

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

1.1. Product identifier

Product form : Mixture
Trade name : CHX-Plus™

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Enhanced 2% chlorhexidine gluconate solution that kills biofilm bacteria in root canals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier:

Please provide the European importer, only representative, downstream user or distributor contact details:

Supplier name:

Street address/P.O. Box

Country ID/Postal code

Telephone number

Email address (this can be a general email for the competent person responsible for the SDS)

Manufacturer:

Inter-Med, Inc. / Vista Dental Products

2200 South Street

Racine, WI 53404

T: (877)-418-4782

1.4. Emergency telephone number

Emergency number : 800-424-9300 (North America) / +1 (703) 527-3887 (International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 2 H319

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P264 - Wash hands thoroughly after handling.
P280 - Wear eye protection, protective gloves.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards not contributing to the classification

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Chlorhexidine digluconate	(CAS-No.) 18472-51-0 (EC-No.) 242-354-0	2	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Give artificial respiration if necessary. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash with water and soap as a precaution. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation persists.
First-aid measures after ingestion	: Rinse mouth. Do not induce vomiting. Get medical advice/attention.

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

Symptoms/effects after inhalation	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: May cause slight irritation to the skin.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Carbon dioxide. Foam.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: On combustion, forms: carbon oxides (CO and CO ₂). Nitrogen oxides. Ammonia. Hydrogen chloride.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Evacuate personnel to a safe area.
Protective equipment for firefighters	: 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

6.1.1. For non-emergency personnel

Protective equipment	: For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: No additional risk management measures required.

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. In case of inadequate ventilation wear respiratory protection.
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6.2. Environmental precautions

No special environmental precautions required.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Dispose of this material and its container at hazardous or special waste collection point.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep cool.
Incompatible materials	: Strong oxidizing agents. Strong alkalis. Mineral acids.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

1-Decanol (112-30-1)		
Bulgaria	Local name	n-децилов алкохол
Bulgaria	OEL TWA (mg/m ³)	10 mg/m ³
Bulgaria	Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр.73 от 4 септември 2018 г.)
Latvia	Local name	n-Decilspirts (1-dekanols)
Latvia	OEL TWA (mg/m ³)	10 mg/m ³
Latvia	Regulatory reference	Ministru kabineta 2007.gada 15.maija noteikumiem Nr.325
Lithuania	Local name	n-decilo alkoholis
Lithuania	IPRV (mg/m ³)	10 mg/m ³
Lithuania	Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Romania	Local name	1-Decanol
Romania	OEL TWA (mg/m ³)	100 mg/m ³
Romania	OEL TWA (ppm)	15 ppm
Romania	OEL STEL (mg/m ³)	200 mg/m ³
Romania	OEL STEL (ppm)	30 ppm
Romania	Regulatory reference	Hotărârea nr. 584/2018

1-Octanol (111-87-5)		
Bulgaria	Local name	n-октилов алкохол (октанол)
Bulgaria	OEL TWA (mg/m ³)	10 mg/m ³
Bulgaria	Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр.73 от 4 септември 2018 г.)
Germany	TRGS 900 Local name	Octan-1-ol (Langkettige Alkohole)
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	106 mg/m ³ (sum of vapor and aerosol)
Germany	TRGS 900 Occupational exposure limit value (ppm)	20 ppm (sum of vapor and aerosol)
Germany	TRGS 900 Limitation of exposure peaks	1(I)
Germany	TRGS 900 Remark	AGS;11
Germany	TRGS 900 Regulatory reference	TRGS900
Latvia	Local name	Oktilspirts (oktanols)
Latvia	OEL TWA (mg/m ³)	10 mg/m ³
Latvia	Regulatory reference	Ministru kabineta 2007.gada 15.maija noteikumiem Nr.325
Lithuania	Local name	n-oktilo alkoholis

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1-Octanol (111-87-5)		
Lithuania	IPRV (mg/m ³)	10 mg/m ³
Lithuania	Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Romania	Local name	1-Octanol/Alcool octilic
Romania	OEL TWA (mg/m ³)	150 mg/m ³
Romania	OEL TWA (ppm)	28 ppm
Romania	OEL STEL (mg/m ³)	250 mg/m ³
Romania	OEL STEL (ppm)	47 ppm
Romania	Regulatory reference	Hotărârea nr. 584/2018

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Hand protection:

Impermeable protective gloves

Eye protection:

Safety glasses with side shields. DIN EN 166. Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Colour	: Blue.
Odour	: Odourless.
Odour threshold	: No data available
pH	: 5 - 6
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: 100 °C (212 °F)
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: 17.535 mm Hg
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.01
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong oxidizing agents. Strong alkalis. Mineral acids.

10.6. Hazardous decomposition products

On combustion, forms: carbon oxides (CO and CO₂). Ammonia. Hydrogen chloride. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Chlorhexidine digluconate (18472-51-0)

LD50 oral rat	2 g/kg
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Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 5 - 6

Serious eye damage/irritation : Causes serious eye irritation.
pH: 5 - 6

Respiratory or skin sensitisation : Not classified (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 (Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : This material has not been tested for environmental effects.

Acute aquatic toxicity : Not classified (Based on available data, the classification criteria are not met)

Chronic aquatic toxicity : Not classified (Based on available data, the classification criteria are not met)

Chlorhexidine digluconate (18472-51-0)

LC50 fish 1	2.08 mg/l
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ErC50 (algae)	>= 0.038 mg/l
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ErC50 (other aquatic plants)	>= 0.49 mg/l
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NOEC (acute)	>= 0.0075 mg/l
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NOEC (chronic)	sediment
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
 Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Substance(s) are not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 3, Highly hazardous to water (Classification according to AwSV, Annex 1)

WGK remark : Most stringent classification due to insufficient data

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

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SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Sources of Key data : according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Eye Irrit. 2	H319	Calculation method
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SDS EU (REACH Annex II)

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