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HYGITECH

# **DENTO VIRACTIS 57 - FS CLP1528**

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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 57

Product code: FS CLP1528.

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

Disinfectant detergent for immersion treatment of rotary instruments.

# 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.

Flammable liquid, Category 3 (Flam. Liq. 3, H226).

Acute oral toxicity, Category 3 (Acute Tox. 3, H301).

Skin corrosion, Category 1 (Skin Corr. 1, H314).

Serious eye damage, Category 1 (Eye Dam. 1, H318).

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

# 2.2. Label elements

Detergent mixture (see section 15).

The mixture is a disinfectant cleaner product for medical device use.

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

Hazard pictograms:







GHS06

GHS02

GHS05

Signal Word:

DANGER

Product identifiers:

POTASSIUM HYDROXIDE EC 215-181-3 ETHOXYLATED ALCOHOL C10 CAS 26183-52-8

Hazard statements:

Flammable liquid and vapour. H226

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

Precautionary statements - General:

Keep out of reach of children.

Precautionary statements - Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed. P260 Do not breathe vapours.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response:

P301 + P310IF SWALLOWED: Immediately call a POISON CENTER or a doctor.

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P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or

shower.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

Precautionary statements - Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

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

# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2. Mixtures

#### Composition:

| Composition.            |                     |      |                    |
|-------------------------|---------------------|------|--------------------|
| Identification          | (EC) 1272/2008      | Note | %                  |
| CAS: 64-17-5            | GHS07, GHS02        | [1]  | 10 <= x % < 25     |
| EC: 200-578-6           | Dgr                 |      |                    |
| REACH: 01-2119457610-43 | Flam. Liq. 2, H225  |      |                    |
|                         | Eye Irrit. 2, H319  |      |                    |
| ETHYL ALCOHOL           |                     |      |                    |
| CAS: 1310-58-3          | GHS07, GHS05        | [1]  | $0 \le x \% < 2.5$ |
| EC: 215-181-3           | Dgr                 |      |                    |
| REACH: 01-2119487136-33 | Met. Corr. 1, H290  |      |                    |
|                         | Acute Tox. 4, H302  |      |                    |
| POTASSIUM HYDROXIDE     | Skin Corr. 1A, H314 |      |                    |
| CAS: 26183-52-8         | GHS07, GHS05        |      | $0 \le x \% < 2.5$ |
|                         | Dgr                 |      |                    |
| ETHOXYLATED ALCOHOL C10 | Acute Tox. 4, H302  |      |                    |
|                         | Eye Dam. 1, H318    |      |                    |

(Full text of H-phrases: see section 16)

### 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 eyes:

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

### In the event of splashes or contact with skin:

Remove any soiled or splashed clothing immediately.

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

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, administer activated medical charcoal and consult a doctor.

Keep the person exposed at rest. Do not force vomiting.

Seek medical attention immediately, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

If swallowed accidentally, do not allow to drink, do not induce vomiting and transfer to hospital immediately by ambulance. Show the label to the doctor.

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#### 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**

Flammable.

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

### 5.1. Extinguishing media

Keep packages near the fire cool, to prevent pressurised containers from bursting.

## Suitable methods of extinction

In the event of a fire, use:

- sprayed water or water mist
- water with AFFF (Aqueous Film Forming Foam) additive
- halon
- foam
- multipurpose ABC powder
- BC powder
- carbon dioxide (CO2)

Prevent the effluent of fire-fighting measures from entering drains or waterways.

#### Unsuitable methods of extinction

In the event of a fire, do not use:

- water jet

#### 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)

#### 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

Because of the organic solvents contained in the mixture, eliminate sources of ignition and ventilate the area.

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

Neutralise with an acidic decontaminant.

If the ground is contaminated, once the product has been recovered by sponging with an inert and non-combustible absorbent material, wash the contaminated area in plenty of water.

Clean preferably with a detergent, do not use solvents.

### 6.4. Reference to other sections

No data available.

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#### **SECTION 7: HANDLING AND STORAGE**

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

#### 7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Ensure that there is adequate ventilation, especially in confined areas.

Emergency showers and eye wash stations will be required in facilities where the mixture is handled constantly.

# Fire prevention:

Handle in well-ventilated areas.

Vapours are heavier than air. They can spread along the ground and form mixtures that are explosive with air.

Prevent the formation of flammable or explosive concentrations in air and avoid vapor concentrations higher than the occupational exposure limits.

Prevent the accumulation of electrostatic charges with connections to earth.

The mixture can become electrostatically charged: always earth during decanting operations. Wear antistatic shoes and clothing and floors should be electrically non-conductive.

Use the mixture in premises free of naked flames or other sources of ignition and ensure that electrical equipment is suitably protected.

Keep packages tightly closed and away from sources of heat, sparks and naked flames.

Do not use tools which may produce sparks. Do not smoke.

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.

Avoid exposure - obtain special instructions before use.

Packages which have been opened must be reclosed carefully and stored in an upright position.

# 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.

Keep the container tightly closed in a dry, well-ventilated place.

Keep away from food and drink, including those for animals.

Keep away from all sources of ignition - do not smoke.

Keep well away from all sources of ignition, heat and direct sunlight.

Avoid accumulation of electrostatic charges.

The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area.

Store at a temperature between 5°C and 35°C.

