

**ACEF S.p.A.****011332 - VITAMIN K2 (MK-7 P2000)**Revision nr.2
Dated 22/11/2021
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Replaced revision:1 (Dated 04/06/2019)

EN

Information Sheet

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

1.1. Product identifier

Code: 011332
Product name: VITAMIN K2 (MK-7 P2000)

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

Intended use: food additive

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 di Milano 02 66101029 (CAV Ospedale Niguarda Ca" Granda)-H24
Centro Antiveleni di Pavia 0382 24444 (CAV IRCCS Fondazione Maugeri)
Centro Antiveleni di Bergamo 800 883300 (CAV Ospedali Riuniti)
Centro Antiveleni di Firenze 055 7947819 (CAV Ospedale Careggi)
Centro Antiveleni di Roma 06 3054343 (CAV Policlinico Gemelli)
Centro Antiveleni di Roma 06 49978000 (CAV Policlinico Umberto I)
Centro Antiveleni di Napoli 081 7472870 (CAV Ospedale Cardarelli)

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:
P410 Protect from sunlight.

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

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SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
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CICLODESTRINE

CAS 7585-39-9 96 ≤ x < 100

EC 231-493-2

INDEX

REACH Reg. 01-2119457012-51-0000

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

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

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

Specific information on symptoms and effects caused by the product are unknown.

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.



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.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

TLV-ACGIH ACGIH 2020

CICLODESTRINE

Threshold Limit Value

Type	Country	TWA/8h	STEL/15min	Remarks / Observations
		mg/m3 ppm	mg/m3 ppm	
TLV-ACGIH		10		

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,64	mg/l
Normal value in marine water	0,064	mg/l
Normal value for fresh water sediment	0,45	mg/kg
Normal value for water, intermittent release	1	mg/l
Normal value of STP microorganisms	100	mg/l
Normal value for the food chain (secondary poisoning)	433300	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers				
	Acute	Acute	Chronic	Chronic	Acute	Chronic	Chronic	Chronic
	local	systemic	local	systemic	local	systemic	local	systemic
Oral			VND	32,5				
				mg/kg				
Inhalation	VND	682,5	VND	227,5	VND	1137,5	VND	379,2
		mg/m3		mg/m3		mg/m3		mg/m3
Skin			VND	32,5			VND	54,2
				mg/kg				mg/kg

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert 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.

8.2. Exposure controls

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

HAND PROTECTION

None required.

**SECTION 8. Exposure controls/personal protection ... / >>****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	powder	
Colour	yellow	
Odour	odourless	
Melting point / freezing point	53 °C	Substance:MENAQUINONE-7
Initial boiling point	Not applicable	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Not applicable	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	insoluble in water, very soluble in hexane, soluble in ethanol 99,5%.	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	0,40-0,45 g/cm3	
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

Total solids (250°C / 482°F)	0 %
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.

**SECTION 10. Stability and reactivity** ... / >>**10.5. Incompatible materials**

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

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

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

CICLODESTRINE

LD50 (Oral):	> 5000 mg/kg ratto, OECD 401
LD50 (Dermal):	> 2000 mg/kg ratto, OECD 402
LC50 (Inhalation mists/powders):	> 4,9 mg/l ratto, OECD 403

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

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

STOT - SINGLE EXPOSURE

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

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances 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**CICLODESTRINE**

LC50 - for Fish

> 7561 mg/l carpa comunwe, OECD 203

EC50 - for Crustacea

> 100 mg/l/48h daphnia magna, OECD 202

EC50 - for Algae / Aquatic Plants

> 100 mg/l/72h desmodemsus subspicatus, OECD 201

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

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances 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.

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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.

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/EC: NoneRestrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
NoneRegulation (EC) No. 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 (EC) Reg. 649/2012:
NoneSubstances subject to the Rotterdam Convention:
NoneSubstances subject to the Stockholm Convention:
NoneHealthcare controls
Information not available**15.2. Chemical safety assessment**

A chemical safety assessment has been performed for the following contained substances



CICLODESTRINE

SECTION 16. Other information

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 (EU) 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)
- 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

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SECTION 16. Other information ... / >>**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 / 08 / 09 / 11 / 12 / 15 / 16.