

Via Laurentina 169 00071 POMEZIA (RM)

# ISACLEAN® SPRAY-BACTRYL SPRAY

# MEDICAL DEVICE class IIb ID CODE ISAS/CE/45

1st Edition

Review no. 0

Review date: 25.06.2019

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# **Material Safety Data Sheet**

## SECTION 1. Identification of the Substance/Mixture and of the Company/Firm

#### 1.1. Product Identifier

Name ISACLEAN® SPRAY-BACTRYL SPRAY

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

Description/Use Cleaning, disinfecting product for disinfection and preservation of Medical Devices.

Classification Medical Device Class IIb Directive 2007/47/CE.

Uses advised against None in particular.

#### 1.3 Details of the Supplier on the Safety Data Sheet

Company Name CANTEL MEDICAL (ITALY) S.R.L.

Address Via Laurentina, n. 169
Town and Country 00071 Pomezia (RM)

ITALY

telephone +39.06/9145399 E-mail: info@ cantelmedical.it

email address of the person responsible,

1.4. Emergency telephone number

For urgent inquiries refer to Poison Centre Milan (CAV Niguarda Ca` Granda Hospital - Milan)

Ph: 02 66101029

CANTEL MEDICAL (ITALY) S.R.L.

Emergency telephone number of the company (24/24 hours):

ph. +39.06/9145399 (Technical Support)

#### **SECTION 2. Hazards Identification.**

### 2.1. Classification of the Substance or Mixture

The product is classified as a dangerous substance pursuant to the provisions laid down in Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and adjustments). The product requires therefore a safety data sheet in accordance with the provisions of Regulation (EC) 1907/2006 and subsequent amendments.

Any additional information concerning the risks posed to health and/or environment are specified in sections 11 and 12 of this data sheet.

Classification and hazard statements:

Flammable liquid, Category 2 H225 Liquid and vapours highly flammable.

Eye irritation, category 2 H319 Causes severe eye irritation.

Hazardous to the aquatic environment, chronic toxicity, H412 Harmful to aquatic organisms with long-term effects.

category 3

#### 2.2. Label elements.

Hazard labelling pursuant to Regulation (EC) 1272/2008 (CLP) and subsequent amendments.



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Warnings:

Hazard indications:

H225 Liquid and vapours highly flammable.

Danger

H319 Causes severe eye irritation.

H412 Harmful to aquatic organisms with long-term effects.

Safety phrases:

P210 Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke.

P280 Wear protective gloves and eye protection/face protection.

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

rinsing.

P337+P313 If eye irritation persists, consult a physician. P273 Do not dispose of it in the environment.

2.3. Other Hazards.

Based on the available data, the product does not contain substances classified as PBT or vPvB in percentage greater than 0.1 %.

### **SECTION 3. Composition/Information on Ingredients**

## 3.1. Substances.

Information not relevant.

### 3.2. Mixtures.

Contains:

Identification. 1272/2008 (CLP) Conc. %. Classification.

**ISOPROPANOL** 

CAS. 67-63-0 15 - 16.5 Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336

CE. 200-661-7 INDEX. 603-117-00-0

No Reg. 01-2119457558-25

Quaternary ammonium compounds, benzyl-C12-

16-alkyldimethyl, chlorides

CAS. 68424-85-1 0.5 - 0.6Met. Corr. 1 H290, Acute Tox.

4 H302, Skin Corr. 1B H314, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410

CE. 270-325-2 INDEX. -



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No Reg. -

D-gluconic acid, compound with N,N"-bis (4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanodiammidine (2:1)

tetraazatetradecanodiammidine (2:1) CAS. 18472-51-0

0.1 - 0.2

Eye Irrit. 2 H319, STOT SE 3

H335, Aquatic Acute 1 H400

M=10

CE. 242-354-0

INDEX. -

No Reg. -

**DIDECYLDIMETHYLAMMONIUM CHLORIDE** 

CAS. 7173-51-5 0 - 0.1

Acute Tox. 3 H301, Skin Corr. 1B H314, Aquatic Acute 1 H400 M=10, Aquatic Chronic

1 H410

CE. 230-525-2

INDEX. 612-131-00-6

No Reg. -

**ETHYLENE GLYCOL** 

CAS. 107-21-1

0 - 0.1

Acute Tox. 4 H302, STOT RE

2 H373

CE. 203-473-3

INDEX. 603-027-00-1

No Reg. 01-2119456816-28

Note: Value exceeding the excluded range.

The full text of hazard statements (H) is specified in section 16 of this data sheet.

## **SECTION 4. First Aid Measures.**

## 4.1. Description of first aid measures.

EYES: Remove any contact lenses. Wash immediately and thoroughly with water for at least 30/60 minutes, with the eyes wide open. Consult a physician immediately.

