

**SECTION 1: Identification of the substance / preparation and of the company**
**1.1 Product identifier**
**Freka-NOL**
**1.2 Relevant identified uses of the substance or mixture and uses advised against**
**1.2.1 Relevant uses**

 Disinfectant  
 Medical device

**1.2.2 Uses advised against**

None known.

**1.3 Details of the supplier of the safety data sheet**
**Company**

 Fresenius Medical Care AG & Co. KGaA  
 Else-Kröner-Str.1  
 61352 Bad Homburg / GERMANY  
 Phone +49 (0)6172-609-0  
 Fax +49 (0)6172-609-2512  
 Homepage www.fmc-ag.com

**Address enquiries to**
**Technical information**
**Safety Data Sheet**

sdb@chemiebuero.de

**1.4 Emergency phone**
**Advisory body**

+49 (0)89-19240 (24h) (english)

**SECTION 2: Hazards identification**
**2.1 Classification of the substance or mixture**
**2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]**

Flam. Liq. 3: H226 Flammable liquid and vapour.

**2.1.2 Classification according to Directive 67/548/EEC or 1999/45/EC**

Flammable - R 10: Flammable.

**2.2 Label elements**

The product is classified and required to be labelled in accordance with EC-Directives

**Labelling according to Regulation (EC) 1272/2008**
**Hazard pictograms**

**Signal word**

WARNING

**Hazard statements**

H226 Flammable liquid and vapour.

**Precautionary statements**

 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**2.3 Other hazards**
**Physico-chemical hazards**

Evolution of flammable mixtures possible in air when heated above flash point and/or during spraying or misting.

**Human health dangers**

Frequent persistent contact with the skin can cause skin irritation.

**Environmental hazards**

Does not contain any PBT or vPvB substances.

**Other hazards**

Further hazards were not determined with the current level of knowledge.

**SECTION 3: Composition / Information on ingredients**
**Product-type:**

The product is a mixture.

Range [%]	Substance
45	Ethanol
	CAS: 64-17-5, EINECS/ELINCS: 200-578-6, EU-INDEX: 603-002-00-5, ECB-Nr.: 01-2119457610-43-XXXX
	GHS/CLP: Flam. Liq. 2: H225 - Eye Irrit. 2: H319
	EEC: F, R 11

**Comment on component parts**

 Substances of Very High Concern - SVHC: substances are not contained or are below 0,1%.  
 For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**
**4.1 Description of first aid measures**
**General information**

Take off contaminated clothing and wash before reuse.

**Inhalation**

 Ensure supply of fresh air.  
 In the event of symptoms seek for medical treatment.

**Skin contact**

 When in contact with the skin, clean with soap and water.  
 Consult a doctor if skin irritation persists.

**Eye contact**

 Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 If eye irritation persists: Get medical advice/attention.

**Ingestion**

 Seek medical advice immediately.  
 Rinse out mouth and give plenty of water to drink.  
 Do not induce vomiting.

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

 Headache  
 Vertigo  
 Irritant effects

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

Treat symptomatically.

**SECTION 5: Fire-fighting measures**
**5.1 Extinguishing media**
**Suitable extinguishing media**

 Carbon dioxide.  
 Water spray jet.  
 Dry powder.  
 Alcohol-resistant foam.

**Extinguishing media that must not be used**

Full water jet.

**5.2 Special hazards arising from the substance or mixture**

Risk of formation of toxic pyrolysis products.

**5.3 Advice for firefighters**

 Use self-contained breathing apparatus.  
 Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.  
 Cool containers at risk with water spray jet.

**SECTION 6: Accidental release measures**
**6.1 Personal precautions, protective equipment and emergency procedures**

 Keep away from all sources of ignition.  
 Ensure adequate ventilation.  
 Use personal protective equipment.

**6.2 Environmental precautions**

Prevent spread over a wide area (e.g. by containment or oil barriers).  
Do not discharge into the drains/surface waters/groundwater.

