

Version: 1

Version date: 17/07/2023

Language: EN

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU)

No. 2020/878)

Safety Data Sheet

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

1.1 Product identifier

Trade name/designation : DENTOCLIC FDV Ivoires.

Article No (user) : FVOV5-1/FVOA5-1.2/FVOJ5-1.3/FVOR5-1.4.

UFI : XY1E3YPXJ10K6EAS

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

Uses advised against : No data available.

1.3 Details of the supplier of the safety data sheet

Supplier : Name: ITENA CLINICAL

Street: Central Parc, Bat B - 97 Allée de la Louve

Postal code/City: 93420 Villepinte

Country: France

Telephone: +33(0)1 45 91 30 06 **E-mail**: Contact@itena-clinical.com

1.4 Emergency Telephone Number

WORLD:

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Hazards identification:

H315 Skin Irrit. 2 Causes skin irritation.

H317 Skin Sens. 1 May cause an allergic skin reaction.

H318 Eye Dam. 1 Causes serious eye damage

H334 Resp. Sens. 1 May cause allergy or asthma symptoms or breathing difficulties if

inhaled.

H350 Carc. 1B May cause cancer.

H412 Aquatic Chronic 3 Harmful to aquatic life with long lasting effects

2.2 Label elements

Label elements according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Labelling

Hazard pictograms



Signal word

Hazard Statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

DENTOCLIC FDV Ivoires

H318	Causes	serious	eye	damage
------	--------	---------	-----	--------

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H350 May cause cancer.

H412 Harmful to aquatic life with long lasting effects

Precautionary Statements - Prevention

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash ... thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

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

Precautionary Statements - Response

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

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

P338 do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P310 Immediately call a POISON CENTER/doctor/...
P321 Specific treatment (see ... on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention.

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

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...

Precautionary Statements - Storage

P405 Store locked up.

Precautionary Statements - Disposal

P501 Dispose of contents/container to ...

Contains

glass, oxide, chemicals, 4,4'-Isopropylidenediphenol, oligomeric reaction products with I-chloro-2,3-epoxypropane, 1,2,3,6-tetrahydromethylphthalic anhydride, benzyldimethylamine

2.3 Other hazards

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

3 Composition/information on ingredients

3.2 Mixtures

In accordance with the product knowledge, no nanomaterials have been identified.

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

Sub	ostance	Concentration (%)	Specific concentration limits		Classification
glass, oxide, cl	hemicals				
CAS N° EC N° IDX N°	65997-17-3 266-046-0	C= 80.0%		H350	Carc. 1B
Registration number	01- 2119488048- 29-XXXX,01- 2119990048- 30-XXXX				



4,4'-Isopropylidenediphenol, oligomeric reaction products with I-chloro-2,3-epoxypropane					
CAS N°	25068-38-6	C= 8.986%	Eye Irrit. 2; H319:	H315	Skin Irrit. 2
EC N°	500-033-5		C ≥ 5 %	H317	Skin Sens. 1
IDX N°	603-074-00-8		Skin Irrit. 2; H315:	H319	Eye Irrit. 2
Registration	01-		C ≥ 5 %	H411	Aquatic Chronic 2
number	2119456619-				
	26-XXXX				
1,2,3,6-tetrahy	dromethylphthalic	anhydride			
CAS N°	26590-20-5	C= 7.62%		H317	Skin Sens. 1
EC N°	247-830-1			H318	Eye Dam. 1
IDX N°	607-240-00-0			H334	Resp. Sens. 1
Registration					
number					
Zirkonium oxid	le Yttrium stab				
CAS N°	114168-16-0	C= 2.412%		H315	Skin Irrit. 2
EC N°	806-108-1			H319	Eye Irrit. 2
IDX N°				H335	STOT SE 3 H335
Registration					
number					
benzyldimethylamine					
CAS N°	103-83-3	C= 0.14%		H226	Flam. Liq. 3
EC N°	203-149-1	1 - 1/ 1		H302	Acute Tox. 4 ORAL
IDX N°	612-074-00-7			H312	Acute Tox. 4 DERMAL
Registration	01-			H314	Skin Corr. 1B
number	2119529232-	V.		H332	Acute Tox. 4 INHALATION
	48-XXXX		3	H412	Aquatic Chronic 3

Remark

Text phrases and H- EUH-: see section 16.