SKIN: Take off contaminated clothing. Take a shower immediately. Consult a physician immediately.

INGESTION: Drink water as much as possible. Consult a physician immediately. Do not induce vomiting if not expressly authorized by the physician. INHALATION: Seek medical advice immediately. Bring the subject outdoors, away from the place of the accident. If breathing stops, provide artificial respiration. Take adequate precautions to the responder.

PROTECTION MEASURES FOR THE FIRST AIDERS: for the PPE needed for first aid refer to section 8.2 of this safety data sheet.

#### 4.2. Most Important Symptoms and Effects, both Acute and Delayed.

For the symptoms and effects due to the substances contained in it, see chap. 11.

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

Information not available.



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## **SECTION 5. Fire-Fighting Measures.**

#### 5.1 Extinguishing Media.

#### SUITABLE EXTINGUISHING MEDIA

Extinguishing media are carbon dioxide, foam, chemical powder. Due to the losses and the sifting of the product that you have not burned down, the atomized water can be used to disperse the flammable vapours and protect the people involved to stop the leak.

UNSUITABLE EXTINGUISHING MEDIA

Do not use water jets. Water is not effective to extinguish the fire but can be used to cool close containers exposed to flames, thus preventing fires and explosions.

#### 5.2. Special Hazards Arising from the Substance or Mixture.

#### DANGERS FROM EXPOSURE IN CASE OF FIRE

Excess pressure may form in containers exposed to fire with explosion hazard. Avoid breathing the products of combustion.

#### 5.3. Advice for Fire-fighters.

#### GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear personal protection devices including fire equipment. Collect contaminated fire fighting water separately. It must not be discharged into the drains. Dispose of the contaminated water used for fire fighting and the residue of the fire according to the rules in force.

EQUIPMENT

Normal equipment for fire fighting such as self-contained breathing apparatus (EN 137), flame retardant turnout gear (EN469), flame-retardant gloves (EN 659) and boots for firemen (HO A29 or A30).

#### SECTION 6. Measures in Case of Accidental Release.

### 6.1. Personal Precautions, Protective Equipment and Procedures in Case of Emergency.

Stop leak if without risk.

Wear appropriate protective devices (including the personal protective equipment referred to in section 8 of the safety data sheet) in order to prevent contamination of the skin, eyes and personal clothing. These guidelines apply to staff who works under both standard and emergency conditions.

## 6.2. Environmental Precautions.

Prevent the product from entering sewers, surface waters, and groundwater.

#### 6.3. Methods And Material For Containment And Remediation.

Suck up the spilled product in appropriate container. Assess the compatibility of the container to use with the product, checking section 10. Absorb the remaining product with inert absorbent.

Ensure adequate ventilation of the area affected by the loss. Check any incompatibility for the material of the containers in section 7. Disposal of contaminated material must be carried out in accordance with the provisions of section 13.



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#### 6.4. References to Other Sections

Any information relating to personal protective equipment and disposal are given in sections 8 and 13.

### **SECTION 7. Handling And Storage.**

#### 7.1 Precautions for Safe Handling

Keep away from heat, sparks and flames, do not smoke or use matches or lighters. The vapors can be ignited with an explosion, so you must avoid accumulation holding open doors and windows and ensuring a cross ventilation. Without proper ventilation, the fumes can accumulate on the ground and ignite even from a distance, if ignited, with danger of backfiring. Avoid the accumulation of electrostatic charges. Connect to a grounded socket in the case of large packaging during the decanting process and wear anti-static shoes. The strong shaking and vigorous flow of liquid in the pipes and equipment may cause formation and accumulation of electrostatic charges. To avoid the danger of fire and explosion, never use compressed air in the movement. Open the containers with caution, because they may be pressurized. Do not eat, drink or smoke during use. Prevent the dispersion of the product into the environment.

## 7.2. Conditions for Safe Storage, Including any Incompatibilities.

Keep only in the original container. Keep the containers closed, in a well-ventilated place, sheltered from direct sunlight. Store in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition. Store containers away from any incompatible materials, making sure the section 10.

#### 7.3. End Uses specific.

No use other than those indicated in section 1.2 of this safety data sheet.

