



Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code:	001936
Product name	OXYBUPROCAINE HYDROCHLORIDE Ph.Eur.
Chemical name and synonym	4-ammino-3-butossibenzoato di 2-(dietilammino)etile cloridrato
EC number	227-808-8
CAS number	5987-82-6

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

Intended use	Active pharmaceutical ingredient.
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1.3. Details of the supplier of the safety data sheet

Name	ACEF S.p.A.
Full address	Via Umbria 8/14
District and Country	29017 FIORENZUOLA D'ARDA (PC) Italia
Tel.	+39 0523 241911
Fax	+39 0523 241929 - 241968

e-mail address of the competent person responsible for the Safety Data Sheet

sicurezza@pec.acef.it

1.4. Emergency telephone number

For urgent inquiries refer to

Centro Antiveleni, Policlinico "Umberto I", Tossicologia d'urgenza, Roma - Tel. +39 06-49978000
Centro Antiveleni, Az. Osp. Niguarda Cà Grande, Milano - Tel. +39 02-66101029
Centro Antiveleni, Az. Osp. "Antonio Cardarelli", Napoli - Tel. +39 081-5453333
Centro Antiveleni, Az. Osp. "Papa Giovanni XXIII", Bergamo - Tel. 800883300
Centro Antiveleni, IRCCS Fondazione Salvatore Maugeri, Pavia - Tel. +39 0382-24444
Centro Antiveleni, Az. Osp. Careggi, U.O. Tossicologia medica, Firenze - Tel. +39 055-7947819
Centro antiveleni del Policlinico "Agostino Gemelli", Roma - Tel. +39 06-3054343
Centro Antiveleni, Az. Osp. Foggia - Tel. 800183459
Centro Antiveleni, Ospedale pediatrico Bambino Gesù, Roma; Tel. +39 06-68593726
Centro Antiveleni dell'Az. Osp. universitaria integrata (AOUI) di Verona, Verona - Tel. 800011858

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Acute toxicity, category 4	H302	Harmful if swallowed.
Acute toxicity, category 4	H312	Harmful in contact with skin.
Acute toxicity, category 4	H332	Harmful if inhaled.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.

**SECTION 2. Hazards identification ... / >>****2.2. Label elements**

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words: Warning

Hazard statements:

H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

Precautionary statements:

P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTRE / doctor / . . . if you feel unwell.
P321	Specific treatment (see . . . on this label).
P337+P313	If eye irritation persists: Get medical advice / attention.
P405	Store locked up.

Contains: BENOXINATE HYDROCHLORIDE

Nr. EC: 227-808-8

2.3. Other hazards

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

The substance does not have endocrine disrupting properties.

SECTION 3. Composition/information on ingredients**3.1. Substances**

Contains:

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
BENOXINATE HYDROCHLORIDE		
CAS 5987-82-6	100	Acute Tox. 4 H302, Acute Tox. 4 H312, Acute Tox. 4 H332, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335
EC 227-808-8		ATE Oral: 500 mg/kg, ATE Dermal: 1100 mg/kg, ATE Inhalation mists/powders: 1,5 mg/l
INDEX		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures**4.1. Description of first aid measures**

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash



SECTION 4. First aid measures ... / >>

contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Information not available

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.



SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

Fire and explosion protection:

Provide measures against the formation of electrostatic charges - keep away from sources of ignition - make a fire extinguisher available. risk of explosion from dust Avoid the formation of dust.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

Further information on storage conditions: Keep container tightly closed and in a dry place.

Protect from temperatures above: 25°C

Protect the packaged product if the indicated storage temperature is exceeded.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for particulate not otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
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**SECTION 9. Physical and chemical properties ... / >>**

Appearance	crystalline powder
Colour	white
Odour	odourless
Melting point / freezing point	> 158 °C
Initial boiling point	446,9 °C
Flammability	not available
Lower explosive limit	not available
Upper explosive limit	not available
Flash point	990 °C
Auto-ignition temperature	not available
pH	5,0-6,0 (10 g/l)
Kinematic viscosity	not available
Solubility	water solubility (20 °c) 500 g/l
Partition coefficient: n-octanol/water	(log Kow): 4,38
Vapour pressure	not available
Density and/or relative density	1
Relative vapour density	not available
Particle characteristics	not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Molecular weight g/mol	344,9
Total solids (250°C / 482°F)	100,00 %

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

No dangerous reactions if the prescriptions/indications for storage and handling are respected.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

The product is stable if the requirements/indications for handling and storage are respected.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

Danger of dust explosion. If finely divided, possibility of self-ignition. Development of toxic gases/vapours.

