

according to Regulation (EC) No 1907/2006

# **VITA ADIVA OXY-PREVENT**

Revision date: 15.08.2023

Product code: 308

Page 1 of 7

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

## 1.1. Product identifier

VITA ADIVA OXY-PREVENT

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

## Use of the substance/mixture

Auxilliary for manufacture of dental prothesis

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

<u> </u>	5. Details of the supplier of the sale	ty data sheet	
	Company name:	VITA Zahnfabrik H.Rauter GmbH & Co.KG	
	Street:	Spitalgasse 3	
	Place:	D-79713 Bad Säckingen	
	Post-office box:	1338	
		D-79704 Bad Säckingen	
	Telephone:	+49(0)7761-562-0	Telefax: +49(0)7761-562-299
	E-mail:	info@vita-zahnfabrik.com	
	Contact person:	regulatory affairs	
	E-mail:	info@vita-zahnfabrik.com	
	Internet:	www.vita-zahnfabrik.com	
	Responsible Department:	Regulatory Affairs	

## **Further Information**

medical device

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

#### Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

## 2.2. Label elements

## 2.3. Other hazards

No information available.

## **SECTION 3: Composition/information on ingredients**

# 3.2. Mixtures

Chemical characterization

Substance, organic

## Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

# **SECTION 4: First aid measures**

# 4.1. Description of first aid measures

# After inhalation

Provide fresh air.

# After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

## After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.



according to Regulation (EC) No 1907/2006

# **VITA ADIVA OXY-PREVENT**

Revision date: 15.08.2023

Product code: 308

Page 2 of 7

# After ingestion

Rinse mouth immediately and drink plenty of water.

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

No information available.

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

Treat symptomatically.

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

## Suitable extinguishing media

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

## 5.2. Special hazards arising from the substance or mixture

Non-flammable. Vapours can form explosive mixtures with air.

## 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

## Additional information

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.

## **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

#### **General advice**

Use personal protection equipment.

## 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

# 6.3. Methods and material for containment and cleaning up

## Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

## 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

## **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

## Advice on safe handling

No special measures are necessary.

## Advice on protection against fire and explosion

No special fire protection measures are necessary.

## Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

## 7.2. Conditions for safe storage, including any incompatibilities

## Requirements for storage rooms and vessels

Keep container tightly closed.



according to Regulation (EC) No 1907/2006

# **VITA ADIVA OXY-PREVENT**

Revision date: 15.08.2023

Product code: 308

Page 3 of 7

# Hints on joint storage

No special measures are necessary.

# 7.3. Specific end use(s)

Auxilliary for manufacture of dental prothesis

# **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

## **Occupational exposure limits**

CAS No	Substance	ppm	mg/m³	fib/cm³	Category	Origin
56-81-5	(OLD) Glycerol, mist	-	10		TWA (8 h)	

## 8.2. Exposure controls

#### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear eye/face protection.

## Hand protection

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. NBR (Nitrile rubber)

## Skin protection

Use of protective clothing.

## **Respiratory protection**

In case of inadequate ventilation wear respiratory protection. Open windows to ensure natural ventilation.

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:		
Odour:	characteristic	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and		192 °C
boiling range:		
Flammability:		not applicable
		not applicable
Flash point:		180 °C
Decomposition temperature:		not determined
pH-Value:		not determined
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density:		not determined
Relative vapour density:		not determined
.2. Other information		

## Information with regard to physical hazard classes

<u>9.</u>



according to Regulation (EC) No 1907/2006

#### **VITA ADIVA OXY-PREVENT** Revision date: 15.08.2023 Product code: 308 Page 4 of 7 Explosive properties The product is not: Explosive. Self-ignition temperature not applicable Solid: not applicable Gas: Oxidizing properties Not oxidisina. Other safety characteristics Evaporation rate: not determined not determined Solid content:

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

## 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

## 10.3. Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4. Conditions to avoid

none

# 10.5. Incompatible materials

No information available.

## 10.6. Hazardous decomposition products

No known hazardous decomposition products.

# **SECTION 11: Toxicological information**

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

## Acute toxicity

Based on available data, the classification criteria are not met.

## ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

## Irritation and corrosivity

Based on available data, the classification criteria are not met.

#### Sensitising effects

Based on available data, the classification criteria are not met.

### Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

#### STOT-single exposure

Based on available data, the classification criteria are not met.

## STOT-repeated exposure

Based on available data, the classification criteria are not met.

## Aspiration hazard

Based on available data, the classification criteria are not met.

## Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].



according to Regulation (EC) No 1907/2006

# **VITA ADIVA OXY-PREVENT**

Revision date: 15.08.2023

Product code: 308

Page 5 of 7

## **SECTION 12: Ecological information**

## 12.1. Toxicity

The product is not: Ecotoxic.

## 12.2. Persistence and degradability

The product has not been tested.

## 12.3. Bioaccumulative potential

The product has not been tested.

## 12.4. Mobility in soil

The product has not been tested.

## 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII. The product has not been tested.

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

## 12.7. Other adverse effects

No information available.

# **Further information**

Avoid release to the environment.

#### **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

## **Disposal recommendations**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

## Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

## **SECTION 14: Transport information**

### Land transport (ADR/RID)

14.1. UN number or ID number: 14.2. UN proper shipping name: 14.3. Transport hazard class(es): 14.4. Packing group: Inland waterways transport (ADN) 14.1. UN number or ID number: 14.2. UN proper shipping name: 14.3. Transport hazard class(es): 14.4. Packing group: Marine transport (IMDG) 14.1. UN number or ID number: 14.2. UN proper shipping name: 14.3. Transport hazard class(es): 14.4. Packing group: Air transport (ICAO-TI/IATA-DGR) 14.1. UN number or ID number:

<u>14.2. UN proper shipping name:</u> 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.

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according to Regulation (EC) No 1907/2006

	VITA ADIVA OXY-PREVENT	
Revision date: 15.08.2023	Product code: 308	Page 6 of 7
14.4. Packing group:	No dangerous good in sense of this transport regulation.	
14.5. Environmental hazards		
ENVIRONMENTALLY HAZARDOUS:	No	
<b>14.6. Special precautions for user</b> No information available.		
14.7. Maritime transport in bulk according to	o IMO instruments	
not applicable		
not applicable SECTION 15: Regulatory information	ations/legislation specific for the substance or mixture	
not applicable SECTION 15: Regulatory information	ations/legislation specific for the substance or mixture	
not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental regulatory	ations/legislation specific for the substance or mixture	
not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental regul EU regulatory information Restrictions on use (REACH, annex XVII):	lations/legislation specific for the substance or mixture Not subject to 2012/18/EU (SEVESO III)	
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not applicable  SECTION 15: Regulatory information  15.1. Safety, health and environmental regul  EU regulatory information Restrictions on use (REACH, annex XVII): Entry 75 Information according to 2012/18/EU (SEVESO III):		
not applicable  SECTION 15: Regulatory information  15.1. Safety, health and environmental regul  EU regulatory information  Restrictions on use (REACH, annex XVII): Entry 75 Information according to 2012/18/EU (SEVESO III): National regulatory information	Not subject to 2012/18/EU (SEVESO III)	

# Changes

This data sheet contains changes from the previous version in section(s): 1.



according to Regulation (EC) No 1907/2006

**VITA ADIVA OXY-PREVENT** 

Revision date: 15.08.2023

Product code: 308

Page 7 of 7

Abbreviations and acronyms ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service LC50: Lethal concentration, 50% LD50: Lethal dose, 50% CLP: Classification, labelling and Packaging REACH: Registration, Evaluation and Authorization of Chemicals GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals UN: United Nations DNEL: Derived No Effect Level DMEL: Derived Minimal Effect Level PNEC: Predicted No Effect Concentration ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50% EC50: Effective Concentration 50% ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration BCF: Bio-concentration factor PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative RID: Regulations concerning the international carriage of dangerous goods by rail ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures) EmS: Emergency Schedules MFAG: Medical First Aid Guide ICAO: International Civil Aviation Organization MARPOL: International Convention for the Prevention of Marine Pollution from Ships IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern For abbreviations and acronyms, see table at http://abbrev.esdscom.eu **Further Information** 

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)