## SECTION 8. Exposure controls/personal protection.

#### 8.1. Control Parameters.

### Reference Standards:

AUS BEL BGR	Österreich Belgique България	Grenzwerteverordnung 2011 - GKV 2011 AR du 11/3/2002. La liste est mise à jour pour 2010 МИНИСТЕРСТВО НА ТРУДА И СОЦИАЛНАТА ПОЛИТИКА МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО НАРЕДБА No 13 от 30 декември 2003 г
CYP	Κύπρος	K.Δ.Π. 268/2001; K.Δ.Π. 55/2004; K.Δ.Π. 295/2007; K.Δ.Π. 70/2012
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja



Via Laurentina 169 00071 POMEZIA (RM)

Norge

Polska

Sloveniia

FRA

**IRL** 

NOR

**POL** 

SVN

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terveysministeriön julkaisuja 2012:5

France JORF n°0109 du 10 mai 2012 page 8773 texte n° 102

**GRB** United Kingdom EH40/2005 Workplace exposure limits

Ελλάδα ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 **GRC** 

Φεβρουαρίου 2012

HRV NN13/09 - Ministarstvo gospodarstva, rada i poduzetništva Hrvatska

50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról HUN Magyarország

Code of Practice Chemical Agent Regulations 2011 Éire

ITA Italia Decreto Legislativo 9 Aprile 2008, n.81

DEL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ LTU Lietuva

MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287

LVA Ķīmisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā Latvija

2012

NLD Databank of the social and Economic Concil of Netherlands (SER) Values, Nederland

AF 2011:18

Veiledning om Administrative normer for forurensning i arbeidsatmosfære ROZPORZADZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia

16 grudnia 2011r

SVK Slovensko NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007

Uradni list Republike Sloveniie 15, 6, 2007

Sverige Occupational Exposure Limit Values, AF 2011:18 **SWE** 

2000/39/EC sayılı Direktifin ekidir **TUR** Türkiye

Direttiva 2009/161/UE; Direttiva 2006/15/CE; Direttiva 2004/37/CE; EU **OEL EU** 

Direttiva 2000/39/CE.

**TLV-ACGIH ACGIH 2014** 

ISOPROPANOL						
Threshold value. Type	Status	TWA/8h		STEL/15min	STEL/15min	
		mg/m3	ppm	mg/m3	ppm	
MAK	AUS	500	200	2000	800	
VLEP	BEL	500	200	1000	400	
TLV	BGR	980		1225		
TLV	CZE	500		1000		SKIN.
AGW	DEU	500	200	1000	400	
MAK	DEU	500	200	1000	400	
TLV	DNK	490	200			
VLA	ESP	500	200	1000	400	
TLV	EST	350	150	600	250	
VLEP	FRA			980	400	
WEL	GRB	999	400	1250	500	
TLV	GRC	980	400	1225	500	
GVI	HRV	999	400	1250	500	
AK	HUN	500		2000		
OEL	IRL		200		400	SKIN.
RD	LTU	350	150	600	250	
RV	LVA	350		600		
OEL	NLD	650				



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OEL

RD

RV

OEL

 $\mathsf{TLV}$ 

ITA

LTU

LVA

NLD

NOR

52

25

52

52

20

10

20

25

104

50

104

104

40

20

40

SKIN.

SKIN.

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SKIN.

