose as hospital waste.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Recommendations for handling: Avoid exposure to light, air, moisture and excessive heat.
Handle in a well-ventilated place. Provide good ventilation in process area to prevent formation of vapor. Avoid breathing dust/fume/gas/mist/vapors/spray.
Avoid contact with incompatible materials.
Wear suitable Personal Protection Equipment (see section 8).
Keep the substance/mixture away from drains, surface or ground waters.

Recommendations for personal hygiene: Do not eat, drink and smoke in the working areas.
Wash hands after handling the substance/mixture.
Remove contaminated clothing and protective equipment.



EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Creation date: 2023/11/27

Version: 1.0

Page 4 on 8

7.2. Conditions for safe storage, including any incompatibilities

Storage: Do not expose to heat sources or high temperature.
Keep container tightly closed. Keep container in a cool.
Do not expose to sunlight. Store in the outer packaging.

Incompatible products: Strong bases. Strong acids

Incompatible materials: Sources of ignition. Direct sunlight.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection:

No additional information available

Benzathine benzylpenicillin (1538-09-6):

No additional information available

LECITHIN (8002-43-5):

No additional information available

8.2. Exposure controls

Appropriate engineering controls: Handle in accordance with good clinical hygiene and safety practice. Wash hands before breaks and at the end of the day.

Hand protection: Handle with gloves (Nitrile rubber). Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. (in accordance with EN374, ASTM F1001 or international equivalent).

Eye protection: Wear safety glasses or goggles if eye contact is possible (in accordance with EN166, ANSI Z87.1 or international equivalent).

Skin and body protection: Wear suitable working clothes.

Respiratory protection: In case of inadequate ventilation wear respiratory protection.

Control of environmental exposure: Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Solid
Appearance:	Clear microcrystalline powder
Color:	white
Odor:	No data available
Odor threshold:	No data available
pH:	pH 4 – 7.5
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Relative evaporation rate (butyl acetate=1):	No data available
Flammability (solid, gas):	Non flammable
Vapor pressure:	No data available
Relative vapor density at 20 °C:	No data available
Absolut density:	No data available
Solubility:	Soluble in water
Partition coefficient n-octanol/water (Log Pow):	No data available



EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Creation date: 2023/11/27

Version: 1.0

Page 5 on 8

Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosion limits:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2. Other information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is stable under normal conditions.
No additional information available.

10.2. Chemical stability

The product is stable at handling and recommended storage conditions.
Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

If heated at high temperatures, the substance/mixture decomposes.
Fumes. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral):	Harmful if swallowed.
Acute toxicity (dermal):	Not classified
Acute toxicity (inhalation):	Not classified

Benzathine benzylpenicillin (1538-09-6)

ATE US (oral) 500 mg/kg body weight

Skin corrosion/irritation: Not classified
pH: 4 – 7.5

Serious eye damage/irritation: Not classified
pH: 4 – 7.5

Respiratory or skin sensitization: May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity: Not classified



EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Creation date: 2023/11/27

Version: 1.0

Page 6 on 8

Carcinogenicity: Not classified
Reproductive toxicity: Not classified
STOT-single exposure: Not classified

LECITHIN (8002-43-5) May cause respiratory irritation.

STOT-repeated exposure: Not classified
Aspiration hazard: Not classified
Viscosity, kinematic: No data available

Potential Adverse human health effects and symptoms:

Based on available data, the classification criteria are not met. Harmful if swallowed.

Symptoms/effects after inhalation:

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

Symptoms/effects after ingestion:

Swallowing a small quantity of this material will result in serious health hazard.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Not established.

12.3. Bioaccumulative potential

Not established.

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Advice on disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste disposal number of waste from residues/unused products : Dispose of waste in accordance with federal, state and local environment control regulations.

Contaminated packaging: Empty containers should be taken for local waste disposal. Contaminated packaging should be emptied as far as possible. Packaging that cannot be cleaned should be disposed of like the product.

Ecology - waste materials: Avoid release to the environment.



SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Not regulated for transport.

14.2 UN proper shipping name

Proper Shipping Name (DOT): Not regulated
Proper Shipping Name (TDG): Not regulated
Proper Shipping Name (IMDG): Not regulated
Proper Shipping Name (IATA): Not regulated

14.3 Transport hazard class(es)

In Accordance with DOT Not regulated for transport
In Accordance with TDG Not regulated for transport
In Accordance with IMDG Not regulated for transport
In Accordance with IATA Not regulated for transport

14.4 Packaging group

Packing group (DOT): Not regulated
Packing group (TDG): Not regulated
Packing group (IMDG): Not regulated
Packing group (IATA): Not regulated

14.5 Environmental hazards

No supplementary information available

14.6 Special precautions for user

DOT: Not regulated
TDG: Not regulated
IMDG: Not regulated
IATA: Not regulated

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

U.S. Regulations:

Toxic Substance Control Act (TSCA): Yes

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

No additional information available

15.3. U.S. STATE REGULATIONS

This product contains no known chemicals regulated by New Jersey's Worker and Community Right to Know Act. No components are subject to the Massachusetts Right to Know Act. This product contains no known chemicals regulated by Pennsylvania's Right to Know Act.



EXTENCILLINE 1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Creation date: 2023/11/27

Version: 1.0

Page 8 on 8

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.

SECTION 16: OTHER INFORMATION

The creation of a safety data sheet in accordance with Article 31 of the Regulation (EC) No 1907/2006 is not legally required for articles. This safety data sheet (SDS) is provided on a voluntary basis for informational purposes only.

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.

EXTENCILLINE 0,6 MUI-1,2 MUI-2,4 MUI, powder and solvent for suspension for IM injection (French imported product)

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity Oral (Category 4)
Resp. Sens. 1	Respiratory sensitization (Category 1)
H302	Harmful if swallowed
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled