

Safety data sheet according to (EC) No. 1907/2006.

Wet Wipe Ethanol Disinfection

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

Product identifier:

Wet Wipe Ethanol Disinfection
Ethanol 70% Blue Maxi

Relevant identified uses of the substance or mixture and uses advised against:

Disinfection wipe for disinfection of surfaces. Approved as Medical device in Class IIA.

Details of the supplier of the safety data sheet:

Wet Wipe A/S
Vallensbaekvej 65 Phone: +45 70 266 244
DK-2625 Vallensbaek www.wetwipe.eu
Responsible person for the safety data sheet (e-mail): info@wetwipe.dk

Emergency telephone:

(DK) Telephone +45 82 12 12 12 (UK) E-mail: UKREACHCA@hse.gsi.gov.uk

SECTION 2: Hazards identification

Classification of the substance or mixture:

Highly flammable liquid in wipe.

EC (67/548 or 1999/45): F;R11

CLP (1272/2008): Flam. Liq. 2;H225

Wording of R-phrases and hazard statements – see section 16.

Label elements:



Danger

H225: Highly flammable liquid and vapour.

P233: Keep container tightly closed.

Other hazards:

None known.

PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures: Water and the below disinfectants in wipe:

| % w/w | Name | CAS | EC-no. | Index-no. | REACH reg.no. | Classification |
|-------|-------------|---------|-----------|--------------|---------------|--|
| 60-80 | Ethanol | 64-17-5 | 200-578-6 | 603-002-00-5 | - | EC: F;R11 CLP: Flam. Liq. 2;H225 |
| 3-8 | Isopropanol | 67-63-0 | 200-661-7 | 603-117-00-0 | - | EC: F;R11 Xi;R36 R67 CLP: Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336 |

Wording of R-phrases and hazard statements – see section 16.

SECTION 4: First-aid measures

Description of first aid measures:

Inhalation: Remove to fresh air. Keep at rest. In case of discomfort: Seek medical advice.
Skin contact: Remove contaminated clothing and wash with soap and water. If irritation persists: Seek medical advice.
Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.
Ingestion: Rinse mouth and drink plenty of water. Keep at rest. In case of discomfort: Seek medical advice.
Burns: Flush with water until pain ceases.

Most important symptoms and effects, both acute and delayed:

May cause skin and eye irritation. Prolonged or frequent contact can cause eczema and inflammation of the skin as a result of degreasing. Prolonged inhalation of vapours may result in inflammation of the nose and gastrointestinal tract and damage on liver, kidneys, blood or central nervous system.

Indication of any immediate medical attention and special treatment needed:

Show this safety data sheet to a physician or emergency ward.

SECTION 5: Fire-fighting measures

Extinguishing media:

Carbon dioxide, dry chemical, sand, foam or water fog. Do not use water jet.

Special hazards arising from the substance or mixture:

Do not breathe smoke fumes. In case of fire (decomposition) it emits toxic fumes such as carbon oxides.

Advice for firefighters:

When extinguishing surrounding fires use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Ventilate area. Remove sources of ignition.

Environmental precautions:

Not relevant.

Methods and material for containment and cleaning up:

Place in a suitable container for disposal. Further handling of spillage - see section 13.

Reference to other sections:

See above.

SECTION 7: Handling and storage

Precautions for safe handling:

Avoid contact with skin and eyes. Wash with water and soap after work. Is not to be used near sparks, flames or hot surfaces. Smoking not allowed.

Conditions for safe storage, including any incompatibilities:

Keep original container tightly closed at temperatures between 10-30°C. Keep out of direct sunlight. Store securely, inaccessible to unauthorized persons, separate from food, foodstuff, medicaments etc.

Specific end use(s):

See section 1.

SECTION 8: Exposure controls/Personal protection

Control parameters:

| | 8-hour TWA | 15-min STEL |
|---|-----------------------------------|----------------------------------|
| Occupational exposure limits (EH40/2007): Ethanol | 1000 ppm = 1920 mg/m ³ | - |
| Isopropanol | 400 ppm = 999 mg/m ³ | 500 ppm = 1250 mg/m ³ |
| DNEL/PNEC: | No CSR. | |

Exposure controls:

Appropriate engineering controls: Provide efficient ventilation.

Personal protective equipment:

Respiratory protection: Normally not necessary. In case of working in not adequate ventilated areas, use an approved mask (EN140) with a gas filter: A. The filter has a limited lifetime and must be changed. Read the instruction.

Skin protection: Wear protective gloves (EN374) of e.g. nitrile or butyl. Breakthrough time: App. 3 hours (nitrile and butyl).

Eye protection: Normally not necessary. Use safety goggles (EN166) when there is a risk of eye contact.

Environmental exposure controls: None particular.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties:

| | |
|------------------|-------------------------------------|
| Appearance: | Wipe impregnated with clear liquid. |
| Odour: | None |
| Odour threshold: | Not determined |

| | |
|---|----------------|
| pH: | Not determined |
| Melting point/freezing point (°C): | Not determined |
| Initial boiling point and boiling range (°C): | Not determined |
| Flash point (°C): | Not determined |
| Evaporation rate: | Not determined |
| Flammability (solid, gas): | Not relevant |
| Upper/lower flammability or explosive limits (vol-%): | Not relevant |
| Vapour pressure: | Not determined |
| Relative density: | Not determined |
| Solubility: | Not determined |
| Partition coefficient: n-octanol/water: | Not determined |
| Auto-ignition temperature (°C): | Not relevant |
| Decomposition temperature (°C): | Not determined |
| Viscosity: | Not determined |
| Other information: | None relevant |

SECTION 10: Stability and reactivity

Reactivity:

No available information.