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			ID CODE	: ISAS/C	E/45			
TLV	NOR	245	100					
NDS	POL	900	100	1200				
NPHV	SVK	500	200	1000				
MV	SVN	500	200	1000				
MAK	SWE	350	150	600	250			
TLV-ACGIH	SWL	492	200	983	400			
Concentration with no predicted	effect on the enviro		200		100			
Reference value in fresh water. Reference value in seawater Reference value for sediments i Reference value for sediments i Reference value for water, disco Reference value for STP microo Reference value for the food con Reference value for ground com Health - Derived no-effect	n seawater ontinuous release organisms ain (secondary poise opartment			140.9 140.9 552 552 140.9 2251 160 28		mg/l mg/l mg/kg mg/kg mg/l mg/kg mg/kg		
nealth - Delived no-effect	Effects on	WICL			Effects on			
Route of Exposure	consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	workers Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	26 mg/kg bw/d				
Inhalation.			VND	89 mg/m3			VND	500 mg/m3
Dermal absorption.			VND	319 mg/kg bw/d			VND	888 mg/kg bw/d
ETHYLENE GLYCOL								
Threshold value. Type	Status	TWA/8h		STEL/15min				
				OTEL/TOTTILI				
		mg/m3	ppm	mg/m3	ppm			
MAK	AUS	mg/m3 26	ppm 10		ppm 20	SKIN.		
MAK TLV	AUS BGR			mg/m3		SKIN. SKIN.		
		26		mg/m3 52				
TLV	BGR	26 52	10	mg/m3 52 104	20	SKIN.		
TLV TLV	BGR CYP	26 52 52	10	mg/m3 52 104 104	20	SKIN. SKIN.		
TLV TLV TLV	BGR CYP CZE	26 52 52 50	10	mg/m3 52 104 104 100	20	SKIN. SKIN. SKIN.		
TLV TLV TLV AGW	BGR CYP CZE DEU	26 52 52 50 26	10 20 10	mg/m3 52 104 104 100 52	20 40 20	SKIN. SKIN. SKIN. SKIN.		
TLV TLV TLV AGW MAK	BGR CYP CZE DEU DEU	26 52 52 50 26 26	10 20 10 10	mg/m3 52 104 104 100 52	20 40 20	SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV AGW MAK TLV	BGR CYP CZE DEU DEU DNK	26 52 52 50 26 26 26	10 20 10 10 10	mg/m3 52 104 104 100 52 52	20 40 20 20	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV AGW MAK TLV VLA	BGR CYP CZE DEU DEU DNK ESP	26 52 52 50 26 26 26 26 52	10 20 10 10 10 20	mg/m3  52  104  104  100  52  52  104	20 40 20 20 40	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV TLV AGW MAK TLV VLA	BGR CYP CZE DEU DEU DNK ESP EST	26 52 52 50 26 26 26 26 52	10 20 10 10 10 20 20	mg/m3  52  104  104  100  52  52  104  104	20 40 20 20 20 40 40	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV TLV AGW MAK TLV VLA TLV	BGR CYP CZE DEU DEU DNK ESP EST FIN	26 52 52 50 26 26 26 26 52 52 52	10 20 10 10 10 20 20 20	mg/m3  52  104  104  100  52  52  104  104  100	20 40 20 20 40 40 40	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV AGW MAK TLV VLA TLV HTP	BGR CYP CZE DEU DEU DNK ESP EST FIN FRA	26 52 52 50 26 26 26 26 52 52 50 52	10 20 10 10 10 20 20 20 20	mg/m3  52  104  104  100  52  52  104  104  104  100  104	20 40 20 20 40 40 40 40	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV TLV AGW MAK TLV VLA TLV HTP VLEP	BGR CYP CZE DEU DEU DNK ESP EST FIN FRA GRB	26 52 52 50 26 26 26 26 52 52 50 52 52	10 20 10 10 10 20 20 20 20 20	mg/m3  52  104  100  52  52  104  100  104  100  104  104	20 40 20 20 40 40 40 40 40	SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN. SKIN.		
TLV TLV TLV AGW MAK TLV VLA TLV HTP VLEP WEL TLV	BGR CYP CZE DEU DEU DNK ESP EST FIN FRA GRB GRC	26 52 52 50 26 26 26 26 52 52 52 50 52 52 52	10 20 10 10 10 20 20 20 20 20 20 50	mg/m3  52  104  104  100  52  52  104  104  100  104  104  104  125	20 40 20 20 40 40 40 40 40 50	SKIN.		



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NPHV	SVK	52	20	104		SKIN.
MAK	SWE	25	10	50	20	SKIN.
ESD	TUR	52	20	104	40	SKIN.
OEL	EU	52	20	104	40	SKIN.
TLV-ACGIH				100 (C)		

Key:

(C) = CEILING; INALAB = Inhalable fraction; RESPIR = Breathable fraction; TORAC = Thoracic fraction.

VND = danger identified but no DNEL/PNEC available ; NEA = negative exposure assessment ; NPI = no danger identified.

#### 8.2. Exposure controls.

Considered that the use of appropriate technical measures should always prevail over personal protective devices, ensure good ventilation in the workplace using an effective local exhaust system. The personal protective equipment should bear the CE marking to certify their compliance with applicable standards.

Provide emergency shower and eye wash facilities.

#### HAND PROTECTION

Protect your hands with gloves of category III (ref. standard EN 374).

Final selection of glove material must be made taking into account these factors: compatibility, degradation, permeation and time to failure.

In the case of preparations the resistance of working gloves to chemical agents must be verified before use because it is not predictable. The gloves have a time to wear that depends on the duration and the mode of use.

#### SKIN PROTECTION

Wear work clothes with long sleeves and safety footwear for professional use of category I (Ref. Directive 89/686/EEC and standard EN iSO 20344). Wash with soap and water after removing protective clothing.

Assess the opportunity to provide antistatic clothing if the work area may present a risk of explosion.

#### **EYE PROTECTION**

It is recommended that you wear protective goggles (ref. standard EN 166).

### RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) of the substance or of one or more of the substances present in the product is exceeded, it is recommended to wear a mask with filter type AX (ref. standard EN 14387) within the limitations on use defined by the manufacturer. In the case were present gases or vapours of a different nature and/or gas or vapors with particles (aerosols, fumes, mists, etc.) you should provide filters of the combined type.

