

## DENTO-VIRACTIS 52 INSTRU +

### 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 52 INSTRU +  
Product code : 10449DV

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

Neutral disinfectant detergent for soaking medical devices..

##### 1.3. Details of the supplier of the safety data sheet

Registered company name : CADENCE.  
Address : 2 Bis , Chemin du Loup, 93290 TREMBLAY EN FRANCE.FRANCE.  
Telephone : +33 1 45 91 31 82. Fax : +33 1 48 65 67 23  
infot@cfpm-medical.fr

##### 1.4. Emergency telephone number : +33 1 40 44 30 00

Association/Organisation: INRS Paris

#### SECTION 2 : HAZARDS IDENTIFICATION

##### 2.1. Classification of the substance or mixture

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

Eye irritation, Category 2 (Eye Irrit. 2, H319).

Hazardous to the aquatic environment - Category 2 (Aquatic Chronic 2, H411).

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

##### 2.2. Label elements

Detergent mixture (see section 15)

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

Hazard pictograms:



GHS07



GHS09

Signal Word :

WARNING

Hazard statements :

H319

Causes serious eye irritation.

H411

Toxic to aquatic life with long lasting effects.

Precautionary statements - Response:

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

##### 2.3. Other hazards

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

The mixture satisfies 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

#### 3.1. Mixtures

##### Composition :

Identification	(CE) 1272/2008	Nota	%
CAS: 94667-33-1 REACH: 01-2119950327-36-000  N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		2.5 <= x % < 10
CAS: 5964-35-2 EC: 227-743-5  TETRAPOTASSIUM ETHYLENEDIAMINETETRAACETATE	GHS07, GHS05 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Acute Tox. 4, H332		2.5 <= x % < 10
INDEX: 607-429-00-8 CAS: 60-00-4 EC: 200-449-4  EDETIC ACID (EDTA)	GHS07 Wng Eye Irrit. 2, H319		0 <= x % < 2.5

### 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. If there is any redness, pain or visual impairment, consult an ophthalmologist

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

Wash with plenty of water

##### In the event of swallowing :

Seek medical attention, 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

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

#### 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 (CO<sub>2</sub>)

#### 5.3. Advice for firefighters

Use self-contained breathing apparatus and full protective gear.

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### 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

Absorb spilled material with non-combustible absorbent materials. Wash the contaminated area in plenty of water.

#### 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.

#### 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. Avoid eye contact with this mixture.

##### 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

Keep the container tightly closed.

##### Storage

Store in a frost-free place.

##### Packaging

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

#### 7.3. Specific end use(s)

Professional use only.

Refer to section 1 for the product use.

### SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

No data available.

#### 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.

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### Eye / face protection

Avoid contact with eyes.

Before handling, wear safety goggles with protective sides accordance with standard EN166.

### Hand protection

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

### Body protection

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

Aspect :	Fluid liquid
Odour:	No Data available
Odour threshold:	No Data available

#### Important information concerning Health, security and environment :

pH :	7,2
Melting point/freezing point :	No Data available
Initial boiling point and boiling range:	No Data available
Flash point :	Not applicable.
Evaporating rate :	No Data available
Flammability (solide, gaz) :	No Data available
Lower and upper flammable or explosive limits:	No Data available
Vapour pressure (50°C) :	Less than 110 kPa (1.10 bar).
Vapour density:	No Data available
Relative density :	> 1
Solubility :	Soluble in water
The n-octyl alcohol/water partition coefficient	No Data available
Auto-ignition temperature:	No Data available
Decomposition temperature:	No Data available
Viscosity :	No Data available
Explosive properties	No Data available

### 9.2. Other information

No data available.

## SECTION 10 : STABILITY AND REACTIVITY

### 10.1. Reactivity

No dangerous reactions if handling and storage conditions are respected.

