

DELTACLEAN[®] hand sanitizer SIMPLY GEL

SAFETY DATA SHEET

Compliant with REACH Regulation (CE) n. 1907/2006 and n. 453/2010

MEDICAL SURGICAL DEVICE	Number revision	04	
REGISTRATION MINISTERY OF HEALTH n. 18826	Date	26-03-2019	

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE COMPANY/ BUSINESS

1.1 PROJECT IDENTIFIER

SIMPLY GEL

- 1.2 RELEVANT IDENTIFIER USES OF THE MIXTURE AND USES ADVISED
- Home and professional use
- Alcoholic antiseptic gel

2. HAZARD IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

In accordance with the directives 67/548/CEE and CLP The product, under normal conditions of storage and use, is easily flammable. 2.2 LABEL ELEMENTS (Classification-GHS) Warning: Danger Pictograms: GHS02



Hazardous components to be indicated on the label
Ethyl alcohol
Hazard statement
H225: Liquid and vapour easily flammable
Precautionary statement
P210: Keep away from heat/ sparks/ open flame/ heat surface. Don't smoke.
P233: Keep the container tightly closed.
P305+P351+P338: In case of contact with eyes: rinse thoroughly for a few minutes. Remove any contact lenses if necessary. Continue to rinse.

2.2 OTHER DANGERS

No data available.

3. COMPOSITION / INFORMATION OF INGREDIENTS

3.1 SUBSTANCES

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No substance corresponds to the criteria set out in Annex II part A of the REACH regulation (CE) no. 1907/2006.

3.2 MIXTURES

Identification	Ingredients	Classification	% p/p	
CAS: 64-17-5	Ethyl alcohol D.	GHS02, GHS07	62,00*	
EINECS: 200-578-6	S.	H: 225, 319		

*equal to 70° or better at 70 % v/v See point 16 for the full legend of the H phrases.

4. FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor. NEVER let a person who has a lost consciousness ingest anything.

4.1 DESCRIPTION OF FIRST AID MEASURES

In case of ingestion: Don't give anything to passed out people. Rinse the mouth with water. Consult a doctor.

In the event of exposure: not dangerous. Not applicable

In the event of splashes or contact with skin: not applicable

In the event of splashes or contact with eyes: act immediately. Rinse thoroughly with water for at least 15 minutes, keeping the eyelid away from the eye. Don't treat the eye with ointments or oils. If irritation or redness persists, consult an ophthalmologist.

4.2 MAIN SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

There are no known delayed effects following its exposure.

4.3 INDICATION OF ANY NEED TO IMMEDIATLY CONSULT A DOCTOR OR SPECIAL TREATMENTS

In the case of ingestion, a doctor must be consulted immediately

5. FIRE-FIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: water spray, foam, resistant, alcohol, dry chemical products or carbon dioxide.

Unsuitable extinguishing media: if rubbed, from a safe distance and upwind.

Work with water, preferably split, from a safe distance and upwind. Cool the containers exposed to the fire and the surrounding area. Don't carry out remediation, cleaning or recovery operations until the entire area has been completely cooled. In the event of decomposition, evidenced by the formation of fumes and overheating of the containers, it is essential to cool with water.

5.2 SPECIAL HAZARDS ARISING FROM THE MIXTURE

The main products of decomposition: carbon oxides and nitrogen oxides.

5.3 RACCOMANDATION FOR FIRE EXTINGUISHERS

If necessary, wear respiratory protective devices with independent air supply in case of fire.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND PROCEDURES IN THE EVENT OF AN EMERGENCY

Use respiratory protection. Avoid breathing vapors/mist/gas. Provide adequate ventilation. Evacuate personnel to safety area.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid spills or additional leaks if this can be done without danger.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND RECLAMATION

Impregnate with inert absorbent material. Store in suitable, closed containers for disposal. Follow the recommendations in paragraph 13.

6.4 REFERENCE TO OTHER SECTIONS

Please refer to section 8 and 13.

7. HAANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Apply the legislation relating to Occupational Safety and Hygiene. Avoid contact with eyes

7.2 CONDITION FOR SAFETY STORAGY, INCLUDING ANY COMPATIBILITIES

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Deny access to unauthorized people. Keep the product:

- in compliance with local/ national regulations.

- in original and closed containers.

