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Version 002

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name HiBiScrub®
Pure substance/mixture Mixture

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

Recommended Use Antimicrobial preparation for pre- and post operative hand disinfection and general antisepsis

Uses advised against No information available

1.3 Details of the supplier of the safety data sheet

Company Information Regent Medical Ltd.
2 Omega Drive
Irlam
Manchester
M44 5BJ
United Kingdom

Telephone +44 (0) 161 777 2600

Fax +44 (0) 161 777 2601

For further information, please contact:

E-mail Address Antiseptics.UK@molnlycke.com

1.4 Emergency telephone number

Emergency telephone +44 (0) 161 621 2121 (9am-5pm)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Xi;R36 N;R50/53

2.2 Label elements



Xi - Irritant

N - Dangerous for the environment

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R-phrase(s)

R36 - Irritating to eyes

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S-phrase(s)

S 2 - Keep out of the reach of children

S25 - Avoid contact with eyes

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S29 - Do not empty into drains

S46 - If swallowed, seek medical advice immediately and show this container or label

S61 - Avoid release to the environment. Refer to special instructions/ Safety data sheets

2.3 Other information

May cause skin irritation. May cause respiratory tract irritation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures.

Chemical Name	EC-No	CAS-No	Weight %	Classification (67/548)	Classification (Reg. 1272/2008)	REACH Registration Number
Chlorhexidine digluconate	242-354-0	18472-51-0	1-5	Xi; R41 N; R50/53	Eye Dam. 1 (H318), Acute Aquatic 1 (H400), Chronic Aquatic 1 (H410) GHS05, GHS09 (Dgr)	no data available
Glycerol	200-289-5	56-81-5	1-5	-	-	-
Propan-2-ol	200-661-7	67-63-0	1-5	F; R11 Xi; R36 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225) GHS02, GHS07 (Dgr)	no data available
Lauryldimethylamine oxide	268-938-5	68155-09-9	1-5	Xi; R41, R38 R52	Skin Irrit.2; (H315) Eye Dam.1; (H318)	no data available

For the full text of R-phrases and H-Statements see Section 16

SECTION 4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms develop obtain medical attention.

Skin contact Wash off immediately with plenty of water. If symptoms develop obtain medical attention.

Ingestion Wash out mouth with water and give 100 - 200 ml of water to drink. Do NOT induce vomiting. If symptoms develop obtain medical attention.

Inhalation Remove to fresh air and keep at a rest position. Administer oxygen if breathing is difficult and you are trained. If symptoms develop obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Main Symptoms Irritating to eyes. May cause skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which shall not be used for safety reasons

None.

5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapours. Carbon oxides; Nitrogen oxides (NOx); Hydrogen chloride. Dangerous for the environment. Runoff may pollute waterways.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with the skin and the eyes. Avoid breathing vapours or mists. Ensure adequate ventilation. Use personal protective equipment.

6.2 Environmental precautions

Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Dike to collect large liquid spills. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Flush spillage area with plenty of water.

6.4 Reference to other sections

See Section 8. Waste Disposal Methods: See also section 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Do not breathe vapours or spray mist. Wash thoroughly after handling. Use only in well-ventilated areas.

Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep away from direct sunlight. Keep at a temperature not exceeding 25 °C.

Store separately from incompatible materials: Oxidising agents; Alkalis.

7.3 Specific end uses

Antimicrobial preparation for pre- and post operative hand disinfection and general antisepsis.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

Chemical Name	Propan-2-ol 67-63-0
The United Kingdom	STEL: 500 ppm STEL: 1250 mg/m ³ TWA: 400 ppm TWA: 999 mg/m ³
France	VLCT: 400 ppm VLCT: 980 mg/m ³
Spain	VLA-EC: 400 ppm VLA-EC: 1000 mg/m ³ VLA-ED: 200 ppm VLA-ED: 500 mg/m ³
Germany	MAK: 200 ppm MAK: 500 mg/m ³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m ³ TWA: 200 ppm TWA: 500 mg/m ³
Portugal	STEL: 400 ppm TWA: 200 ppm
Finland	TWA: 200 ppm TWA: 500 mg/m ³ STEL: 250 ppm STEL: 620 mg/m ³
Denmark	TWA: 200 ppm TWA: 490 mg/m ³
Austria	STEL 800 ppm STEL 2000 mg/m ³ MAK: 200 ppm MAK: 500 mg/m ³
Switzerland	STEL: 400 ppm STEL: 1000 mg/m ³ MAK: 200 ppm MAK: 500 mg/m ³
Poland	NDSch: 1200 mg/m ³ NDS: 900 mg/m ³ Skin
Norway	TWA: 100 ppm TWA: 245 mg/m ³ STEL: 150 ppm STEL: 306.25 mg/m ³
Ireland	TWA: 200 ppm STEL: 400 ppm Skin
Chemical Name	Glycerol 56-81-5
The United Kingdom	STEL: 30 mg/m ³ TWA: 10 mg/m ³
France	VME: 10 mg/m ³
Spain	VLA-ED: 10 mg/m ³
Germany	MAK: 50 mg/m ³ Ceiling / Peak: 100 mg/m ³
Portugal	TWA: 10 mg/m ³
Finland	TWA: 20 mg/m ³
Switzerland	STEL: 100 mg/m ³ MAK: 50 mg/m ³
Poland	NDS: 10 mg/m ³
Ireland	TWA: 10 mg/m ³

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2 Exposure controls

Appropriate engineering controls Provide adequate ventilation, including appropriate local extraction, to ensure that occupational exposure limits are not exceeded.