# **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:

- France (INRS - ED984:2016):

| CAS       | VME-ppm: | VME-mg/m3: | VLE-ppm: | VLE-mg/m3: | Notes: | TMP No: |
|-----------|----------|------------|----------|------------|--------|---------|
| 64-17-5   | 1000     | 1900       | 5000     | 9500       | -      | 84      |
| 1310-58-3 | -        | -          | -        | 2          | -      | -       |

- UK / WEL (Workplace exposure limits, EH40/2005, 2011) :

| CAS     | TWA:                   | STEL:   | Ceiling: | Definition: | Criteria: |
|---------|------------------------|---------|----------|-------------|-----------|
| 64-17-5 | 1000 ppm               | - ppm   |          |             |           |
|         | 1920 mg/m <sup>3</sup> | - mg/m³ |          |             |           |

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| 1310-58-3 | - ppm               | - ppm                |  |  |
|-----------|---------------------|----------------------|--|--|
|           | - mg/m <sup>3</sup> | $ 2 \text{ mg/m}^3 $ |  |  |

## 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 with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

#### - Hand protection

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)

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.

Wear suitable protective clothing, in particular overalls and boots. These items must be kept in good condition and cleaned after use.

Suitable type of protective boots :

In the event of minor spatter, wear protective boots or half-boots against chemical risks in accordance with standard EN13832-2.

In the event of prolonged contact, wear boots or half-boots with liquid-chemical-resistant and waterproof soles and uppers in accordance with standard EN13832-3.

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:

Density:

Physical state : Fluid liquid.

Color: Colorless to pale yellow

Odor: Fragrant

Important health, safety and environmental information

H: 13.50 +/- 0.5.

Strongly basic.

0.99 +/- 0.01 g/mL

Boiling point/boiling range:

Flash Point:

Vapour pressure (50°C):

Not relevant.

Not relevant.

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Water solubility: Dilutable.

Viscosity:  $v < 7 \text{ mm2/s } (40^{\circ}\text{C})$ 

Melting point/melting range :Not relevant.Self-ignition temperature :Not relevant.Decomposition point/decomposition range :Not relevant.

### 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

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

#### 10.4. Conditions to avoid

Any apparatus likely to produce a flame or to have a metallic surface at high temperature (burners, electric arcs, furnaces etc.) must not be allowed on the premises.

#### Avoid:

- accumulation of electrostatic charges.
- heating
- heat
- flames and hot surfaces
- frost

## 10.5. Incompatible materials

Aluminum.

# 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

Toxic if swallowed.

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure for up to three minutes.

Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars.

# 11.1.1. Substances

No toxicological data available for the substances.

# 11.1.2. Mixture

# Acute toxicity:

Oral route: Highly toxic if swallowed.

Species : Rat

50 < LD50 <= 200 mg/kg

OECD Guideline 423 (Acute Oral toxicityAcute Toxic Class Method)

#### Skin corrosion/skin irritation:

Corrosive classification is based on an extreme pH value.

#### **Respiratory or skin sensitisation:**

Guinea Pig Maximisation Test (GMPT): Non-sensitiser.

Species : Guinea pig Other guideline

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# Monograph(s) from the IARC (International Agency for Research on Cancer):

CAS 64-17-5: IARC Group 1: The agent is carcinogenic to humans.

### **SECTION 12: ECOLOGICAL INFORMATION**

#### 12.1. Toxicity

#### 12.1.1. Substances

ETHOXYLATED ALCOHOL C10 (CAS: 26183-52-8)

Crustacean toxicity: EC50 = 15 mg/l

Species : Daphnia sp. Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

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Algae toxicity: ECr50 = 19.6 mg/l

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

#### **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

ETHOXYLATED ALCOHOL C10 (CAS: 26183-52-8)

Biodegradability: no degradability data is available, the substance is considered as not degrading

auickly.

#### 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.

### 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**

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2017 - IMDG 2016 - ICAO/IATA 2017).

#### 14.1. UN number

2924

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# 14.2. UN proper shipping name

UN2924=FLAMMABLE LIQUID, CORROSIVE, N.O.S.

(ethyl alcohol, potassium hydroxide)

### 14.3. Transport hazard class(es)

- Classification:





3+8

# 14.4. Packing group

Ш

# 14.5. Environmental hazards

#### 14.6. Special precautions for user

| ADR/RID | Class | Code | Pack gr. | Label | Ident. | LQ  | Provis. | EQ | Cat. | Tunnel |
|---------|-------|------|----------|-------|--------|-----|---------|----|------|--------|
|         | 3     | FC   | III      | 3+8   | 38     | 5 L | 274     | E1 | 3    | D/E    |
|         |       |      |          |       |        |     |         |    |      |        |

| IMDG | Class | 2°Label | Pack gr. | LQ  | EMS     | Provis. | EQ |
|------|-------|---------|----------|-----|---------|---------|----|
|      | 3     | 8       | III      | 5 L | F-E,S-C | 223 274 | E1 |

| IATA | Class | 2°Label | Pack gr. | Passager | Passager | Cargo | Cargo | note | EQ |
|------|-------|---------|----------|----------|----------|-------|-------|------|----|
|      | 3     | 8       | III      | 354      | 5 L      | 365   | 60 L  | A3   | E1 |
|      | 3     | 8       | III      | Y342     | 1 L      | -     | -     | A3   | E1 |

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

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

No data available.

# **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. 2018/669 (ATP 11)

# - Container information:

No data available.

# - Particular provisions:

No data available.

# - Labelling for detergents (EC Regulation No. 648/2004,907/2006):

- less than 5 % : nonionic surfactants

- disinfectants
- perfumes
- allergenic fragrances :

linalool

d-limonene

#### 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.

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# Wording of the phrases mentioned in section 3:

H225 Highly flammable liquid and vapour.

H290 May be corrosive to metals. H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.
H319 Causes serious eye irritation.

#### **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).

GHS02 : Flame GHS05 : Corrosion

GHS06: Skull and crossbones

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