**6.3 Methods and material for containment and cleaning up**

Take up with absorbent material (e.g. sand).  
Dispose of absorbed material in accordance within the regulations.

**6.4 Reference to other sections**

See SECTION 8+13

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Use only in well-ventilated areas.  
Use solvent-resistant equipment.  
Avoid spilling or spraying in enclosed areas.  
Keep away from all sources of ignition - Refrain from smoking.  
Ignitable mixtures can be formed in the empty container.  
Take precautionary measures against static discharges.  
Do not eat, drink, smoke or take drugs at work.  
Use barrier skin cream.  
Wash hands before breaks and after work.  
Take off contaminated clothing and wash before reuse.

**7.2 Conditions for safe storage, including any incompatibilities**

Keep only in original container.  
Provide solvent-resistant and impermeable floor.  
Prevent penetration into the ground.  
Do not store together with oxidizing agents.  
Do not store together with food and animal food/diet.  
Keep container tightly closed.  
Keep container in a well-ventilated place.  
Protect from heat/overheating.

**7.3 Specific end use(s)**

See product use, SECTION 1.2

**SECTION 8: Exposure controls / personal protection**
**8.1 Control parameters**
**Ingredients with occupational exposure limits to be monitored (GB)**

Range [%]	Substance
45	Ethanol
	CAS: 64-17-5, EINECS/ELINCS: 200-578-6, EU-INDEX: 603-002-00-5, ECB-Nr.: 01-2119457610-43-XXXX
	Long-term exposure: 1000 ppm, 1920 mg/m <sup>3</sup>

**DNEL**

Range [%]	Substance
45	Ethanol, CAS: 64-17-5
	Industrial, inhalative, Long-term - systemic effects: 950 mg/m <sup>3</sup> .
	Industrial, inhalative, Acute - local effects: 1900 mg/m <sup>3</sup> .
	Industrial, dermal, Long-term - systemic effects: 343 mg/kg bw/d.
	general population, inhalative, Long-term - systemic effects: 114 mg/m <sup>3</sup> .
	general population, inhalative, Acute - local effects: 950 mg/m <sup>3</sup> .
	general population, dermal, Long-term - systemic effects: 206 mg/kg bw/d.
	general population, oral, Long-term - systemic effects: 87 mg/kg bw/d.

**PNEC**

Range [%]	Substance
45	Ethanol, CAS: 64-17-5
	oral (food), 0,72 mg/kg.
	soil, 0,63 mg/kg.
	sediment (freshwater), 3,6 mg/kg.
	seawater, 0,79 mg/l.
	freshwater, 0,96 mg/l.

**8.2 Exposure controls**

<b>Additional advice on system design</b>	Ensure adequate ventilation on workstation.
<b>Eye protection</b>	Safety glasses.
<b>Hand protection</b>	butyl rubber, > 120 min (EN 374) The details concerned are recommendations. Please contact the glove supplier for further information.
<b>Skin protection</b>	light protective clothing
<b>Other</b>	Avoid contact with eyes and skin. Do not breathe vapour/spray. Personal protective equipment should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of these equipments to chemicals should be ascertained with the respective supplier.
<b>Respiratory protection</b>	Breathing apparatus in the event of high concentrations. Short term: filter apparatus, filter A.
<b>Thermal hazards</b>	none
<b>Delimitation and monitoring of the environmental exposition</b>	See SECTION 6+7.