Personal protective equipment**Eye Protection**

Safety glasses with side-shields (EN 166).

Hand Protection

Protective gloves (EN 374).

Skin and body protection

Wear suitable protective clothing; Protective shoes or boots.

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment; (BS EN 14387:2004+A1).

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Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls Avoid release to the environment. The product should not be allowed to enter drains, water courses or the soil.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Viscous
Odour	Citrus
Colour	Red
Odour Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Methods</u>
pH	5.2 - 6.2	
Melting/freezing point		No information available
Freezing Point		No information available
Boiling point/boiling range		No information available
Flash Point		No information available
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Flammability Limits in Air		No information available
upper flammability limit		
lower flammability limit		
Vapour pressure		No information available
Vapour density		No information available
Relative density		No information available
Water solubility		Completely miscible
Solubility in other solvents		No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity, kinematic		No information available
Viscosity, dynamic		No information available

Explosive properties	Not explosive
Oxidizing Properties	Not applicable

9.2 Other information

Softening point	No information available
Molecular Weight	No information available
VOC Content(%)	No information available
Density	No information available
Bulk Density	No information available

SECTION 10. STABILITY AND REACTIVITY**10.1 Reactivity**

Stable under normal conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None under normal processing.

10.4 Conditions to Avoid

High temperatures. Ignition sources.

10.5 Incompatible Materials

Oxidizing agents. Alkalis.

10.6 Hazardous Decomposition Products

Thermal decomposition can lead to release of irritating and toxic gases and vapours: Carbon oxides. Nitrogen oxides (NOx). Hydrogen chloride.

SECTION 11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Chlorhexidine digluconate	> 2 g/kg (Rat)	> 5000 mg/kg (Rabbit)	
Glycerol	12600 mg/kg (Rat)	>21900 mg/kg (Rat)	-
Propan-2-ol	4396 mg/kg (Rat)	12800 mg/kg (Rat) 12870 mg/kg (Rabbit)	72.6 mg/L (Rat) 4 h

Skin corrosion/irritation Repeated or prolonged contact may cause irritation.

Serious Damage/Eye Irritation Irritating to eyes.

Respiratory or Skin Sensitisation Not sensitising.

Mutagenicity Not classified.

Carcinogenicity Not classified.

Chemical Name	European Union	IARC
Propan-2-ol		Group 3

Reproductive toxicity Not classified.

STOT - Single exposure Not classified.

STOT - Repeated exposure Not classified.

Aspiration hazard Not classified.

Other information No information available.

SECTION 12. ECOLOGICAL INFORMATION**12.1 Toxicity**

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Propan-2-ol	>1000: 72 h Desmodesmus subspicatus mg/L EC50 >1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through >1400000: 96 h Lepomis macrochirus µg/L LC50	13299: 48 h Daphnia magna mg/L EC50
Glycerol		>1000: 96h mg/l LC50	>500: 24 h Daphnia magna mg/L EC50
Chlorhexidine digluconate	ErC10: 0.03 mg/l 72 h scenedesmus subspicatus	LC50: 2.08 mg/l 96h Brachydanio rerio	EC50: 0.087 mg/l 48h Daphnia magna NOEC: 0.0206 mg/l 21d Daphnia magna

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Chemical Name	log Pow
Propan-2-ol	0.05
Glycerol	0

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects

Chemical Name	Toxicity to microorganisms
Chlorhexidine digluconate	COD: 219000 mg/l BOD5: 0 mg/l

SECTION 13. DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Waste from residues / unused products**

Dispose of in accordance with local regulations.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

	ADR/RID/ADN	ICAO/IATA	IMDG / IMO
14.1 UN Number	3082	3082	3082
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (chlorhexidine digluconate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (chlorhexidine digluconate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (chlorhexidine digluconate)
14.3 Transport hazard class(es)	9	9	9
14.4 Packing Group	III	III	III
14.5 Environmental Hazards	Marine pollutant	Marine pollutant	Marine pollutant
14.6 Special precautions for users		Avoid release to the environment	
14.7 Transport in bulk according to MARPOL 73/78 and the IBC Code			

SECTION 15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Classification according to EU Directives 67/548/EEC or 1999/45/EC. This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

Chemical Safety Assessment has not been carried out.

SECTION 16. OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

R11 - Highly flammable

R36 - Irritating to eyes

R38 - Irritating to skin

R41 - Risk of serious damage to eyes

R52 - Harmful to aquatic organisms

R67 - Vapours may cause drowsiness and dizziness

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Full text of H-Statements referred to under sections 2 and 3

H225 - Highly flammable liquid and vapour

H315 - Causes skin irritation

H318 - Causes serious eye damage

H319 - Causes serious eye irritation

H336 - May cause drowsiness or dizziness

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

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Revision Note This SDS was updated according to regulation (EU) No 453/2010. (M)SDS sections updated: 2, 3, 14, 16.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Disclaimer

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