### 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

- frost

### 10.5. Incompatible materials

### 10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO<sub>2</sub>)

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### SECTION 11 : TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

##### 11.2. Substances

##### Acute toxicity:

TETRAPOTASSIUM ETHYLENEDIAMINETETRAACETATE (CAS: 5964-35-2)  
Inhalation route (Dusts/mist): 1 < CL50 <= 5 mg/l

PROPIONATE DE N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM (CAS: 94667-33-1)  
Oral route: DL50 = 1157 mg/kg  
Species : Rat

##### Skin corrosion/skin irritation :

PROPIONATE DE N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM (CAS: 94667-33-1)  
Corrosivity: Causes severe skin burns.  
Species : Rabbit

##### 11.1.1. Mixture

##### Serious damage to eyes/eye irritation :

Causes serious eye irritation.

Corneal haze:	2 <= Average score < 3 and effects totally reversible within 21 days of observation Species : Rabbit
Iritis :	1 <= Average score <= 1.5 and effects totally reversible within 21 days of observation Species : Rabbit
Conjunctival redness :	Average score >= 2.5 and effects totally reversible within 21 days of observation Species : Rabbit
Conjunctival oedema:	Average score >= 2 and effects totally reversible within 21 days of observation Species : Rabbit OCDE Guideline 405 (Irritating effect / corrosive on the eyes) and NF EN ISO 10993-10

### SECTION 12 : ECOLOGICAL INFORMATION

Toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

#### 12.1. Toxicity

##### 12.1.1. Substances

PROPIONATE DE N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM (CAS: 94667-33-1)	
Fish toxicity:	CL50 = 0.78 mg/l Species : Danio rerio Exposure time : 96 h OCDE Guideline 203 (fish, acute toxicity test)
Crustaceans toxicity:	CE50 = 0.07 mg/l Species : Daphnia magna Exposure time : 48 h OCDE Guideline 202 (Daphnia sp., immediat immobilization test)
Algae toxicity :	CEr50 = 0.15 mg/l Species : Desmodesmus subspicatus Exposure time : 72 h OCDE Guideline 201 (Algae, growth inhibition test)

##### 12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

##### 12.2.1. Persistence and degradability

##### 12.2.2. Substances

PROPIONATE DE N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM (CAS: 94667-33-1)  
Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

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### 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 2013 - IMDG 2012 - ICAO/IATA 2014).

### 14.1. UN Number

3082

### 14.2. UN proper shipping name

UN3082=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(propionate de n,n-didecyl-n-methyl-poly(oxyethyl)ammonium)

### 14.3. Transport hazard classz

- Classification :



9

### 14.4. Packing group

III

### 14.5. Environmental hazard

- Environmentally hazardous material:



### 14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis	EQ	Cat.	Tunnel
	9	M6	III	9	90	5 L	274 335 375 601	E1	3	E

Not subject to this regulation if Q ≤ 5L/5kg (ADR 3.3.1- DS 375)

IMDG	Class	2°Label	Pack gr.	QL	FS	Dispo.	EQ
	9	-	III	5 L	F-A,S-F	274 335 969	E1

Not subject to this regulation if Q ≤ 5L/5kg (IMDG 2.10.2.7- DS 969)

IATA	Class	2°Label	Pack gr.	Passenger	Passenger	Cargo	Cargo	note	EQ
	9	-	III	964	450 L	964	450 L	A97 A158 A197	E1

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	9	-	III	Y964	30 kg G	-	-	A97 A158 A197	E1
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Not subject to this regulation if Q <= 5L/5kg (IATA 4.4.4- DS A197)

15 For hazardous goods limited quantities, refer to ADR and IMDG chapter 3.4 and IATA part 2.7.

16 For quantities except of hazardous goods, refer to ADR and IMDG chapter 3.5 and IATA part 2.6.

### 16.1. 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 n°1272/2008 amended by EU Regulation No 487/2013
- EU Regulation (CE) n°1272/2008 amended by EU Regulation No 758/2013
- EU Regulation (CE) n°1272/2008 amended by EU Regulation No 944/2013
- EU Regulation (CE) n°1272/2008 amended by EU Regulation No 605/2014

##### - Container information:

- No data available.

##### - Particular provisions :

- No data available.

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

- 5 % ou plus, mais moins de 15 % de : agents de surface cationiques
- moins de 5 % de : agents de surface non ioniques
- 5 % ou plus, mais moins de 15 % de : EDTA et sels
- désinfectants

### 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 :

H302	Harmful if swallowed..
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

### 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.

GHS05 : Corrosion

GHS09 : Environment