7.3 SPECIFIC END USES

The solution is exclusively dedicated as an antiseptic hand gel.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

ETHYL ALCOHOL TLV units: ACGIH-TLV 1000 ppm (TWA) PEL units: OSHA-PEL 1000 ppm (TWA)

8.2 EXPOSURE CONTROL Han protection (protective gloves) Not relevant.
Eye / face protection Not relevant.
Skin protection Not relevant.
Respiratory protection Not relevant.

9. PHISICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON FUNDAMENTAL PHISICAL AND CHEMICAL PROPERTIES

	CHARACTERISTIC		MU	VALUE
	Appearance			Transparent gel
	Smell			Typical alcoholic
	Odor threshold			N.A. (Unavailable)
	рН	ι	J of pH	N.A. (Unavailable)
	Boiling point / boiling range		°C	N.A. (Unavailable)
	Closed-Cup flash point ASTM D3278		°C	< 21 °C
	DIN 51794 flammability		°C	N.A. (Unavailable)
	Explosive properties			It hasn't explosive properties
	Oxidizing properties			N.A. (Unavailable)
	Steam pressure			N.A. (Unavailable)
	Relative density UNI EN ISO 12185-00		d _{20/20}	0,880 ± 0,010
	Water solubility			Miscible
	Lipid			Partially miscible
	Partition coefficient (n-Octanol/Water)		logPow	N.A. (Unavailable)
	Viscosity at 20 °C ISO UNI EN 3104	1	mPa*s	N.A. (Unavailable)
	Vapor density	;	air = 1	N.A. (Unavailable)
	Evaporation rate			N.A. (Unavailable)
	VOC content %		%	N.A. (Unavailable)
9.2	OTHER INFORMATIOM			
	CHARACTERISTIC	MU		VALUE
	Autoinflammability	°C	N.A. (Unavailable)
	Melting point / range	°Č		Unavailable)

10. STABILITYB AND REACTIVITY

10.1 REACTIVITY

No data available-

10.2 CHEMICAL STABILITY

The product is stable within the terms indicated on the label, under normal conditions of storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Reactions with alkalis (bases). Exothermic reaction.

10.4 CONDITIONS TO AVOID

No data available.

10.5 INCOMPATIBLES MATIRIALS

Strong acid, strong bases, strong oxidizing agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

The main products of combustion / decomposition are: carbon dioxide and carbon monoxide.

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11. TOXICOLOGICAL INFORMATIONS

11.1 INFORMATIONS ON TOXICOLOGICAL EFFECTS

11.1.1. SUBSTANCES

ETHYL ALCOHOL

Acute Toxicity - IngestionDL50 (lethal dose - rat) 7.060 mg/kgAcute Toxicity - InhalationCL50 (rat - 10 h)20.000 ppm

Skin – on rabbit – Irritating for the skin. - 24 h

Eyes – on rabbit – Slight eyes irritation- 24 h – Draize test

Respiratory and skin sensitization

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

Rat-Oral: doubtful oncogenic agent according to RTECS Liver: blood cancers: lymphomas incloding Hodgkin disease. IARC: No component of this product present at levels greater than or equal 0.1% is identified as a carcinogen known expected by the iarc.

Reproductive toxicity

Reproductive toxicity - human - female - Oral: effects on infants: index Apgar (only for men). Others effects on infant: drug addiction. No data available.

Specific target organ toxicity-single exposure

Inhalation - Can irritate the respiratory tract.

Specific target organ toxicity- repeated exposure

No data available

Aspiration hazard

No data available

Potential health consequences

Inhalation: It can be harmful if inhaled. Causes irritation to the respiratory tract.

Ingestion: It could be dangerous if swallowed.

Skin: No potential risk.

Eyes: Causes eye irritation.

Signs and symptoms of exposure

Central nervous system depression, narcosis, heart injury.

11.1.2. **MIXTURE**

No toxicological information is available on the mixture.

11.1.3. OTHER INFORMATIONS

No data available.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

12.1.1. SUBSTANCES

The product must be used according to good working practices avoiding its dispersion in the environment. The ecotoxicity data of the individual components of the preparation are shown below.

ETHYL ALCOHOL

Toxicity to fish: LC50 - Oncorhynchus mykiss (rainbow trout) - 13.000 mg/l - 96 h

LC₅₀ - Oncorhynchus mykiss (rainbow trout) - 10.400 mg/l - 96 h

LC50 - Pimephales promelas (American chub) - 15.300 mg/l - 96 h

 $LC_{50}-Other\ fishes\ -\ 10.000\ mg/l$ - 24 h

12.1.2. MIXTURE

No toxicological information is available on the mixture.