4 First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Remove victim out of the danger area.

Keep affected person warm, still and covered.

Do not leave affected person unattended.

Following inhalation:

Remove person to fresh air and keep comfortable for breathing.

If the victim is unconscious but breathing normally, place her in recovery position and seek medical advice.

In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

No resuscitation mouth-to-mouth or mouth-to-nose. Ambu use a mask or respirator.

If breathing is irregular or stopped, administer artificial respiration.

Following skin contact:

Take off contaminated clothing.

In case of skin irritation, consult a physician.

Remove contaminated, saturated clothing immediately.

After contact with skin, wash immediately with plenty of water and soap.

In case of skin reactions, consult a physician.

Following eye contact:

Remove contact lenses, if present and easy to do. Continue rinsing.

Protect unharmed eye.



DENTOCLIC FDV Ivoires

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion:

Never give anything by mouth to an unconscious person or a person with cramps.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

Self-protection of the first aider:

First aider: Pay attention to self-protection!.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Foam.

Extinguishing powder.

Carbon dioxide (CO2).

Sand.

Unsuitable extinguishing media:

Strong water jet.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Do not inhale vapors and fumes.

Co-ordinate fire-fighting measures to the fire surroundings.

Move undamaged containers from immediate hazard area if it can be done safely.

Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen.

Use water spray jet to protect personnel and to cool endangered containers.

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment.

Remove persons to safety.

Use appropriate respiratory protection.

Provide adequate ventilation.

6.2 Environmental precautions



DENTOCLIC FDV Ivoires

Ensure that waste is collected and contained.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Avoid release to the environment.

Cover drains.

Ensure all waste water is collected and treated via a waste water treatment plant.

Do not allow to enter into soil/subsoil.

Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

6.3 Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal.

Collect in closed and suitable containers for disposal.

Clean contaminated objects and areas thoroughly observing environmental regulations.

Ventilate affected area.

6.4 Reference to other sections

Safe handling: see section 7.

Disposal: see section 13.

Personal protection equipment: see section 8.

Additional information

Not available

7 Handling and Storage

7.1 Precautions for safe handling

Avoid exposure - obtain special instructions before use.

PROTECTIVE MEASURES:

Avoid contact with skin, eyes and clothes.

Wear personal protective clothing (see section 8).

Sewers and ducts must be protected against the entry of the product.

Do not put any product-impregnated cleaning rags into your trouser pockets.

Use only in well-ventilated areas.

If local exhaust ventilation is not possible or not enough, the entire work area must be ventilated by technical means.

Provide adequate ventilation as well as local exhaustion at critical locations.

Only allow access to authorised staff.

Provide for retaining containers, eg. floor pan without outflow.

Dust should be exhausted directly at the point of origin.

Avoid breathing dust.

Advices on general occupational hygiene:

Wash hands before breaks and after work.

Wash contaminated clothing before reuse.

Street clothing should be stored seperately from work clothing.

Remove contaminated, saturated clothing immediately.

Work in well ventilated zones or use proper respiratory protection.

In the immediate working surroundings there must be:

Provide eye shower and label its location conspicuously.

7.2 Conditions for safe storage, including any incompatibilities

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

Keep container in upright position in order to prevent leakage.

Requirements for storage rooms and vessels:





Ensure adequate ventilation of the storage area.

Store locked up.

Use isolated drainage to prevent discharge to soil.

Advice on joint storage:

Keep away from food, drink and animal feedingstuffs.