Chemical stability:

Stable under normal conditions (see section 7).

Possibility of hazardous reactions:

Vapours can be ignited by a spark, a hot surface or a glow. Vapours are heavier than air.

Conditions to avoid:

Formation of sparks and glows. Excessive heating and sources of ignition.

Incompatible materials:

May react with strong oxidising agents.

Hazardous decomposition products:

When heated to high temperatures (decomposition) it emits toxic fumes such as carbon oxides.

SECTION 11: Toxicological information

Information on toxicological effects:

| Hazard class | Data | Test | Reference |
|-----------------------|--|--|---|
| Acute toxicity: | | | |
| Inhalation | LC50 (rat) = 117-125 mg/l/4H (Ethanol) LC50 (rat) = 46,5 mg/L/4h (Isopropanol) LDLo (rabbit) = 20000 mg/kg (Ethanol) LD50 (rabbit) = 12800 mg/kg (Isopropanol) LD50 (rat) = 1780 mg/kg (Ethanol) | OECD 403 No info No info No info No info | ECHA diss. Merck IUCLID RTECS IUCLID ECHA diss. |
| Dermal | LD50 (rat) = 4570 mg/kg (Isopropanol) | No info No info info | |
| Oral | | | |
| Corrosion/irritation: | No skin irritation, rabbit (Ethanol) None to moderate eye irritation, rabbit (Ethanol) Eye irritation, rabbit (Isopropanol) | OECD 404 OECD 405 Draize | IUCLID IUCLID IUCLID |
| Sensitization: | No skin sensitisation, guinea pig (Ethanol) No skin sensitization, guinea pig (Isopropanol) | GPMT etc. Buehler | IUCLID IUCLID |
| CMR: | Data for mutagenicity is unambiguous (Ethanol) | Multiple | IUCLID |

Information on likely routes of exposure: Skin, lungs and gastrointestinal tract.

Symptoms:

Inhalation: Vapours may irritate the upper respiratory tract and cause discomfort, headache and dizziness.

Skin: May cause irritation and degrease skin.

Eyes: May cause irritation with redness and pain.

Ingestion: May irritate the mucous membranes in mouth, throat and stomach.

Chronic effects: Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system.

SECTION 12: Ecological information

Toxicity:

| Aquatic | Data | Test (Media) | Reference |
|------------|---|--------------|-----------|
| Fish | LC50 (Pimephales promelas, 96h) = 15300 mg/l (Ethanol) | No info (FW) | IUCLID |
| Crustacean | EC50 (Daphnia magna, 48h) = 9268 - 14221 mg/l (Ethanol) | No info (FW) | IUCLID |
| Algae | No applicable/available data | - | - |

Persistence and degradability:

Ethanol and Isopropanol are readily biodegradable.

Bioaccumulative potential:

Ethanol and Isopropanol: Log Kow < 1 – No significant bioaccumulation is expected.

Mobility in soil:

Ethanol and Isopropanol: Koc < 10 – Very large mobility expected in soil.

Results of PBT and vPvB assessment:

The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

Other adverse effects:

None known.

SECTION 13: Disposal considerations

Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose through authority facilities or pass to a chemical disposal company.

EWC-Code: 18 01 04 (wastes whose collection and disposal is not subject to special requirements in view of the prevention of infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers).

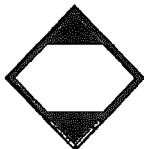
However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. It is the responsibility of the holder of the waste to determine the actual classification).

SECTION 14: Transport information

LQ

The product is dangerous goods in limited quantities of Class 4.1, II

For specifications and requirements - see the applicable regulations on ADR /RID/IMDG/ICAO.



UN classification according to ADR not applicable as the product is transported as dangerous under limited quantity.

UN-no.: 3175

UN proper shipping name: SOLIDS or mixtures of solids (such as preparations and wastes) CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethanol)

Transport hazard class(es): 4.1

Packing group: II

Environmental hazards: None.

Special precautions for user: None.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant.

SECTION 15: Regulatory information

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

Medical device (93/42/EEC): Class IIa.

Active substance:

Ethanol/ Isopropanol.

Chemical Safety Assessment:

No CSR.

SECTION 16: Other information

EU



Highly flammable

R 11: Highly flammable.

S 7: Keep container tightly closed.

R-phrases and hazard statement mentioned in section 2 and 3:

R 11: Highly flammable.

R 36: Irritating to eyes.

R 67: Vapours may cause drowsiness and dizziness.

H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC50 = Effect Concentration 50 %

ECB = European Chemicals Bureau.

ECHA = European Chemicals Agency

FW = Fresh Water

LC50 = Lethal Concentration 50 %

LD50 = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

Litterature:

ECHA diss. = REACH Registreringsdossier from ECHA's homepage.

IUCLID = International Uniform Chemical Database Information (International kemikaliedatabase med information om kemiske stoffer)

Merck (Safety Data Sheet)

RTECS = Register of Toxic Effects of Chemical Substances (database over toksiske effekter af kemiske stoffer)

Training advice:

No special training is required. However, the user should be well instructed in the execution of the task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.