The use of respiratory protection is necessary in the event the technical measures taken are not sufficient to limit the exposure of the worker to the threshold values taken into consideration. The protection provided by masks is in any case limited.

In the case where the substance in question is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in case of emergency, wear a self-contained breathing apparatus to compressed air to open circuit (ref. EN 137) or a respirator to outdoor air intake (ref. EN 138). For the proper choice of the device to protect the respiratory tract, refer to the standard EN 529.

#### ENVIRONMENTAL EXPOSURE CONTROLS.

Emissions from manufacturing processes, including those from ventilation equipment, should be controlled for the purposes of compliance with the rules and regulations on environmental protection.

The product residues should not be disposed of uncontrollably in waste water or water courses.

### **SECTION 9. Physical And Chemical Properties.**



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#### 9.1. Information on Basic Physical and Chemical Properties.

**Physical State** clear liquid Colour liaht blue Odour citrus light Olfactory threshold. Not available.  $6.5 \pm 1$ Not available. Melting o Freezing Point. > 35 °C. Initial boiling point. Boiling point. Not available. Flash point. 38°C. Evaporation rate Not available. Flammability of solids and gases Not available. Lower Flammability Limit. Not available. Upper Flammability Limit. Not available. Lower Explosive Limit. Not available. Upper Explosive Limit. Not available. Vapour pressure. Not available. Vapour Density. Not available. Relative density.  $1.0 \pm 0.05 \text{ kg/l}$ Solubility Not available. Partition coefficient: n-octanol/water: Not available. Ignition Temperature. Not available.

Viscosity Not available.
Explosive properties non-explosive based on composition.

Explosive properties non-explosive based on composition. Oxidizing properties Non-oxidizing based on composition.

Not available.

### 9.2. Other Information.

Decomposition Temperature.

Information not available.

## **SECTION 10. Stability and Reactivity.**

#### 10.1. Reactivity.

Under normal conditions of use there are no particular risk of reaction with other substances.

#### 10.2. Chemical Stability.

The product is stable under normal conditions of use and storage.

## 10.3. Possibility of Hazardous Reactions.

Vapours may form explosive mixtures with air.

#### 10.4. Conditions to Avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any ignition source.



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#### 10.5. Incompatible Materials.

Information not available.

#### 10.6. Hazardous Decomposition Products.

As a result of thermal decomposition, or in case of fire, gases and vapours dangerous to health can be released.

## **SECTION 11. Toxicological Information.**

#### 11.1. Information on Toxicological Effects.

In the absence of the toxicological data on experimental product itself, the possible dangers of the product for health were evaluated on the basis of the properties of the substances contained in it, according to the criteria provided by the legislation of reference for the classification. Consider therefore the concentration of each hazardous substances possibly mentioned in sect. 3 to assess the toxicological effects resulting from exposure to the product. Acute effects: contact with eyes causes irritation; symptoms may include: redness, swelling, pain and tearing. Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting.

Data referring to the mixture:

ACUTE TOXICITY INHALATION: Data not available.

ACUTE TOXICITY ORAL: Data not available.

ACUTE TOXICITY SKIN: Data not available.

CORROSION/ SKIN IRRITATION: Data not available.

SEVERE EYE LESIONS/SEVERE EYE IRRITATIONS: it causes severe eye irritation due to its composition specified in section 3.2.

RESPIRATORY SENSITISATION OR SKIN: Data not available;

MUTAGENICITY OF GERM CELLS: Data not available.

CANCEROGENICITÀ: Data not available.

TOXICITY FOR PLAYBACK: Data not available.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - SINGLE EXPOSURE: Data not available;

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: Data not available.

DANGER IN THE CASE OF SUCTION: Data not available.

Data referred to the hazardous substances in the mixture:

#### ISOPROPANOL

SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: irritating, rabbit, OECD TG 405 data available in the MSDS of the manufacturer);

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - SINGLE EXPOSURE: may cause drowsiness or dizziness as per harmonized classification in Annex VI Reg. CLP.

D-GLUCONIC ACID, COMPOUND WITH N,N"-BIS (4-CHLOROPHENYL)-3,12-DIIMINO-2,4,11,13-TETRAAZATETRADECANODIAMMIDINE (2:1) SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: irritating, rabbit, equivalent or similar to OECD TG 405;

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: it may irritate the respiratory tract, classification data available in the MSDS of the supplier.

QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES ACUTE TOXICITY



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LD50 (Oral).795 mg/kg Rat, data available in the MSDS of the supplier. SKIN CORROSION/IRRITATION: corrosive, rabbit, OECD TG 404;

SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: causes severe eye damage.

