

**ACEF S.p.A.****007926 - METHYL COBALAMINE**Revision nr.7
Dated 12/04/2022
Printed on 23/10/2024
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EN

Information Sheet

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

1.1. Product identifier

Code:	007926
Product name	METHYL COBALAMINE
Chemical name and synonym	Cobalamina
EC number	236-535-3
CAS number	13422-55-4
Registration Number	esente < 1 T annua

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

Intended use	nutritional use
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1.3. Details of the supplier of the Information 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 information 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 not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

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SECTION 2. Hazards identification ... / >>

This product is not subject to hazard labeling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

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**

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

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

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

No episodes of damage to health ascribable to the product have been reported.

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**

Use breathing equipment if fumes or powders are released into the air. 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.

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SECTION 6. Accidental release measures ... / >>**6.3. Methods and material for containment and cleaning up**

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. 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.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

Store containers hermetically closed in a dry and cool place. Protect from light.
The product decomposes upon exposure to light.

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

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

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
Appearance	crystalline powder	
Colour	red	
Odour	characteristic	
Melting point / freezing point	not available	
Initial boiling point	not applicable	
Flammability	not available	
Lower explosive limit	not available	

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SECTION 9. Physical and chemical properties ... / >>

Upper explosive limit	not available
Flash point	not applicable
Auto-ignition temperature	not available
pH	not available
Kinematic viscosity	not available
Solubility	not available
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	not determined
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

Explosive properties	non determinato
Oxidising properties	non determinato

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

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

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

10.4. Conditions to avoid

Avoid environmental dust build-up.

Exposure to light.
Heat**10.5. Incompatible materials**

Information not available

10.6. Hazardous decomposition products

Information not available

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

Information not available

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

Information not available

Interactive effects

**SECTION 11. Toxicological information ... / >>**

Information not available

ACUTE TOXICITY

Does not meet the classification criteria for this hazard class

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

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

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

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

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs

Information not available

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SECTION 11. Toxicological information ... / >>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

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

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

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. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
Solid residues may be suitable for disposal in an authorised landfill site.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

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

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**Seveso Category - Directive 2012/18/EU: NoneRestrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
NoneRegulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicableSubstances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.Substances subject to authorisation (Annex XIV REACH)
NoneSubstances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
NoneSubstances subject to the Rotterdam Convention:
NoneSubstances subject to the Stockholm Convention:
NoneHealthcare controls
Information not available**15.2. Chemical safety assessment**

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

SECTION 16. Other information**LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate

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SECTION 16. Other information ... / >>

- 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)
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.



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SECTION 16. Other information ... / >>

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 / 09 / 11 / 12 / 15 / 16.