

Safety Data Sheet

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 06/06/2013 Revision date 08/07/2020
Supersedes 13/03/2017

1.1. Product identifier

Product form	: Mixture
Product name	: Chlorhexidine digluconate solution 20%
Product code	: 467405
Product group	: Blend

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Industrial/Professional use spec	: Industrial For professional use only
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals

No additional information available

Supplier

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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation, Category 1	H318
Hazardous to the aquatic environment — Acute Hazard, Category 1	H400
Hazardous to the aquatic environment — Chronic Hazard,	H410

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Category 1

Full text of H statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)

:



GHS05



GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H318 - Causes serious eye damage.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P273 - Avoid release to the environment.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P310 - Immediately call a POISON CENTER/doctor.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Purified water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	80	Not classified	Not classified
Chlorhexidine digluconate	(CAS-No.) 18472-51-0 (EC-No.) 242-354-0	20	Xi; R36 N; R50/53	Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Get medical advice and attention if you feel unwell. Allow affected person to breathe fresh air Allow the victim to rest.
First-aid measures after skin contact	: Rinse with plenty of water.
First-aid measures after eye contact	: Rinse immediately with plenty of water Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth Obtain emergency medical attention.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not combustible.
Explosion hazard	: Heating may cause an explosion.
Hazardous decomposition products in case of fire	: In case of fire hazardous gases / vapors may form: flue gas.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with substance.

6.1.1. For non-emergency personnel

Protective equipment	: Use the personal protective equipment as indicated in chapter 8.
Emergency procedures	: Evacuate unnecessary personnel.

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6.1.2. For emergency responders

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Absorb with liquid binding material: Sand, silica, acid binder, saw dust. Clean contaminated surfaces with an excess of water.

6.4. Reference to other sections

Reference to other sections (8, 13). See Heading 8. Exposure controls and personal protection.

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

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilitiesStorage conditions : Store in dry, well-ventilated area
Keep container closed when not in use
Protect from light.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Avoid all unnecessary exposure. Safety glasses. Dust/aerosol mask with filter type P1. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

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Respiratory protection:

Dustmask with filtertype P1



Other information:

Wash hands before break and at end of works. Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: clear.
Odour	: odourless.
Odour threshold	: No data available
pH	: 5.5 - 7
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 105 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.065 g/cm ³ 20 ° C
Solubility	: Highly soluble in water. Ethanol: 21 g/l Acetone: 44 g/l
Log Pow	: < 4
Viscosity, kinematic	: 1.47 cSt
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Open flame

Direct sunlight

Extremely high or low temperatures.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

release of (highly) toxic gases/vapours.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Not classified

Chlorhexidine digluconate solution 20%

LD50 oral rat 2000 mg/kg

Skin corrosion/irritation : Not classified
pH: 5.5 - 7Additional information : Irritating to respiratory system and skin
Based on available data, the classification criteria are not metSerious eye damage/irritation : Causes serious eye damage.
pH: 5.5 - 7

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

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Viscosity, kinematic	1.47 mm ² /s
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Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : Very toxic to aquatic life with long lasting effects.

Chlorhexidine digluconate solution 20%

LC50 fish 1	2.08 mg/l
EC50 Daphnia 1	0.087 mg/l
EC50 72h algae (l)	0.081 mg/l

12.2. Persistence and degradability

Chlorhexidine digluconate solution 20%

Biodegradation	70 %
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12.3. Bioaccumulative potential

Chlorhexidine digluconate solution 20%

Log Pow	< 4
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : disinfectants. Toxic to aquatic organisms. Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of this material and its container to hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADN / ADR / IATA / IMDG / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
3082	3082	3082	3082	3082
14.2. UN proper shipping name				
ENVIRONMENTAL	ENVIRONMENTAL	Environmentally	ENVIRONMENTAL	ENVIRONMENTAL

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ADR	IMDG	IATA	ADN	RID
LY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	LY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	hazardous substance, liquid, n.o.s.	LY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	LY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es)				
9	9	9	9	9
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

14.6. Special precautions for user

. Overland transport

Classification code (ADR)	: M6
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Special packing provisions (ADR)	: PP1
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1, TP29
Tank code (ADR)	: LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V12
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	:
Tunnel restriction code (ADR)	: -
EAC code	: .3Z

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- Transport by sea

Special provisions (IMDG)	: 274, 335, 969
Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP01, P001
Special packing provisions (IMDG)	: PP1
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP2, TP29
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y964
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 964
PCA max net quantity (IATA)	: 450L
CAO packing instructions (IATA)	: 964
CAO max net quantity (IATA)	: 450L
Special provisions (IATA)	: A97, A158, A197
ERG code (IATA)	: 9L

- Inland waterway transport

Classification code (ADN)	: M6
Special provisions (ADN)	: 274, 335, 375, 601
Limited quantities (ADN)	: 5 L
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T
Equipment required (ADN)	: PP
Number of blue cones/lights (ADN)	: 0

- Rail transport

Classification code (RID)	: M6
Special provisions (RID)	: 274, 335, 375, 601
Limited quantities (RID)	: 5L
Excepted quantities (RID)	: E1
Packing instructions (RID)	: P001, IBC03, LP01, R001
Special packing provisions (RID)	: PP1
Mixed packing provisions (RID)	: MP19
Portable tank and bulk container instructions (RID)	: T4
Portable tank and bulk container special provisions (RID)	: TP1, TP29

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Tank codes for RID tanks (RID) : LGBV
Transport category (RID) : 3
Special provisions for carriage – Packages (RID) : W12
Special provisions for carriage - Loading, unloading and handling (RID) : CW13, CW31
Colis express (express parcels) (RID) : CE8
Hazard identification number (RID) : 90

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	H318 for H319
8.2	Appropriate engineering controls	Added	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. None.

Full text of R-, H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.