DENTO VIRACTIS 53 READY TO USE - FS CLP1307

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SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name: DENTO VIRACTIS 53 READY TO USE

Product code: FS CLP1307.

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

Disinfection in a medical and hospital environment.

1.3. Details of the supplier of the safety data sheet

Registered company name: HYGITECH.

Address: 109 bis Avenue Charles de Gaulle.92200. Neuilly sur Seine. FRANCE.

Telephone: +33 (0)1 48 01 32 89. Fax: +33 (0)1 48 01 32 80.

export@hygitech.fr

1.4. Emergency telephone number: +33 (0)1 45 42 59 59.

Association/Organisation: INRS / ORFILA http://www.centres-antipoison.net.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Skin sensitisation, Category 1A (Skin Sens. 1A, H317).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

The mixture is a disinfectant product for medical device use.

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms:



GHS07

Signal Word : WARNING

Product identifiers:

605-022-00-X GLUTARAL

Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements - General :

P102 Keep out of reach of children.

 $Precaution ary\ statements\ -\ Prevention:$

P261 Avoid breathing vapours.

P280 Wear protective gloves/protective clothing/eye protection.

Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of water and soap.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

 $Precautionary\ statements\ -\ Disposal\ :$

P501 Dispose of contents/container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition:

(EC) 1272/2008	Note	%
GHS06, GHS05, GHS09, GHS08	[1]	$0 \le x \% < 2.5$
Dgr		
Acute Tox. 3, H301		
Skin Corr. 1B, H314		
Skin Sens. 1A, H317		
Acute Tox. 2, H330		
Resp. Sens. 1B, H334		
STOT SE 3, H335		
Aquatic Chronic 2, H411		
Aquatic Acute 1, H400		
M Acute = 1		
EUH:071		
GHS07, GHS05, GHS09		0 <= x % < 2.5
Dgr		
Acute Tox. 4, H302		
Skin Corr. 1B, H314		
Eye Dam. 1, H318		
Aquatic Chronic 2, H411		
Aquatic Acute 1, H400		
M Acute = 10		
	GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Acute Tox. 2, H330 Resp. Sens. 1B, H334 STOT SE 3, H335 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1 EUH:071 GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 2, H411 Aquatic Acute 1, H400	GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Acute Tox. 2, H330 Resp. Sens. 1B, H334 STOT SE 3, H335 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1 EUH:071 GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 2, H411 Aquatic Acute 1, H400

Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of splashes or contact with skin :

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

In the event of an allergic reaction, seek medical attention.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing:

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Seek medical attention immediately, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

Suitable methods of extinction

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed:

- carbon monoxide (CO)
- carbon dioxide (CO2)

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5.3. Advice for firefighters

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7: HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

Individuals with a history of skin sensitisation should not, under any circumstance, handle this mixture.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention:

Prevent access by unauthorised personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep out of reach of children.

Store away from frost.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
111-30-8			0,05 ppm	SEN; A4	

- Germany - AGW (BAuA - TRGS 900, 21/06/2010):

CAS	VME:	VME:	Excess	Notes
111-30-8		0,05 ppm		2(I)
		0,2 mg/m3		

⁻ France (INRS - ED984:2012):

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CAS	VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP No:
111-30-8	0.1	0.4	0.2	0.8	-	65.66

- UK / WEL (Workplace exposure limits, EH40/2005, 2007):

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
111-30-8	0,05 ppm	0,05 ppm		Sen	
	0,2 mg/m3	0,2 mg/m3			

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles in accordance with standard EN166.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question: other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended:

- Natural latex
- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- PVC (polyvinyl chloride)
- Butyl Rubber (Isobutylene-isoprene copolymer)

Recommended properties:

- Impervious gloves in accordance with standard EN374

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing:

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact.

In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Physical state : Fluid liquid.
Color Colourless
Odour : Fragrant

$Important\ health,\ safety\ and\ environmental\ information$

pH: 5.00 . Neutral.

Boiling point/boiling range : Not relevant.
Flash point interval : Not relevant.
Vapour pressure (50°C) : Not relevant.

Density: = 1
Water solubility: Dilutable.
Melting point/melting range: Not relevant.
Self-ignition temperature: Not relevant.
Decomposition point/decomposition range: Not relevant.

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9.2. Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid:

- frost

10.5. Incompatible materials

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO2)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause an allergic reaction by skin contact.

11.1.1. Substances

No toxicological data available for the substances.

Acute toxicity:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5) Oral route: LD50 = 329 mg/kg

Species: Rat

OECD Guideline 401 (Acute Oral Toxicity)

Dermal route: LD50 > 1000 mg/kgSpecies: Rabbit

Skin corrosion/skin irritation:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Corrosivity: Causes severe skin burns.

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Effect observed: Overall irritation score

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Respiratory or skin sensitisation:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Buehler Test: Non-sensitiser.

Species: Guinea pig Other guideline

Germ cell mutagenicity:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Mutagenesis (in vivo): Negative.

Species: Rat

OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)

Mutagenesis (in vitro): Negative. SAFETY DATA SHEET (REGULATION (EC) n° 1907/2006 - REACH)

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Species: Bacteria

OECD Guideline 471 (Bacterial Reverse Mutation Assay)

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Ames test (in vitro): Negative.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Fish toxicity: LC50 = 0.5 mg/l

Factor M = 1

Species : Brachydanio rerio Duration of exposure : 96 h

Crustacean toxicity: EC50 = 0.03 mg/l

Species : Daphnia magna Duration of exposure : 48 h

NOEC = 0.021 mg/l Species : Daphnia magna Duration of exposure : 21 days

OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity: ECr50 = 0.06 mg/l

Species: Selenastrum capricornutum

Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

 $Surfactants\ in\ this\ preparation\ comply\ with\ the\ standards\ of\ biodegradability\ as\ defined\ in\ Regulation\ (EC)\ No\ 648/2004\ on\ detergents.$

The data proving this statement shall be made available to the competent authorities of the Member States and shall be supplied to them at their express request or at the request of the detergent manufacturer.

12.2.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5) Biodegradability: Rapidly degradable.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Do not discharge into waterways.

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Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14: TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number

-

14.2. UN proper shipping name

4

14.3. Transport hazard class(es)

14.4. Packing group

-

14.5. Environmental hazards

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14.6. Special precautions for user

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SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2016/1179. (ATP 9)

- Container information:

No data available.

- Particular provisions:

No data available.

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704)

NFPA 704, Labelling: Health=2 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3:

H301 Toxic if swallowed. H302 Harmful if swallowed. SAFETY DATA SHEET (REGULATION (EC) n° 1907/2006 - REACH)

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H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H330 Fatal if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. H334 H335 May cause respiratory irritation. H400 Very toxic to aquatic life. Toxic to aquatic life with long lasting effects. H411 EUH071 Corrosive to the respiratory tract.

Abbreviations:

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods. IATA : International Air Transport Association. ICAO : International Civil Aviation Organisation

RID: Regulations concerning the International carriage of Dangerous goods by rail.

WGK: Wassergefahrdungsklasse (Water Hazard Class).

GHS07: Exclamation mark

PBT: Persistent, bioaccumulable and toxic. vPvB: Very persistent, very bioaccumulable. SVHC: Substances of very high concern.