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

<b>Form</b>	liquid
<b>Color</b>	colourless
<b>Odor</b>	characteristic
<b>Odour threshold</b>	not applicable
<b>pH-value</b>	6 - 8
<b>pH-value [1%]</b>	not determined
<b>Boiling point [°C]</b>	~ 85
<b>Flash point [°C]</b>	24
<b>Flammability [°C]</b>	> 425
<b>Lower explosion limit</b>	3,5 Vol.%
<b>Upper explosion limit</b>	15 Vol.%
<b>Oxidizing properties</b>	no
<b>Vapour pressure/gas pressure [kPa]</b>	not determined
<b>Density [g/ml]</b>	0,93 (20 °C / 68,0 °F)
<b>Bulk density [kg/m<sup>3</sup>]</b>	not applicable
<b>Solubility in water</b>	miscible
<b>Partition coefficient [n-octanol/water]</b>	not determined
<b>Viscosity</b>	not applicable
<b>Relative vapour density determined in air</b>	not determined
<b>Evaporation speed</b>	not determined
<b>Melting point [°C]</b>	< -10
<b>Autoignition temperature [°C]</b>	not determined
<b>Decomposition temperature [°C]</b>	not applicable

**9.2 Other information**

none

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

No dangerous reactions known if used as directed.

**10.2 Chemical stability**

Stable under normal ambient conditions (ambient temperature).

**10.3 Possibility of hazardous reactions**

Reactions with strong oxidizing agents.

Evolution of flammable mixtures possible in air when heated above flash point and/or during spraying or misting.  
Uncleaned empty vessels may contain product gases which can form explosive mixtures with air.**10.4 Conditions to avoid**

See SECTION 7

**10.5 Incompatible materials**

Strong oxidizing agent.

**10.6 Hazardous decomposition products**

No hazardous decomposition products known.

**SECTION 11: Toxicological information**
**11.1 Information on toxicological effects**
**Acute toxicity**

Range [%]	Substance
45	Ethanol, CAS: 64-17-5
	LD50, dermal, Rabbit: > 2000 mg/kg (OECD 402).
	LD50, oral, Rat: 10470 mg/kg (OECD 401).
	LC50, inhalative, Rat: 117-125 mg/l/4h (OECD 403).
	NOAEL, Rat: > 3000 mg/kg/d (24 month OECD 451).

<b>Serious eye damage/irritation</b>	not determined
<b>Skin corrosion/irritation</b>	not determined
<b>Respiratory or skin sensitisation</b>	not determined
<b>Specific target organ toxicity — single exposure</b>	not determined
<b>Specific target organ toxicity — repeated exposure</b>	not determined
<b>Mutagenicity</b>	not determined
<b>Reproduction toxicity</b>	not determined
<b>Carcinogenicity</b>	not determined
<b>General remarks</b>	

No classification on the basis of the calculation procedure of the preparation directive.  
 Toxicological data of complete product are not available.  
 The toxicity data listed pertaining to the ingredients are intended for those working in the medicinal professions, experts for occupational health and safety and toxicologists. The toxicity data pertaining to the ingredients were supplied by the manufacturers of raw materials.

**SECTION 12: Ecological information**
**12.1 Toxicity**

Range [%]	Substance
45	Ethanol, CAS: 64-17-5
	LC50, (96h), <i>Oncorhynchus mykiss</i> : 13000 mg/l (OECD 203).
	LC50, (48h), <i>Daphnia magna</i> : 12340 mg/l.
	EC50, (72h), Algae: 275 mg/l (OECD 201).
	EC50, (48h), <i>Selenastrum capricornutum</i> : 12900 mg/l (OECD 201).

**12.2 Persistence and degradability**

<b>Behaviour in environment compartments</b>	not determined
<b>Behaviour in sewage plant</b>	not determined
<b>Biological degradability</b>	not determined

**12.3 Bioaccumulative potential**

Accumulation in organisms is not expected.

**12.4 Mobility in soil**

not determined

**12.5 Results of PBT and vPvB assessment**

Based on all available information not to be classified as PBT or vPvB respectively.

**12.6 Other adverse effects**

No classification on the basis of the calculation procedure of the preparation directive.  
 The toxicity data pertaining to the ingredients were supplied by the manufacturers of raw materials.

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

**Product**

Disposal in an incineration plant in accordance with the regulations of the local authorities.  
Dispose of as hazardous waste.

