

EPO Istituto Farmochimico Fitoterapico S.r.l.

Via Stadera 19 - 20141 Milano
tel.: +39-02-89557.1 fax +39-02-89557.390

MATERIAL SAFETY DATA SHEET

In accordance with Regulation 2006/1907/EC and amendments

Propolis 80° hydroalcoholic tincture DER 1/10

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

1.1. Product identifier

Product: Propolis 80° hydroalcoholic tincture DER 1/10
Botanical name: Propolis
Code: 1926280.1
Description: *hydroalcoholic solution of "Propolis"*
INCI name: PROPOLIS EXTRACT
CAS number: 85665-41-4
EINECS/ELINCS number: 288-130-6

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

Raw material for food and cosmetics.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: EPO Istituto Farmochimico Fitoterapico S.r.l., Via Stadera 19 - 20141 Milano

Competent person for data sheet: rgatti@eposrl.com +39 02-89557327

1.4. Emergency telephone number

Contact the nearest poison centre.

On the website of the World Health Organization (WHO) (www.who.int), in correspondence of the International Programme on Chemical Safety (IPCS) is available the World directory of poisons centres.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Hazard classification in accordance with Regulation 2008/1272/EC: This product is classified as:

H225 Highly flammable liquid and vapour (Category 2)

H319 Causes serious eye irritation (Category 2)

Main physicochemical symptoms to human health and the environment: Due to exposure to high concentrations of vapours: irritation of nose and eyes, sense of heat, headache, nausea, drowsiness. It generates steam at any temperature, the heavier vapors than air tend to accumulate in the environment as close to the ground.

2.2. Label elements



H225: Highly Flammable liquid and vapour

H319: Causes serious eye irritation

P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P233: Keep container tightly closed.

P240: Ground/bond container and receiving equipment.

P241: Use explosion-proof electrical/ventilating/lighting/equipment.

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P370+P378: In case of fire: Use CO₂, fire extinguisher powder or fine water spray for extinction.

P403+P235: Store in a well-ventilated place. Keep cool.

P501: Dispose of contents / container in accordance with local regulations.

2.3. Other hazards

PBT: The product contains no components considered PBT

vPvB: The product contains no components considered vPvB

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Components	%	CAS	EINECS/ELINCS	Classification in accordance with Reg. 2008/1272/EC
Water	a 100.0	7732-18-5	231-791-2	N.A.
Propolis extract	< = 5.0	85665-41-4	288-130-6	N.A.
Ethanol	77.0 - 82.0	64-17-5	200-578-6	Flam. Liq. (Cat.2), Eye Irrit. (Cat. 2), H225, H319, P210, P233, P240, P241, P242, P243, P264, P280, P303+P361+P353, P305+P351+P338, P337+P313, P370+P378, P403+P235, P501.

SECTION 4: First aid measures

4.1. Description of first aid measures

If inhaled: go away in ventilated area. If you feel unwell consult a doctor. If not breathing, give artificial respiration.

In case of skin contact: remove contaminated clothes and wash contaminated area thoroughly with water. In case of skin irritation consult a doctor.

In case of eye contact: rinse with fresh clean water. Remove eventual contact lenses. Consult a doctor.

If swallowed: check the ingested quantity. Don't cause vomit. Never give anything by mouth to an unconscious person.

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

Due to exposure to high concentrations of vapours: slight irritation of nose and eyes, sense of heat, headache, nausea, drowsiness. In case of contact with skin, may cause irritation.

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

Should any symptom-caused by inhalation, skin and eye contact or ingestion arise and persist seek medical advise. Show this safety data sheet to doctor.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable fire extinguishing: water spray, foam, CO₂, chemical powders. For large fires use foam, keeping a distance as greater as possible.
Unsuitable fire extinguishing: none in particular.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberate carbon monoxide (CO) and carbon dioxide (CO₂); exposure to combustion or decomposition can lead to injuries, also serious ones.

Vapours can combine with air an explosive mixture.