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

Not available

Biological limit values:

Not available

Exposure limits at intended use:

Not available

Remark:

Not available

8.2 Exposure controls

Appropriate engineering controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment. Provide adequate ventilation as well as local exhaustion at critical locations.

Individual protection measures, such as personal protective equipment:





Eye/face protection

: Suitable eye protection:

Wear eye protection equipment.

Recommended eye protection articles:

Eye glasses with side protection.



Skin protection

Hand protection:

Suitable gloves type:

Wear protective gloves.

Suitable material:

NBR (nitrile rubber).

Butyl caoutchouc (butyl rubber).

Additional hand protection measures:

Do not wear gloves near machines and rotating tools.

Use gloves only once.

Remark:

When handling with chemical substances, protective gloves must be worn

with the CE-label including the four control digits.

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of

hazardous substances.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the

supplier of these gloves.

Breakthrough times and swelling properties of the material must be taken

into consideration. **Body protection**:

Suitable protective clothing:

Lab coat.

Respiratory protection

Respiratory protection necessary at:

If technical exhaust or ventilation measures are not possible or insufficient,

respiratory protection must be worn.

Suitable respiratory protection apparatus:

Wear respiratory protection.

Remark:

The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained

breathing apparatus must be used.

Observe the wear time limits as specified by the manufacturer.

Use only respiratory protection equipment with CE-symbol including four

digit test number.

Environmental exposure controls:

Not available

Consumer exposure controls:

Not available

Additional information

Not available

9 Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Physical state : Solid

Colour : Not available
Odour : Not available
pH : Not applicable
Melting point/freezing point : Not available
Initial boiling point and boiling range : Not applicable
Flash point : Not applicable
Flammability : Not available



Upper/lower flammability or explosive

limits

Vapour pressure Not available **Vapour density** Not applicable Relative density Not available Solubility(ies) Not available Partition coefficient n-octanol/water (log : Not applicable

Not applicable

Auto-ignition temperature Not applicable **Decomposition temperature** Not available **Dynamic viscosity** Not available **Kinematic viscosity** Not available **Oxidising properties** Not available **Solubility in other Solvents** Not available **Particle characteristics** Not available

9.2 Other safety information

Information concerning to the classes of physical hazards

Not available

Other security characteristics

Not available

10 Stability and Reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is stable when stored at normal ambient temperatures.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

Additional information

Not available

$oldsymbol{1}oldsymbol{1}$ Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity:



The product is not classified.

Substances:

Not available

Acute dermal toxicity:

The product is not classified.

Substances:

Not available

Acute inhalation toxicity:

The product is not classified.

Substances:

Not available

Skin corrosion/irritation:

The product is not classified.

Substances:

Not available

Serious eye damage/irritation:

The product is classified Eye Dam. 1 according to the referenced regulation.

Causes serious eye damage.

Substances:

Not available

Skin sensitisation:

The product is classified Skin Sens. 1 according to the referenced regulation.

May cause an allergic skin reaction.

Substances:

Not available

Specific target organ toxicity (repeated exposure):

The product is not classified.

Substances:

Not available

Specific target organ toxicity (single exposure):

The product is not classified.

Substances:

Not available

Carcinogenicity:

The product is classified Carc. 1B according to the referenced regulation.

May cause cancer.

Substances:

Not available

Reproductive toxicity:

The product is not classified.

Substances:

Not available

Germ cell mutagenicity:

The product is not classified.

Substances:

Not available

Sensitisation to the respiratory tract:

The product is not classified.

Substances:

Not available

Additional information:

Not available

11.2 Information on other hazards

DENTOCLIC FDV Ivoires

Endocrine disrupting properties:

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

12 Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Substances:

Not available

12.2 Persistence and degradability

The product has not been tested.

Substances:

Not available

12.3 Bioaccumulative potential

The product has not been tested.

Substances:

Not available

12.4 Mobility in soil

The product has not been tested.