**Waste no. (recommended)**

180106\*  
070604\*

**Contaminated packaging**

Uncontaminated packaging may be taken for recycling.

**Waste no. (recommended)**

150110\*  
150102

**SECTION 14: Transport information**

**14.1 UN number**

See SECTION 14.2 in accordance with UN shipping name

**14.2 UN proper shipping name**

**Transport by land according to ADR/RID** UN 1170 Ethanol solution 3 III

**- Classification Code**

F1

**- Label**



**- ADR LQ**

5 I

**- ADR 1.1.3.6 (8.6)**

Transport category (tunnel restriction code) 3 (D/E)

**Inland navigation (ADN)**

UN 1170 Ethanol solution 3 III

**- Classification Code**

F1

**- Label**



**Marine transport in accordance with IMDG** UN 1170 Ethanol solution 3 III

**- EMS**

F-E, S-D

**- Label**



**- IMDG LQ**

5 I

**Air transport in accordance with IATA** UN 1170 Ethanol solution 3 III

**- Label**



**14.3 Transport hazard class(es)**

See SECTION 14.2 in accordance with UN shipping name

**14.4 Packing group**

See SECTION 14.2 in accordance with UN shipping name

**14.5 Environmental hazards**

See SECTION 14.2 in accordance with UN shipping name

**14.6 Special precautions for user**

Relevant information under SECTION 6 to 8.

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

not applicable

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

<b>EEC-REGULATIONS</b>	1967/548 (1999/45); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006 (Reach); 1272/2008; 75/324/EEC (2008/47/EC); 453/2010/EC
<b>TRANSPORT-REGULATIONS</b>	DOT-Classification, ADR (2013); IMDG-Code (2013, 36. Amdt.); IATA-DGR (2013).
<b>NATIONAL REGULATIONS (GB):</b>	EH40/2005 Workplace exposure limits (Second edition, published December 2011). CHIP 3/ CHIP 4
- <b>Observe employment restrictions for people</b>	Observe employment restrictions for mothers-to-be and nursing mothers. Observe employment restrictions for young people.
- <b>VOC (1999/13/CE)</b>	45 %

**15.2 Chemical safety assessment**

not applicable

**SECTION 16: Other information****16.1 R-phrases (SECTION 3)**

R 11: Highly flammable.

**16.2 Hazard statements (SECTION 3)**

H319 Causes serious eye irritation.  
H225 Highly flammable liquid and vapour.



**16.3 Abbreviations and acronyms:**

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route  
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses  
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure  
CAS = Chemical Abstracts Service  
CLP = Classification, Labelling and Packaging  
DMEL = Derived Minimum Effect Level  
DNEL = Derived No Effect Level  
EC50 = Median effective concentration  
ECB = European Chemicals Bureau  
EEC = European Economic Community  
EINECS = European Inventory of Existing Commercial Chemical Substances  
ELINCS = European List of Notified Chemical Substances  
GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
IATA = International Air Transport Association  
IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
IC50 = Inhibition concentration, 50%  
IMDG = International Maritime Code for Dangerous Goods  
IUCLID = International Uniform Chemical Information Database  
LC50 = Lethal concentration, 50%  
LD50 = Median lethal dose  
MARPOL = International Convention for the Prevention of Marine Pollution from Ships  
PBT = Persistent, Bioaccumulative and Toxic substance  
PNEC = Predicted No-Effect Concentration  
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals  
TLV@/TWA = Threshold limit value – time-weighted average  
TLV@STEL = Threshold limit value – short-time exposure limit  
VOC = Volatile Organic Compounds  
vPvB = very Persistent and very Bioaccumulative

**16.4 Other information****Classification procedure**

Flam. Liq. 3: H226 Flammable liquid and vapour. (On basis of test data)

**Modified position**

SECTION 2 been added: P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SECTION 2 been added: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

SECTION 4 been added: Irritant effects

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