10.4. Conditions to avoid

Avoid environmental dust build-up.

Avoid electrostatic charges. Avoid the formation of dust.

10.5. Incompatible materials

Materials to avoid:
acids, alkalis, oxidizing agents, reducing agents, water

10.6. Hazardous decomposition products

Hazardous decomposition products:
carbon monoxide; carbon oxide, carbon dioxide, hydrogen chloride
nitrogen oxides, toxic gases/vapours



SECTION 11. Toxicological information

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Irritating to eyes, respiratory tract and skin.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

BENOXINATE HYDROCHLORIDE

ATE (Oral):	500 mg/kg estimate from table 3.1.2 of Annex I of the CLP
ATE (Dermal):	1100 mg/kg estimate from table 3.1.2 of Annex I of the CLP
ATE (Inhalation mists/powders):	1,5 mg/l estimate from table 3.1.2 of Annex I of the CLP

Acute toxicity, category 4. Harmful if swallowed, in contact with skin or if inhaled.

Acute toxicity assessment:

Harmful by inhalation, contact with skin and if swallowed.

Experimental/calculated data:

(oral):No data available.

(inhalation):No data available.

(dermal):No data available.

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Respiratory sensitization

Information not available

Skin sensitization

Information not available

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Mutagenicity tests did not reveal genotoxic potential.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

No data on carcinogenic effects are available.



SECTION 11. Toxicological information ... / >>

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

No data available.

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

May cause respiratory irritation

No data available.

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

No data available.

Target organs

Information not available

Route of exposure

Information not available

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Aquatic plants:

No data available.

Microorganisms/Effects on activated sludge:

EC20 (180 min) 80.2 mg/l, (OECD - guideline 209, static)

Nominal concentration.

Chronic toxicity on fish:

No data available on chronic toxicity to fish.

Chronic toxicity to aquatic invertebrates:

**SECTION 12. Ecological information ... / >>**

No data available on chronic toxicity for daphnia.

BENOXINATE HYDROCHLORIDE
EC50 - for Crustacea

30,2 mg/l/48h Daphnia magna (OECD - linea guida 202, parte 1, statico)

12.2. Persistence and degradability

No data available on biodegradability.

12.3. Bioaccumulative potential

Evaluation of bioaccumulation potential:
Based on the n-octanol/water partition coefficient (log Pow) enrichment in organisms is possible.
Bioaccumulative potential:
Based on the n-octanol/water partition coefficient (log Pow) enrichment in organisms is possible.

12.4. Mobility in soil

Volatility: No data available.

12.5. Results of PBT and vPvB assessment

In accordance with Annex (very persistent/very bioaccumulative) Self-classification

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

12.6. Endocrine disrupting properties

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

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

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
Waste transportation may be subject to ADR restrictions.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information**14.1. UN number or ID number**

ADR / RID, IMDG, IATA: 2811

14.2. UN proper shipping name

ADR / RID: TOXIC SOLID, ORGANIC, N.O.S. (BENOXINATE HYDROCHLORIDE)
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (BENOXINATE HYDROCHLORIDE)
IATA: TOXIC SOLID, ORGANIC, N.O.S. (BENOXINATE HYDROCHLORIDE)

**SECTION 15. Regulatory information ... / >>****15.2. Chemical safety assessment**

Has not been performed / is not yet available a chemical safety assessment for the substance.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 4	Acute toxicity, category 4
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H302	Harmful if swallowed.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)

**SECTION 16. Other information ... / >>**

16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

02 / 03 / 07 / 09 / 10 / 11 / 12 / 15 / 16.