5.3. Advice for firefighters

Wear in case of fire, if necessary, respiratory protection devices with independent air supply. Do not breathe fumes. Limit the area staying windward. Water spray may be used to cool closed containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment to avoid inhalation and contact with skin and eyes. Remove sources of ignition. Keep away unprotected persons. Ensure adequate ventilation. Pay attention to the densed vapors that can lead to explosive concentrations. Vapors can accumulate in low areas.

6.2. Environmental precautions

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Do not let product enter drains. Keep spills away from any surface water and groundwater. Spills or additional losses should be avoided, if this can be done safely. Inform the competent authorities, should the product reach waterways or sewers.

6.3. Methods and material for containment and cleaning up

Contain and collect spillage with absorbent non-combustible material. Store the collected in closed containers, suitable for disposal. If the liquid should be collected with a pump, use an explosion proof pump (EX) or a manual pump.

6.4. Reference to other sections

For information on personal protective equipment see section 8.
For information on disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in locations with an adequate system of ventilation to prevent accumulation of vapours in the air that can cause explosive mixtures. Avoid contact between the product and vapours with ignition sources such as open flames, sparks. Take measures to prevent the build up of electrostatic charge.
Wear protective equipment before use.
Return the origin labelling on each container used for the sampling.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool, dry and ventilated place, protected from light into the original well closed drums or in plastic containers suitable for dangerous goods. Smoking not allowed in the storehouse and keep far from flames. Take preventive measures to avoid the build up of electrostatic charge.
Eventual storage tanks shall be electrically grounded.
Cap tightly after use open containers and kept upright to prevent leakage. Keep away from incompatible substances referred to in section 10.

7.3. Specific end use(s)

bacteriostatic, anti-inflammatory, for viral diseases, immunostimulant; external use:antiseborrheic, moisturising, smoothing.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Control of exposure (ACGIH):
TLV-TWA (64-17-5 Ethanol):
1000 ppm; 1880 mg/m³ – A3

DNEL (64-17-5 Ethanol):
Inhalation (short term, local): 1900 mg/m³ (1000 ppm)
Inhalation (long term, systemic): 950 mg/m³ (500 ppm)
Dermal (long term, systemic): 343 mg/m³ (mg/kg bw/day)

PNEC (64-17-5 Ethanol):
Fresh water: 0,96 mg/l
Sea water: 0,96 mg/l
Sediment (fresh water): 3,60 mg/kgdw
Sediment (sea water): 2,90 mg/kgdw
Soil: 0,63 mg/kgdw
Oral: 0,72 mg/kgdw

8.2. Exposure controls

Design for appropriate times work processes and technical control. Use adequate and materials. Apply collective protection measures at source, such as adequate ventilation and appropriate organization measures. When exposure can not be avoided by other means, apply individual protection measures, such as Personal Protective Equipment.

Respiration protection: If you exceed the limit values (vapor) or if they are causing bad smell and/or presence of aerosols, mists and smoke, use full face mask with filter A1 or half-face mask filter A1 as a backup to engineering controls..

Hand protection: Handle with gloves,of nitrilic rubber, butyl rubber, with high breakthrough time (In accordance with EN 374-3).

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Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws. Wash and dry hands.

Eye protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166 (EU)

Body protection: Wear suitable antistatic protective clothing (overalls, aprons, shoes).

The use of the above PPE, as well as for safety reasons, it is recommended to avoid any signs of allergic sensitization in subject at risk.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	from brown to yellow
Ethanol content:	77,0 - 82,0 % v/v
Density:	0,840 - 0,910 g/ml
pH:	4,5 - 6,0
Hydrosolubility:	slightly soluble
Flashing point:	18-21 °C
Boiling point:	nearly 80 °C
Melting point/freezing point:	-114 °C (ethanol 96 °C)
Ignition temperature:	363 °C (ethanol 96 °C)
Upper/lower explosive limit:	19,0 - 3,3 % (V) (ethanol 96 °C)
Viscosity:	n.a.

9.2. Other information

n.a.