#### DIDECYLDIMETHYLAMMONIUM CHLORIDE

LD50 (Oral) > 238 mg/kg Rat (Method: OECD TG 401)

SKIN CORROSION/ IRRITATION: corrosive, in vivo test on rabbit (Method: OECD TG 404).

#### ETHYLENE GLYCOL

If swallowed, it initially stimulates the CNS that enters a depression phase. Kidney damage, with anuria and uremia may also appear. The symptoms of overexposure are: vomiting, drowsiness, difficulty breathing, seizures. Penetration pathways: inhalation and ingestion.

Lethal doses for humans are of 1000-2000 mg/kg bw (100 mL). [Source: Sheftel, V.O.; Indirect Food Additives and Polymers. Migration and Toxicology. Lewis Publishers, Boca Raton, FL. 2000., p. 726]

ACUTE TOXICITY: Harmful if swallowed. (Harmonised classification, Annex VI of Reg. CLP)

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - REPEATED EXPOSURE: may cause damage to organs (Harmonised classification, Annex VI of Reg. CLP)

## **SECTION 12. Ecological Information.**

The product is considered dangerous to the environment and is harmful to aquatic organisms with long-term adverse effects on the aquatic environment.

#### 12.1. Toxicity.

#### **ISOPROPANOL**

ETHYLENE GLYCOL

LC50 - Fish. > 10000 mg/l/96h Pimephales promelas, method: US-EPA. EC50 - Shellfish. > 10000 mg/l/48h Daphnia Magna; method: US-EPA.

EC50 - Algae / Aquatic 6500 mg/l/72h 13000 Pseudokirchnerella subcapitata, method US-EPA.

plants.

EC10 Algae / Aquatic plants. > 10000 mg/l/72h Desmodesmus subspicatus (7d)

Chronic NOEC fish. > 10000 mg/l/96h Pimephales promelas, method: US-EPA.

Chronic NOEC Algae / 8590 mg/l 7d Ceriodaphnia sp. (Source: Environ. Toxicology and Chemistry, Vol. 14, No 2:

Aquatic plants. 311-315)

D-GLUCONIC ACID, COMPOUND WITH N,N"-BIS (4-CHLOROPHENYL)-3,12-DIIMINO-2,4,11,13-

TETRAAZATETRADECANODIAMMIDINE (2:1)

LC50 - Fish. 2.08 mg/l/96h zebrafish, OECD TG 203.

EC50 - Shellfish. 0.087 mg/l/48h Daphnia magna, OECD TG 202.

EC50 - Algae / Aquatic > 0.081 mg/l/72h Desmodesmus subspicatus, OECD TG 201.

plants.

QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES



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LC50 - Fish. > 0.085 mg/l/96h Onchorhynchus mykiss , OECD 203 (information available in the MSDS of

the supplier)

EC50 - Shellfish. 0.016 mg/l/48h Daphnia magna (information available in the MSDS of the supplier)

EC50 - Algae / Aquatic 0.025 mg/l/72h Selenastrum capricornutum OECD 201 (information available in the MSDS of

plants. the supplier)

NOEC Chronic shellfish. 0.025 mg/l Daphnia magna, OECD 211.

DIDECYLDIMETHYLAMMONIUM CHLORIDE

LC50 - Fish.
 EC50 - Shellfish.
 0.19 mg/l/96h Pimephales promelas (Method: US-EPA)
 EC50 - Shellfish.
 0.062 mg/l/48h Daphnia Magna (Method: EPA-FIFRA)

EC50 - Algae / Aquatic 0.026 mg/l/96h Pseudokirchneriella subcapitata (Information available in the SDS of the

plants. supplier9

Chronic NOEC fish. 0.032 mg/l/34 d Danio Rerio (Method: OECD TG 210)

NOEC Chronic shellfish. 0.01 mg/l/21 d Daphnia Magna (Reproductive test, method: OECD TG 211)

#### 12.2. Persistence and Degradability.

QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES Rapidly Biodegradable (OECD TG 301 D).

ISOPROPANOL: degradability > 70% in 10 days (data available in the MSDS of the manufacturer).

#### DIDECYLDIMETHYLAMMONIUM CHLORIDE

Stability in water: abiotic degradation, hydrolytically stable (Method EPA-FIFRA)

Modified Sturn essay: 72%, rapidly degradable, Duration of the experiment: 28 d, Method: OECD TG 301 B

Die-Away test: 93.3%, Experiment duration: 28 d, OECD Confirmatory Test: 91%, Experiment duration: 24 - 70 d, Method: OECD TG 303 A.

D-GLUCONIC ACID, COMPOUND WITH N,N"-BIS (4-CHLOROPHENYL)-3,12-DIIMINO-2,4,11,13-TETRAAZATETRADECANODIAMMIDINE (2:1)

Rapidly Biodegradable (OECD TG 301 A).

