# according to Regulation (EC) No. 1907/2006 (REACH)

Trade name : Vector® Fluid polish

**Revision date:** 17.01.2023 **Version (Revision):** 4.0.0 (3.0.1)

**Print date :** 31.07.2023

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

#### 1.1 Product identifier

Vector® Fluid polish

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

Vector® Fluid polish is a suspension for use in the Vector® System, that gently and intensively cleans tooth, denture, and root surfaces with ultrasound dynamics.

#### **Products Category [PC]**

PC 0 - Other

## Uses advised against

None, if handled according to order.

#### Remark

The product is intended for professional use.

# 1.3 Details of the supplier of the safety data sheet

#### Supplier

orochemie GmbH + Co. KG

**Street:** Max-Planck-Straße 27

Postal code/City: 70806 Kornwestheim

**Telephone:** +49 7154 1308-0 **Telefax:** +49 7154 1308-40

Information contact: DÜRR DENTAL SE, Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany

Tel: +49 7142 705-0, Fax: +49 7142 705-500, info@duerrdental.com

in Great Britain/Ireland:

DÜRR DENTAL [Products] UK Ltd., 14 Linnell Way - Telford Way Industrial Estate, Kettering Northants NN16 8PS,

United Kingdom, info@duerruk.com

#### 1.4 Emergency telephone number

INT: +49 6132 84463 (24 h/7 d)

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Although there is no labelling required for this product, we nevertheless advise observation of the safety recommendations.

# Classification according to Regulation (EC) No 1272/2008 [CLP]

None

## **Classification procedure**

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

# 2.2 Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

### **Precautionary statements**

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

#### Special rules for supplemental label elements for certain mixtures

EUH210 Safety data sheet available on request.

# **Additional information**

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

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#### 2.3 Other hazards

The mixture contains < 0.15 % substances with potential endocrine disrupting properties. The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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

#### 3.2 Mixtures

#### Description

Vector® Fluid polish contains hydroxylapatite, calcium phosphate, dispersing agents, PHB ester, adjuvants and aroma (contains limonene).

#### **Hazardous ingredients**

ETHANOL; REACH No.: 01-2119457610-43; EC No.: 200-578-6; CAS No.: 64-17-5

Weight fraction :  $\geq 1 - < 5 \%$ 

Classification 1272/2008 [CLP] : Flam. Liq. 2 ; H225 Eye Irrit. 2 ; H319 Specific Conc. Limits : Eye Irrit. 2 ; H319:  $C \ge 50 \%$ 

#### **Additional information**

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

#### **SECTION 4: First aid measures**

# 4.1 Description of first aid measures

#### **General information**

When in doubt or if symptoms are observed, get medical advice.

#### Following inhalation

No special measures are necessary.

## In case of skin contact

Wash with plenty of water. When in doubt or if symptoms are observed, get medical advice.

#### After eve contact

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

When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

## 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

None

#### **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

#### Suitable extinguishing media

Carbon dioxide (CO2) Extinguishing powder Water spray jet Water mist The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

## Unsuitable extinguishing media

Full water jet

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

None known.

# **Hazardous combustion products**

None known.

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#### 5.3 Advice for firefighters

Adapt protective equipment to surrounding fire.

#### Special protective equipment for firefighters

Adapt protective equipment to surrounding fire.

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

## 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. See protective measures under point 7 and 8.

#### For non-emergency personnel

Use personal protection equipment. See protective measures under point 7 and 8.

#### For emergency responders

#### **Personal protection equipment**

See protective measures under point 7 and 8.

#### 6.2 Environmental precautions

No special environmental measures are necessary.

# 6.3 Methods and material for containment and cleaning up

#### For cleaning up

No special measures are necessary.

#### 6.4 Reference to other sections

None

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

# 7.1 Precautions for safe handling

Keep/Store only in original container. Please note safety instructions and directions for use on the drum.

#### **Protective measures**

# Measures to prevent fire

Usual measures for fire prevention. When using do not smoke.

# 7.2 Conditions for safe storage, including any incompatibilities

## **Requirements for storage rooms and vessels**

Keep/Store only in original container. Keep container tightly closed and in a well-ventilated place. Do not store in temperatures below 5 °C. Do not store in temperatures exceeding 25 °C. Protect to direct exposure to the sun.

# Hints on joint storage

Store the foodstuffs separately.

#### 7.3 Specific end use(s)

None

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

# 8.1 Control parameters

#### Occupational exposure limit values

ETHANOL; CAS No.: 64-17-5

Limit value type (country of origin): TLV/TWA ( GB )

Limit value : 1000 ppm / 1920 mg/m<sup>3</sup>

#### **DNEL-/PNEC-values**

There are no data available on the preparation itself.

