

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006
(amended by Regulation (EU) 2015/830)

Kik après Pic

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

1.1. Product identifier

Product code None.

Synonyms None.

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

Use of the Substance/Mixture Medical device

1.3. Details of the supplier of the safety data sheet

Company/Undertaking Identification MEDENA AG
Industriestrasse 16
CH-8910 Affoltern a. Albis
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1.4. Emergency telephone number 145 (Tox Info Suisse)

Issuing date 01.07.2016

Version GHS 2 (Previous versions: 1.1)

2. Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 Flammable liquids, Cat. 3, H226

Additional information For the full text of the phrases mentioned in this Section, see Section 16.

2.2. Label elements



Signal Word	Warning
Hazard Statements	H226: Flammable liquid and vapour.
Precautionary statements	P102: Keep out of reach of children. P210b: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed.
Supplemental information	Contains . May produce an allergic reaction.
Product identifier	Ethanol; Ethyl alcohol, CAS-No. 64-17-5, EC-No. 200-578-6 DL-Menthol, CAS-No. 89-78-1, EC-No. 201-939-0 Niaouli oil, CAS-No. 8014-68-8, EC-No. 310-217-5 Tea tree oil, CAS-No. 68647-73-4, EC-No. 285-377-1

2.3. Other hazards In use, may form flammable/explosive vapour-air mixture.

3. Composition/information on ingredients

Chemical characterization Alcoholic solution with active ingredients

Components		CLP Classification	Product identifier
Ethanol; Ethyl alcohol	50% - 60%	Flam. Liq. 2 H225	CAS-No.: 64-17-5 EC-No.: 200-578-6 Index-No: 603-002-00-5
DL-Menthol	1% - 2,5%	Skin Irrit. 2 H315, Eye Irrit. 2 H319	CAS-No.: 89-78-1 EC-No.: 201-939-0
Niaouli oil	0,1% - 1%	Skin Irrit. 2 H315, Skin Sens. 1 H317, Asp. Tox. 1 H304, Aquatic Chronic 2 H411, Flam. Liq. 3 H226	CAS-No.: 8014-68-8 EC-No.: 310-217-5
Tea tree oil	0,1% - 1%	Acute Tox. 4 H302, Skin Irrit. 2 H315, Skin Sens. 1 H317, Asp. Tox. 1 H304, Aquatic Chronic 2 H411, Flam. Liq. 3 H226	CAS-No.: 68647-73-4 EC-No.: 285-377-1

For the full text of the phrases mentioned in this Section, see Section 16.

Hazardous impurities None known.

4. First aid measures

4.1. Description of first aid measures

Inhalation	No special measures required.
Skin contact	If skin irritation persists, call a physician.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.
Ingestion	Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed None known.

4.3. Indication of any immediate medical attention and special treatment needed None known.

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Use dry chemical, CO₂, water spray or alcohol foam.

Extinguishing media which must not be used for safety reasons None.

5.2. Special hazards arising from the substance or mixture Flammable. Vapours are heavier than air and may spread along floors.

5.3. Advice for firefighters

Special protective equipment for firefighters Standard procedure for chemical fires.

Specific methods Water mist may be used to cool closed containers.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel Remove all sources of ignition. Vapours are heavier than air and may spread along floors.

Advice for emergency responders Immediately evacuate personnel to safe areas. Remove all sources of ignition.

6.2. Environmental precautions No special environmental precautions required.

6.3. Methods and material for containment and cleaning up	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
6.4. Reference to other sections	See chapter 8 and 13.

7. Handling and storage

7.1. Precautions for safe handling	When using, do not eat, drink or smoke.
7.2. Conditions for safe storage, including any incompatibilities	Keep containers tightly closed in a dry, cool and well-ventilated place.
7.3. Specific end use(s)	No information available.

8. Exposure controls/personal protection

8.1. Control parameters

Exposure limit(s) No data is available on the product itself.

Ethanol (CAS 64-17-5)

United Kingdom - Workplace Exposure Limits (WELs) - STELs	3000 ppm STEL (calculated) 5760 mg/m ³ STEL (calculated)
United Kingdom - Workplace Exposure Limits (WELs) - TWAs	1000 ppm TWA 1920 mg/m ³ TWA

8.2. Exposure controls

Occupational exposure controls Not required.

Personal protection equipment

Respiratory protection No personal respiratory protective equipment normally required.

Hand protection No special measures required.

Eye protection No special measures required.

Skin and body protection No special measures required.

Thermal hazards Keep product and empty container away from heat and sources of ignition.