ETHYLENE GLYCOL: readily biodegradable Passes OECD test (s) for ready biodegradability. The material is basically biodegradable. Reaches more than 70% of mineralization in OECD test due to inherent biodegradability. 90 - 100 % 10 d Test OECD 301A.

#### 12.3. Potential for bio-accumulation.

ETHYLENE GLYCOL: no potential to bio-accumulate (log Ko/w<1)Bioaccumulation: The bio-concentration potential is low (FBC< 100 or Log Pow<3) Partition coefficient n-octanol/water (log Pow): -1.36 Measured. (Source: Washington, DC: American Chemical Society., 1995., p. 5. cited in HSDB 20.9.2006)

D-GLUCONIC ACID, COMPOUND WITH N,N"-BIS (4-CHLOROPHENYL)-3,12-DIIMINO-2,4,11,13-TETRAAZATETRADECANODIAMMIDINE

(2:1)

Partition coefficient: -1,81 Log Kow OECD Guideline 107.

n-octanol/water.

BCF. 42 - (I/Kg) Leuciscus idus melanotus, (Source: publ. on ECHA website)

### 12.4. Mobility in Soil.

Information not available.

### 12.5. Results of PBT and vPvB Assessment.



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Based on the available data, the product does not contain substances classified as PBT or vPvB in percentage greater than 0.1 %.

#### 12.6. Other Adverse Effects

Information not available

## **SECTION 13. Disposal Considerations.**

#### 13.1. Methods of Waste Treatment.

Reuse, when possible. Product residues should be considered special hazardous waste. The dangerousness of the wastes that contain part of this product should be evaluated according to the legislative provisions proposed in the Legislative Decree no. 152/2006 and subsequent amendments. Disposal should be entrusted to an authorized waste management firm, in compliance with national and local regulations. CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## **SECTION 14. Transport Information.**

#### 14.1. UN Number.

ADR / RID, IMDG, 1219

#### 14.2. UN shipping name

ADR / RID: ISOPROPANOL (ISOPROPYL ALCOHOL) IMDG: ISOPROPANOL (ISOPROPYL ALCOHOL) IATA: ISOPROPANOL (ISOPROPYL ALCOHOL)

## 14.3. Danger Classes connected to the transport.

ADR / RID: Class: 3 Label: 3

IMDG: Class: 3 Label: 3

IATA: Class: 3 Label: 3



### 14.4. Packaging group.

ADR / RID, IMDG, II IATA:

### 14.5. Dangers for the environment.

ADR / RID: NO



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14.6. Speci	al precautions	for	users.

ADR / RID: HIN - Kemler: 33 Limited Code of Amounts 1 l restriction in

Special Provision: -

IMDG: EMS: F-E, S-D Limited

IATA: Cargo: Amounts 1 I Maximum quantity: 60 I

Pass.: Maximum Packaging quantity: 5 L Instructions:

Special instructions: A180

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tunnels (D/E)

Packaging

Instructions:

14.7. Bulk transport according to Annex II of MARPOL 73/78 and the IBC code

Information not relevant.

## **SECTION 15 Regulatory Information.**

15.1. Standards and Legislation on Health, Safety and Environmental Specifications for the Substance or Mixture.

Seveso Category. 7b LIQUID HIGHLY FLAMMABLE

Restrictions concerning the product or substances contained as per Annex XVII Regulation (EC) 1907/2006.

Product:

Point. 3. The substances or the liquid mixtures that are considered dangerous pursuant to Directive 1999 /45/CE or

that match the criteria for one of the following classes or categories of danger referred to in Annex I of

Regulation (EC) no. 1272/2008:

a) classes of danger from 2.1 to 2.4 , 2.6 and 2.7 , 2.8 types A and B, 2.9 , 2.10 , 2.12 , 2.13 categories 1 and 2,

2.14 categories 1 and 2, 2.15 types A to F;

b) classes of danger from 3.1 to 3.6, 3.7 harmful effects on sexual function and fertility or development, 3.8

effects other than narcotic effects, 3.9 and 3.10;

c) hazard class 4.1; d) hazard class 5.1.

Point. 40 Substances classified as flammable gases of category 2 or 1, 2, flammable liquids of category 3 or 1,

flammable solids of category 2 or 1, 2, substances and mixtures which, in contact with water, release flammable gases of category 3 or 1, pyrophoric liquids category 1 or pyrophoric solids of category 1, even if

not listed in Annex VI, part 3 of Regulation (EC) n. 1272/2008.

Candidate List Substances (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.



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Substances subject to export notification Reg. (EC) 649/2012:

None.

