

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

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

1.1. Product identifier

Product name : DENTO-VIRACTIS 56 INSTRUPOWDER

Product code : 010436DV.

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

Powdered enzymatic disinfectant detergent for manual soaking of 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 54 67 23.

info@cfpm-medical.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 corrosion, Category 1B (Skin Corr. 1B, H314).

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

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, 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 :



GHS09

GHS05

Signal Word :

DANGER

Product identifiers :

EC 287-089-1

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES

Hazard statements :

H314

Causes severe skin burns and eye damage.

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P280

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

Precautionary statements - Response :

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.

P310

Immediately call a POISON CENTER/doctor/...

2.3. Other hazards

In use, may form flammable/explosive dust-air mixture.

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>

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

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

The mixture does not contain substances > = 0.1% with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	Classification (EC) 1272/2008	Note	%
INDEX: 011-005-00-2 CAS: 497-19-8 EC: 207-838-8 REACH: 01-2119485498-19-xxxx SODIUM CARBONATE	GHS07 Wng Eye Irrit. 2, H319		25 <= x % < 50
CAS: 85409-22-9 EC: 287-089-1 COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 1		2.5 <= x % < 10
CAS: 7173-51-5 EC: 230-525-2 DIDECYLDIMETHYLAMMONIUM CHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 2, H411		2.5 <= x % < 10
CAS: 64-02-8 EC: 200-573-9 TETRASODIUM ETHYLENE DIAMINE TETRAACETATE	GHS07, GHS05, GHS08 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318 Acute Tox. 4, H332 STOT RE 2, H373		0 <= x % < 2.5
INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 PROPAN-2-OL	GHS02, GHS07 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	[1]	0 <= x % < 2.5

Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 7173-51-5 EC: 230-525-2 DIDECYLDIMETHYLAMMONIUM CHLORIDE		oral: ATE = 411 mg/kg BW

Information on ingredients :

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

[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.

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

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

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.

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

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

No data available.

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

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

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.

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

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.

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV**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 - Outils 65 / 2021-1849, 2021-1763, decree of 09/12/2021) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
67-63-0	-	-	400	980	-	84

- UK / WEL (Workplace exposure limits, EH40/2005, Fourth Edition 2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
67-63-0	400 ppm 999 mg/m ³	500 ppm 1250 mg/m ³			

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

TETRASODIUM ETHYLENE DIAMINE TETRAACETATE (CAS: 64-02-8)

Final use:Exposure method:
Potential health effects:
DNEL :**Workers.**Inhalation.
Short term local effects.
2.5 mg of substance/m3Exposure method:
Potential health effects:
DNEL :Inhalation.
Long term local effects.
2.5 mg of substance/m3**Final use:**Exposure method:
Potential health effects:
DNEL :**Consumers.**Ingestion.
Long term systemic effects.
25 mg/kg body weight/dayExposure method:
Potential health effects:
DNEL :Inhalation.
Short term local effects.
1.5 mg of substance/m3Exposure method:
Potential health effects:
DNEL :Inhalation.
Long term local effects.
1.5 mg of substance/m3**Predicted no effect concentration (PNEC):**

TETRASODIUM ETHYLENE DIAMINE TETRAACETATE (CAS: 64-02-8)

Environmental compartment: Soil.
PNEC : 0.72 mg/kgEnvironmental compartment: Fresh water.
PNEC : 2.2 mg/m3Environmental compartment: Sea water.
PNEC : 0.22 mg/lEnvironmental compartment: Intermittent waste water.
PNEC : 1.2 mg/lEnvironmental compartment: Waste water treatment plant.
PNEC : 43 mg/l

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES (CAS: 85409-22-9)

Environmental compartment: Fresh water.

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

PNEC :	0.000342 mg/l
Environmental compartment: PNEC :	Sea water. 0.0342 ppm
Environmental compartment: PNEC :	Fresh water sediment. 5.61 mg/kg
Environmental compartment: PNEC :	Marine sediment. 0.561 mg/kg
Environmental compartment: PNEC :	Waste water treatment plant. 0.273 mg/l

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.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

Prescription glasses are not considered as protection.

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 EN ISO 374-1.

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.

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

These clothes shall be chosen to ensure there is no inflammation or irritation of the skin at the neck and wrist by contact with the powder

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1/A1 to prevent skin contact.

Wear suitable protective clothing and, in particular, an apron and boots. These items of clothing shall be maintained in good condition and cleaned after use.

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.

- Respiratory protection

Avoid inhaling dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149/A1.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****Physical state**

Physical state : Powder or dust.

Colour

Unspecified

Odour

Odour threshold : Not stated.

Freezing point

Freezing point / Freezing range : Not stated.

Boiling point or initial boiling point and boiling range

Boiling point/boiling range : Not relevant.

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV**Flammability**

Flammability (solid, gas) : Not stated.

Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) : Not stated.