SECTION 10: Stability and reactivity

10.1. Reactivity

Avoid reactions with strong oxidizing agents, alkali metals in contact with ethanol develop hydrogen, sodium hypochlorite added to ethanol can result in explosions. The addition of ethanol to concentrated hydrogen peroxide leads to the formation of an explosive compound to impact.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

A contact with sources of ignition possibility of fire or explosion (formation of the mixture explosive air /vapor)

10.4. Conditions to avoid

Heat, flames and sparks. Avoid storage in poorly ventilated areas. Do not store the substance under direct sunlight. Avoid extreme humidity conditions. Avoid the accumulation of electrostatic charges.

10.5. Incompatible materials

Alkali metals, strong oxidizing agents, sodium hypochlorite, hydrogen peroxide. Reactions with strong oxidizing agents may have an explosive course. Alkali metals in contact with the ethanol develop hydrogen (flammable gas). The hypochlorite added to ethanol can give rise to explosion. The addition of ethanol to hydrogen peroxide concentrated leads to the formation of an explosive compound.

10.6. Hazardous decomposition products

In case of fire, oxides of carbon.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (sperimental data in reference to ethanol):
LD 50 (Oral): 6200 – 15000 mg/kg (rat) (OECD401 equivalent)
LC 50 (Inhalation): > 50 mg/m³ (rat) (OECD403 equivalent)

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Irritation (in reference to ethanol CAS:64-17-5):

Studies conducted according to OECD guidelines 405, showed a moderate eye irritation. The level, in terms of conjunctival response, is sufficient to require a classification as an irritant to Category 2 in accordance with Regulation 1272/2008 / EC.

Corrosivity (in reference to ethanol CAS: 64-17-5):

Non corrosive

Sensitisation: no available data.

Specific Target Organ Toxicity (in reference to ethanol CAS: 64-17-5):

Repeated exposure: no available data

Single exposure: no available data

Carcinogenicity:

no component of this product present at levels $\geq 0.1\%$ is identified as a known carcinogen or expected carcinogen by IARC.

ACGIH: A3, Confirmed animal carcinogen with unknown relevance to humans (ethanol CAS: 64-17-5).

Mutagenicity (ethanol CAS: 64-17-5):

Available data indicate that the classification criteria are not satisfied

Toxicity to the reproductive system:

No data available

Potential health effects:

Inhalation: Inhalation of vapors highly concentrated, can cause transient respiratory tract irritation, headaches, nausea.

Ingestion: Ingestion of large amounts may cause nervous system depression, nausea, vomiting, symptoms similar to intoxication by alcohol beverage.

Skin: may cause slight irritation of the skin.

Eyes: may cause eye irritation.

Signs and symptoms of exposure: exposure to high concentrations of vapours: mild irritation of the nose and eyes, the feeling of warmth, headache, visual disturbances, nausea, vomiting, dizziness, soporific state. For ingestion of large amounts: flushing, headache, visual disturbances, vomiting, dizziness, soporific state, breathing and heart block.

More information: take care in case of allergies or hypersensitivity to products of the hive or the bees.

SECTION 12: Ecological information

12.1. Toxicity

In reference to ethanol CAS: 64-17-5:

LC50 (96 h) – Fish – *Salmo gairdneri*: 13 g/l - 96 h

LC50 (96 h) – Pimephales promelas: 13.5, 14.2 and 15.3 g/l

EC50 (48 h) – *Daphnia Magna* - 12,34 mg/l

NOEC (Reproduction, 21 days) - *Daphnia Magna* - > 10 mg/l

NOEC (developmental, 10 days) – *Palaemonetes pugio* - 79 mg/l

EC50 (24 h) – *Artemia salina* – 23,9 g/l

EC50 (48 h) – *Artemia salina* nauplii – 857 mg/l

CE50 (72 h) – *Chlorella vulgaris* – 275 mg/l

CE10 (72 h) – *Chlorella vulgaris* – 11,5 mg/l

CE50 (72 h) – *Selenastrum Capricornutum* – 12,9 g/l

CE10 (72 h) – *Selenastrum Capricornutum* – 0,44 g/l

CE50 (48 h) – *Chlamydomonas eugametos* – 18 g/l

NOEC – *Chlamydomonas eugametos* – 7,9 g/l

NOEC (5 days) – *Skeletonema costatum* – 3,24 g/l

12.2. Persistence and degradability

Readily biodegradable.