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None.

#### Public health control.

Workers exposed to this chemical agent must undergo health checks for the health surveillance carried out in accordance with the provisions of art. 41 of the Legislative Decree 81 of 9 April 2008, unless the risk to the safety and health of the worker has been assessed irrelevant, in accordance with art. 224 paragraph 2.

Law Decree 152/2006 and subsequent amendments.

Emissions:

TAB. D Class 3 00.02 % TAB. D Class 4 15.00 %

#### 15.2. Chemical Safety Assessment.

A chemical safety assessment for the mixture and substances contained therein was not prepared. At the time of drafting of this safety data sheet, the exposure scenario of the substance was not available: ISOPROPANOL Registration number: 01-2119457558-25.

## **SECTION 16. Other Information.**

Text of hazard indications (H) mentioned in sections 2-3 of this sheet:

Flam. Liq. 2 Flammable liquid, Category 2

Met. Corr. 1 Substance or mixture corrosive for metals, category 1

Acute Tox. 3 Acute toxicity, category 3
Acute Tox. 4 Acute toxicity, category 4

STOT RE 2 Specific target organ toxicity - repeated exposure, category 2

Skin Corr. 1B Skin corrosion, category 1B

Eye Irrit. 2 Eye irritation, category 2

STOT SE 3 Specific target organ toxicity - single exposure, category 3

Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1

Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1

Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3

**H225** Liquid and vapours highly flammable.

H290 Can be corrosive to metals.

H301 Toxic if swallowed.



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H302 Harmful if swallowed.

H373 It may damage the organs in case of prolonged or repeated exposure.

H314 Causes severe skin burns and eye damage.

H319 Causes severe eye irritation. H335 May cause respiratory irritation H336 May cause drowsiness or dizziness. H400 Very toxic to aquatic organisms.

H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic organisms with long-term effects.

#### Training for workers:

Training of workers must provide content, updates, and duration relating to the types of risks assigned to the specific work areas, according to the regulations laid down in Legislative Decree 81/2008.

#### LEGEND:

- ADR: European Agreement concerning the transport of dangerous goods by road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Concentration that has effect on 50% of the population subject to test
- EC NUMBER: identification number in ESIS (european archive of existing substances)
- CLP: Regulation EC 1272/2008
- DNEL: derivative level without effect
- EMS: Emergency Schedule
- GHS: Harmonized System overall for the classification and labelling of chemicals
- IATA DGR: Regulation for the transport of dangerous goods of international air transport association
- IC50: Concentration of immobilization of 50% of the population subject to test
- IMDG Code: international maritime transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: identification number in the Annex VI of the CLP
- LC50: lethal concentration 50%
- LD50: lethal dose 50%
- OEL: Level of occupational exposure
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: PEC environmental concentration predictable
- PEL: anticipated level of exposure
- PNEC: foreseeable concentration without effects
- REACH: Regulation CE 1907/2006
- RID: Regulation for the international carriage of dangerous goods by train
- TLV: threshold Value
- TLV CEILING: Concentration that must not be exceeded during any time of the working exposure.
- TWA STEL: short term exposure limit
- TWA: weighted average exposure limit
- VOC: volatile organic compound
- VPVB: very persistent and very bioaccumulative according to the REACH
- WGK: hazard class aquatic (Germany).

#### GENERAL BIBLIOGRAPHY:

- 1. European Parliament Regulation (EC) 1907/2006 (REACH)
- 2. European Parliament Regulation (EC) 1272/2008 (CLP)
- 3. European Parliament Regulation (EC) 790/2009 (I Atp. CLP)
- 4. European Parliament Regulation (EC) 2015/830
- 5. European Parliament Regulation (EC) 286/2011 (II Atp. CLP)
- 6. European Parliament Regulation (EC) 618/2012 (III Atp. CLP)
- 7. European Parliament Regulation (UE) 487/2013 (IV Atp. CLP) 8. European Parliament Regulation (EC) 944/2013 (V Atp. CLP)
- 9. European Parliament Regulation (EC) 605/2014 (VI Atp. CLP)
- The Merck Index. 10th Edition



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Handling Chemical Safety

- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition

- ECHA Agency Website

Note for user:

The information contained in this sheet is based on knowledge achieved on the date of the last version. User must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, the user must, under his own responsibility, comply with the current health and safety laws and regulations.. We accept no liability for any unauthorised or improper use.

Provide adequate training for personnel assigned to use chemical products.

Changes made since the previous revision.

Changes have been made to the following sections:

01 / 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.

Current Rev. Date STATUS AND REASON OF REVISIONS
1 0 25.06.2019 Change of Notified Body (CE0051)