Explosive properties, upper explosivity limit (%) : Not stated.

Flash point

Flash point interval : Not relevant.

Auto-ignition temperature

Self-ignition temperature : Not relevant.

Decomposition temperature

Decomposition point/decomposition range : Not relevant.

pH

pH (aqueous solution) : 10.5

pH : Not stated.

Slightly basic.

Kinematic viscosity

Viscosity : Not stated.

Solubility

Water solubility : Soluble.

Fat solubility : Not stated.

Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water : Not stated.

Vapour pressure

Vapour pressure (50°C) : Below 110 kPa (1.10 bar).

Density and/or relative density

Density : Not stated.

Relative vapour density

Vapour density : Not stated.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

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 :

- formation of dusts
- frost

Dusts can form an explosive mixture with air.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

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

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV**SECTION 11 : TOXICOLOGICAL INFORMATION****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

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**Acute toxicity :**

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Oral route : LD50 = 411 mg/kg bodyweight/day

Dermal route : LD50 > 2000 mg/kg bodyweight/day

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES (CAS: 85409-22-9)

Oral route : 300 < LD50 <= 2000 mg/kg

Species : Rat

Skin corrosion/skin irritation :

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES (CAS: 85409-22-9)

Corrosivity : Causes severe skin burns.

Species : Rabbit

11.1.2. Mixture

No toxicological data available for the mixture.

11.2. Information on other hazards**SECTION 12 : ECOLOGICAL INFORMATION**

Very 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**

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES (CAS: 85409-22-9)

Fish toxicity : 0.01 < LC50 <= 0.1 mg/l

Factor M = 10

0.001 < NOEC <= 0.01 mg/l

Factor M = 1

Species : Pimephales promelas

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Fish toxicity : LC50 = 0.49 mg/l

Species : Brachydanio rerio

Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity :

EC50 = 0.03 mg/l

Species : Daphnia magna

Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

NOEC = 0.021 mg/l

Species : Daphnia magna

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity :

ECr50 = 0.06 mg/l

Species : Selenastrum capricornutum

Duration of exposure : 48 h

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

OECD Guideline 201 (Alga, Growth Inhibition Test)

NOEC = 0.013 mg/l

Species : Pseudokirchnerella subcapitata

OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Biodegradability : Rapidly degradable.

COMPOSÉS DE L'ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-14 DIMÉTHYLES, CHLORURES (CAS: 85409-22-9)

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. Endocrine disrupting properties

No data available.

12.7. 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, 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 2021 - IMDG 2020 [40-20] - ICAO/IATA 2022 [63]).

14.1. UN number or ID number

1759

14.2. UN proper shipping name

UN1759=CORROSIVE SOLID, N.O.S.

(composés de l'ion ammonium quaternaire, benzylalkyl en c12-14 diméthyles, chlorures)

14.3. Transport hazard class(es)

- Classification :



8

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV**14.4. Packing group**

III

14.5. Environmental hazards

- Environmentally hazardous material :

**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C10	III	8	80	5 kg	274	E1	3	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	8	-	III	5 kg	F-A. S-B	223 274	E1	Category A	-

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	8	-	III	860	25 kg	864	100 kg	A3 A803	E1
	8	-	III	Y845	5 kg	-	-	A3 A803	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.

Marine pollutant (IMDG 3.1.2.9):(composés de l'ion ammonium quaternaire, benzylalkyl en c12-14 diméthyles, chlorures)

14.7. Maritime transport in bulk according to IMO instruments

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. 2022/692 (ATP 18)

Container information:The mixture does not contain any substance restricted under Annex XVII of Regulation (EC) No. 1907/2006 (REACH):
<https://echa.europa.eu/substances-restricted-under-reach>.**Particular provisions :**

No data available.

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

- 30 % and more : phosphates
- 5 % or over but less than 15 % : cationic surfactants
- 5 % or over but less than 15 % : non-ionic surfactants
- less than 5 % : EDTA and salts thereof
- enzymes
- disinfectants
- perfumes

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 :

- | | |
|------|--|
| H225 | Highly flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |

DENTO-VIRACTIS 56 INSTRUPOWDER - 010436DV

H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure .
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.
LC50 : The concentration of a test substance resulting in 50% lethality in a given period.
EC50 : The effective concentration of substance that causes 50% of the maximum response.
ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.
NOEC : The concentration with no observed effect.
REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.
ATE : Acute Toxicity Estimate
BW : Body Weight
DNEL : Derived No-Effect Level
PNEC : Predicted No-Effect Concentration
STEL : Short-term exposure limit
TWA : Time Weighted Averages
TMP : French Occupational Illness table
TLV : Threshold Limit Value (exposure)
AEV : Average Exposure Value.
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
PBT: Persistent, bioaccumulable and toxic.
vPvB : Very persistent, very bioaccumulable.
SVHC : Substances of very high concern.