12.3. Bioaccumulative potential

There are no known significant phenomena of bioaccumulation.

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12.4. Mobility in soil

No available data.

12.5. Results of PBT and vPvB assessment

This product is not and does not contain a substance defined as PBT and vPvB

12.6. Other adverse effects

Experimental data not available. Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product Disposal: entrust to licensed disposal company, in compliance with all European, national and local regulations about environmental protection; take all measures that are necessary to prevent waste production. Do not discharge into drains or the environment.
Disposal of uncleaned packages: dispose of as unused product.
Empty containers may contain hazardous residues.
Do not remove the label on the package until it is cleaned.

SECTION 14: Transport information:

14.1. UN number

UN1170 (ADR/RID; IMDG; IATA)

14.2. UN proper shipping name

ADR/RID: Ethanol solution (Ethyl Alcohol Solution) - IMDG: Ethanol solution (Ethyl Alcohol Solution) - IATA: Ethanol solution

14.3. Transport hazard class(es)

class 3 (ADR/RID; IMDG; IATA); EMS n. F-E S-D (IMDG)

14.4. Packing group

II (ADR/RID; IMDG; IATA)

14.5. Environmental hazards

Marine pollutant: NO (ADR/RID; IMDG; IATA)

14.6. Special precautions for user

Warning: Flammable liquids _ Kemler Code: 33 _ EMS Number: FE, SD

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

n.a.

SECTION 15: Regulatory information

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

This MSDS complies with the requirements of Reg. 2006/1907/EC, of Reg. 2008/1272/EC and of Reg. 2010/453/EU. Please remember, however, the user need to check and comply with specific European, national, regional, and local regulations about hazardous activities and environmental protection.

15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Reason for revision: Update

Changes were made to the following sections: 2 / 3 / 4 / 5 / 7 / 8 / 10 / 11 / 12 / 13/ 14 / 15 / 16

Abbreviations and acronyms:

INCI: International Nomenclature of Cosmetic Ingredients

CAS: Chemical Abstracts Service

EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European list of notified chemical substances
PBT: Chemicals which are Persistent, Bioaccumulative and Toxic.
vPvB: Chemicals which are very Persistent and very Bioaccumulative.
Flam. Liq.(Cat.2): flammable liquid (Category 2)
Eye Irrit. (Cat. 2): Eye Irritant (Category 2)
ACGIH: American Conference of Governmental Industrial Hygienists
TLV-TWA: Threshold Limit Value – Time Weighted Average
DNEL: Derived No-Effect Level
PNEC: Predicted No-Effect Concentration
DL 50: Lethal Dose 50 %
CL 50: Lethal Concentration 50 %
EC 50: Effective Concentration
EC 10: Effective Concentration
NOEC: No Observed Effect Concentration
ADR: The European Agreement Concerning the International Carriage of Dangerous Goods by Road
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail
IMDG: International Maritime Dangerous Goods
IATA: International Air Transport Association
Kemler code: identification code of the substance
EMS Number: Code for emergencies - maritime transport
N.A.: not applicable
n.a.: data not available

References:

- European Commission - Institute of Health and Consumer protection;
- Decision 2006/257/EC;
- IARC (International Agency for Research on Cancer);
- Regulation 1907/2006/EC;
- Regulation 1272/2008/EC;
- Regulation 453/2010/EC;
- Regulation 1223/2009/EC;
- Regulation UE n. 1169/2011;
- European Commission Health and Consumers CosIng;
- EFSA – Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern.
- ECHA – European Chemicals Agency

Text of hazard (H phrases) statements, supplemental hazard information , safety warnings and precautionary statements (P phrases) is not fully set out in Sections 2 to 15:

P264: Wash ... thoroughly after handling.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

Above information derives from our knowledge to this day and, in lack of specific literature, from our own experience in this field and from Good Manufacturing Practice. The user should however, make sure that all the information here in contained be complete and in conformance with the specific use for which the product is destined.

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