12.2 PERSISTENCE AND DEGRADABILITY

12.2.1. SUBSTANCES

ETHYL ALCOHOL No data available.

12.2.2. MIXTURE No data available.

12.3 BIOACCUMULATION POTENTIAL 12.3.1. SUBSTANCES

ETHYL ALCOHOL

No data available.

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12.3.2. MIXTURE No data available

12.4 MOBILITÀ NEL SUOLO 12.4.1. SUBSTANCES ETHYL ALCOHOL No data available 12.4.2. MIXTURE No data available

12.5 EVALUATION RESULTS PBT E vPvB

No data available.

12.6 OTHER ADVERSE EFFECTS No data available.

13. DISPOSAL CONSIDERATION

Appropriate management of the waste of the mixture and / or its container must be determined in accordance with the provisions of the directive 2008/98/CE.

13.1 WASTE TREATMENT METHODS

Residues

The residues must be handled and disposed of in accordance with the local and national regulations in force. Sewerage disposal.

Dirty empty packaging

Empty and contaminated packaging must be disposed of in accordance with local and national regulations in force. Assimilable to urban waste to be collected with the "undifferentiated dry". **Product**

Dispose through sewer system

Waste code (Decision 2001/573/CE, Directive 2006/12/CEE, Directive 94/31/CEE relating to hazardous waste):

15 01 02 plastic packaging.

18 01 07 Chemical substances other than those mentioned in 18 01 06.

14. TRANSPORT INFORMATION

Follow the rules established ADR for road transport (ADR 2010), RID for rail transport, IMDG for sea transport (IMDG 2011), ICAO/IATA for air transport (ICAO/IATA 2011).

14.1 ONU NUMBER

1987

14.2 ONU SHIPPING NAME

UN 1987: Alcohols N.A.S.

14.3 DANGER CLASSES RELATED TO TRANSPORT

3

14.4 PACKAGIN GROUP

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14.5 ENVIRONMENTAL HAZARD

14.6 The solution is not dangerous for the environment.

14.7 SPECIAL PRECAUTIONS FPOR USERS

ADR/RID	Class	Code	Number	Label	Identif.	LQ	Dispo.	EQ	Cat.	Tunnel
	3	F1		3	30	51	274	E	3	E
IMDG	Class	2° Label	Number	LQ	Ems	Dispo.	EQ	Marine pollutant NO (NO)		llutant
	3	-		51	F-A, S-B	274	E3			0)
IATA	Class	2° Label	Number							
	3	-								

14.8 TRANSPORT OF BULK IN ACCORDANCE WITH ANNEX II MARPOL 73/78 AND THE IBC CODE

Not relevant.

15. REGULATORY INFORMATION

15.1 LEGISLATIVE AND REGULATORY PROVISIONS ON HEALTH, SAFETY AND ENVIRONMENT SPECIFIC FOR THE SUBSTANCE OR MIXTURE

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This safety data sheet complies with the provisions of regulation (EC) no. 1907/2006 and regulation no. 453/2010. The hazard classification of the mixture complies with Directive 1999/45/CE and regulation 1272/2008 (regulation CLP).

15.2 CHEMICAL SAFETY ASSESSMENT

No chemical safety assessment has been performed for this mixture.

16. OTHER INFORMATIONS

This complete sheet does not replace the technical information for use. The information it contains is based on the state of our knowledge of the product in question on the date indicated. They are provided in good faith. Users' attention is also drawn to possible risks in the event that a product is used for purposes other than those for which it is intended.

FULL TEXT OF THE H EUH PHRASES INDICATED IN SECTION 3.

H PHRASES

H225: Liquor and vapour easily flammable.

H319: Causes serious eye irritation.

REVISIONS

00 13 December 2014 First issue

01 08 March 2016 Adjustment of information to the actual use of the product.

02 15 September 2016 Adjustment to the regulation 1272/2008 (Regulation CLP).

03 10 April 2017 Adaptation of the Safety Data Sheet to the Regulation UE 2015/830

04 26 March 2019 Adaptation of the H phrases and respective symbols of the ethyl alcohol raw material in point 3.2

The information contained in this safety data sheet is based on our current knowledge and is provided in compliance with the provisions of EC Regulation no. 1907/2006 of 18.12.2006 (REACH). It is always the user's responsibility to comply with the hygiene, safety and environmental protection standards provided for by current legislation. The information contained in this sheet is intended as a description of the characteristics of the product for safety purposes. For any technical information, please refer to the Technical Data Sheet.