Substances:

Not available

12.5 Results of PBT and vPvB assessment

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

12.6 Endocrine disrupting properties

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

12.7 Other adverse effects

Not available

Additional ecotoxicological information

Not available

13 Disposal considerations

13.1 Waste treatment methods

Product/Packaging disposal:

Waste codes/waste designations according to EWC/AVV:

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Waste treatment options:

Appropriate disposal/Product:

Waste requiring special supervision.

DENTOCLIC FDV Ivoires

Dispose of waste according to applicable legislation.

Delivery to an approved waste disposal company.

Appropriate disposal/Package:

Non-contaminated packages must be recycled or disposed of.

Contaminated packing must be completely emptied and can be reused after proper cleaning.

Packing which cannot be properly cleaned must be disposed of.

Handle contaminated packages in the same way as the substance itself.

Dispose of waste according to applicable legislation.

Remark:

For recycling, contact manufacturer.

Collect the waste separately.

Consult the appropriate authorities about waste disposal.

Do not mix with other wastes.

The waste is to be kept separate from other types of waste until its disposal.

Concerning the waste it has to be checked, whether a transport authorisation is required.

Additional information

Not available

14 Transport information

14.1 UN number

Not available

14.2 UN proper shipping name

Not available

14.3 Transport hazard class(es)

Not available

14.4 Packing group

Not available

14.5 Environmental hazards

Not available

14.6 Special precautions for user

Not available

14.7 Bulk shipping according to IMO instruments

Not available

Additional information

Not available

15 Regulatory information

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

This SDS has been established in accordance with REACH regulation, including its amendments: REACH Regulation (EC) No





1907/2006.

This SDS has been established in accordance with CLP regulation, including its amendments: CLP Regulation EC No. 1272/2008.

EU legislation:

REACH: Annex XVII (Restrictions):

Substance	CAS	EC
benzyldimethylamine	103-83-3	203-149-1

National regulations:

U.S. - NY - RTK:

Substance	CAS	EC
benzyldimethylamine	103-83-3	203-149-1

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Additional information

Not available

16 Other information

Indication of changes

Not applicable (first edition of the MSDS).

Abbreviations and acronyms

CAS: Chemical Abstract Service Number.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods Code.

DPD Dangerous Preparation Directive. UN number: United Nations number. No EC: European Commission Number.

ADN/ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways.

ADR/RID: European Agreement concerning the International Carriage of Dangerous Goods by Road/Regulations concerning the international carriage of dangerous goods by rail.

CLP: Classification, labeling and packaging.

VPvB: very persistent and very bioaccumulative substances.

Key literature references and sources for data

No data available.

Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008. Complies with ATP 18, Regulation (EU) n°2022/692.

Relevant R-, H- and EUH-phrases (Number and full text)

H226	Flam. Liq. 3	Flammable liquid and vapour.
H302	Acute Tox. 4 ORAL	Harmful if swallowed
H312	Acute Tox. 4 DERMAL	Harmful in contact with skin.
H314	Skin Corr. 1B	Causes severe skin burns and eye damage



H315	Skin Irrit. 2	Causes skin irritation.
H317	Skin Sens. 1	May cause an allergic skin reaction.
H318	Eye Dam. 1	Causes serious eye damage
H319	Eye Irrit. 2	Causes serious eye irritation
H332	Acute Tox. 4 INHALATION	Harmful if inhaled.
H334	Resp. Sens. 1	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	STOT SE 3 H335	May cause respiratory irritation
H350	Carc. 1B	May cause cancer.
H411	Aquatic Chronic 2	Toxic to aquatic life with long lasting effects.
H412	Aquatic Chronic 3	Harmful to aquatic life with long lasting effects

Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

Additional information

Creation date: 17/07/2023 Version date: 17/07/2023 Printing date: 02/04/2024

The information given in this Safety Data Sheet is based on our present knowledge and on European and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.