Environmental exposure controls No special measures required.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	Liquid.
Colour	Yellowish.
Odour	Mint-like.
Odour Threshold	No information available.
pH:	6 - 7
Melting point/range:	No information available.
Boiling point/range:	No information available.
Flash point:	> 25 °C
Evaporation Rate:	No information available.
Flammability:	distance of ignition
Explosion limits:	No information available.
Vapour pressure:	No information available.
Vapor density:	No information available.
Relative density:	0.887 - 0.907 g/ml
Water solubility:	partly soluble
Partition coefficient (n-octanol/water):	No information available.
Autoignition temperature:	No information available.
Decomposition temperature:	No information available.
Viscosity:	No information available.
Combustion/explosion hazards:	liquid, flammable
Oxidizing properties:	None

9.2. Other information

General Product Characteristics	No information available.
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10. Stability and reactivity

10.1. Reactivity	Risk of ignition.
10.2. Chemical stability	Stable at normal conditions.
10.3. Possibility of hazardous reactions	Vapours may form explosive mixture with air.
10.4. Conditions to avoid	Heat, flames and sparks.
10.5. Incompatible materials	None.
10.6. Hazardous decomposition products	None reasonably foreseeable.

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Ethanol; Ethyl alcohol (CAS 64-17-5) Inhalation LC50 Rat = 124.7 mg/L 4 h(OECD_SIDS) Oral LD50 Rat = 7060 mg/kg (NLM_CIP) DL-Menthol (CAS 89-78-1) Oral LD50 Rat = 3180 mg/kg (NLM_CIP) Tea tree oil (CAS 68647-73-4) Oral LD50 Rat = 1.9 mL/kg (NZ_CCID)
Skin corrosion/irritation	None.
Serious eye damage/eye irritation	None.
Respiratory / Skin Sensitisation	May cause sensitization of susceptible persons by skin contact.
Carcinogenicity	Carcinogenicity classification not possible from current data.
Germ cell mutagenicity	Classification not possible from current data.
Reproductive toxicity	Classification not possible from current data.
Specific target organ toxicity (single exposure)	No data available.
Specific target organ toxicity (repeated exposure)	No data available.
Aspiration hazard	No data available.
Human experience	No data available.

12. Ecological information

12.1. Toxicity	No data is available on the product itself.
Ethanol (CAS 64-17-5) Ecotoxicity - Freshwater Fish - Acute Toxicity Data	96 h LC50 Oncorhynchus mykiss: 12.0 - 16.0 mL/L [static] (EPA) 96 h LC50 Pimephales promelas: >100 mg/L [static] (EPA) 96 h LC50 Pimephales promelas: 13400 - 15100 mg/L [flow-through] (EPA)
Ecotoxicity - Water Flea - Acute Toxicity Data	48 h LC50 Daphnia magna: 9268 - 14221 mg/L (IUCLID) 48 h EC50 Daphnia magna: 2 mg/L [Static] (EPA)
12.2. Persistence and degradability	Expected to be biodegradable.
12.3. Bioaccumulative potential	Bioaccumulation is unlikely.
12.4. Mobility in soil	No data available.
12.5. Results of PBT and vPvB assessment	No information available.

12.6. Other adverse effects No information available.

13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Cardboard boxes can be delivered to the local recycling facilities.

14. Transport information

ADR/RID	Not regulated.
IMDG	Not regulated.
IATA	Not regulated.
Further Information	Not classified as dangerous in the meaning of road and railway transport regulations. Special provision 601: pharmaceutical products (medicines), ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption, are not subject to the requirements of ADR.

15. Regulatory information

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

Regulatory Information	The product is classified and labelled according to Regulation (EC) No. 1272/2008.
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Ethanol (CAS 64-17-5) EU - Biocides (1451/2007) - Existing Active Substances	Active substance
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EU - REACH (1907/2006) - Article 15(1) - Substances Regarded as Being Registered - Plant Health Products	Present
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EU - REACH (1907/2006) - List of Registered Substances	Present
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DL-Menthol (CAS 89-78-1) EU - Biocides (1451/2007) - Existing Active Substances	Active substance
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EU - REACH (1907/2006) - List of Registered Substances	Present
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Tea tree oil (CAS 68647-73-4)
EU - Biocides (1451/2007) -
Existing Active Substances

Active substance

**15.2. Chemical safety
assessment**

Not required.

16. Other information

Revision Note

Safety datasheet sections which have been updated: 2, 3.

**Key or legend to abbreviations
and acronyms**

CLP: Classification according to Regulation (EC) No. 1272/2008
(GHS)

Classification procedure

Calculation method.

**Full text of phrases referred to
under sections 2 and 3**

H225: Highly flammable liquid and vapour.
H226: Flammable liquid and vapour.
H302: Harmful if swallowed.
H304: May be fatal if swallowed and enters airways.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H411: Toxic to aquatic life with long lasting effects.

Instructions for use

Keep away from sources of ignition - No smoking. Keep away from children.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.