**DNEL/DMEL** 

ETHANOL; CAS No.: 64-17-5

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Limit value type : DNEL Consumer (local)

Exposure route: Inhalation
Exposure frequency: Short-term
Limit value: 950 mg/m³

Limit value type : DNEL Consumer (systemic)

Exposure route:

Cral
Exposure frequency:

Limit value:

87 mg/kg

Assessment factor:

24 h

Limit value type : DNEL Consumer (systemic)

Exposure route: Dermal
Exposure frequency: Long-term
Limit value: 206 mg/kg
Assessment factor: 24 h

Limit value type : DNEL Consumer (systemic)

Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 114 mg/m³
Limit value type : DNEL worker (local)

Exposure route: Inhalation
Exposure frequency: Short-term
Limit value: 1900 mg/m³

Limit value type : DNEL worker (systemic)

Exposure route: Dermal
Exposure frequency: Long-term
Limit value: 343 mg/kg
Assessment factor: 24 h

Limit value type : DNEL worker (systemic)

Exposure route: Inhalation
Exposure frequency: Long-term
Limit value: 950 mg/m³

**PNEC** 

ETHANOL; CAS No.: 64-17-5

Limit value type : PNEC (Aquatic, freshwater)

Limit value : 0,96 mg/l

Limit value type : PNEC (Aquatic, marine water)

Limit value : 0,79 mg/l
Limit value type : PNEC (Industrial)

Exposure route: Soil
Limit value: 0,63 mg/kg

Limit value type : PNEC (Sediment, freshwater)

Limit value : 3,6 mg/kg

Limit value type : PNEC (Sediment, marine water)

Limit value : 2,9 mg/kg

Limit value type : PNEC (Secondary poisoning)

Limit value : 729 mg/kg

Limit value type : PNEC (Sewage treatment plant)

Limit value : 580 mg/l

# 8.2 Exposure controls

# **Personal protection equipment**

### **Eye/face protection**

Eye glasses with side protection EN 166

# Skin protection

**Hand protection** 

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Short-term exposure (Level 2: < 30 min): disposable gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.1 mm

Long-term exposure (Level 6: < 480 min): protective gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.7 mm.

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

#### **Body protection**

Body protection: not required.

#### **Respiratory protection**

No special measures are necessary.

#### **General information**

Keep away from food, drink and animal feedingstuffs. Wash hands before breaks and after work. Separate storage of work clothes. When using do not eat, drink, smoke, sniff.

#### Other protection measures

Provide adequate ventilation.

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

# 9.1 Information on basic physical and chemical properties

Appearance: viscous
Colour: white
Odour: characteristic

Safety characteristics

Melting point/freezing point: No data available Initial boiling point and boiling No data available (1013 hPa) range: **Decomposition temperature:** (1013 hPa) No data available Flash point: not applicable Auto-ignition temperature : not applicable Lower explosion limit: not applicable Upper explosion limit: not applicable Vapour pressure : (50 °C) No data available

**Density:** (20 °C) approx. 1,1 g/cm $^3$  **Solvent separation test:** (20 °C) < 3 % **Water solubility:** (20 °C) approx. 90 Weight-%

**pH value :** ( 20 °C / 20 g/l ) 6,5 - 7,5

log P O/W: No data available

Flow time :  $(20 \, ^{\circ}\text{C})$  <  $20 \, \text{s}$  DIN-cup 4 mm

**Odour threshold :** No data available

Maximum VOC content (EC): 4 Weight-%

Oxidising liquids:

Explosive properties:

Corrosive to metals:

Not applicable.

Not corrosive to metals.

#### 9.2 Other information

None

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

None, if handled according to order.

## 10.2 Chemical stability

Stable under recommended storage and handling conditions (see section 7).

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## 10.3 Possibility of hazardous reactions

None, if handled according to order.

## 10.4 Conditions to avoid

No information available.

# 10.5 Incompatible materials

No information available.

## 10.6 Hazardous decomposition products

None known.

## **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.

**Acute oral toxicity** 

Parameter: LD50 Exposure route: Oral Species: Rat > 5 mL/kg Effective dose: Method: **OECD 401** Parameter: **ATEmix** Exposure route: Oral Effective dose: not relevant

#### Practical experience/human evidence

Avoid contact with eyes. Acute dermal toxicity

Parameter:

**ATEmix** Exposure route: Dermal Effective dose : not relevant

LD50 (ETHANOL; CAS No.: 64-17-5) Parameter:

Exposure route: Dermal Species: Rabbit Effective dose: 20 g/kg

Acute inhalation toxicity

**ATFmix** Parameter:

Exposure route: Inhalation (vapour) Effective dose: not relevant

LC50 (ETHANOL; CAS No.: 64-17-5) Parameter:

Exposure route: Inhalation Species: Rat Effective dose: 125 mg/l Exposure time: 4 h OECD 403 Method:

#### Corrosion

Based on available data, the classification criteria are not met. Rabbit's eye: no irritation. Method: ISO 10993-10.

# Respiratory or skin sensitisation

Based on available data, the classification criteria are not met. Guinea-pig: non-sensitizing. Method: ISO 10993-10.

# Repeated dose toxicity (subacute, subchronic, chronic)

Subacute oral toxicity

NOAEL(C) ( ETHANOL ; CAS No. : 64-17-5 ) Parameter:

Exposure route: Oral Species: Rat

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Effective dose : 1730 mg/kg
Exposure time : 24 h
Method : OECD 408

**Subacute inhalation toxicity** 

Parameter: NOAEL(C) ( ETHANOL ; CAS No. : 64-17-5 )

Exposure route: Inhalation
Species: Rat
Effective dose: > 20 mg/l

## CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

#### Carcinogenicity

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

#### Germ cell mutagenicity

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

#### Reproductive toxicity

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.

#### 11.2 Information on other hazards

## **Endocrine disrupting properties**

The mixture contains < 0.15 % substances with potential endocrine disrupting properties.

## **Additional information**

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

# **SECTION 12: Ecological information**

# 12.1 Toxicity

# **Aquatic toxicity**

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

## Acute (short-term) fish toxicity

Parameter: LC50 ( ETHANOL ; CAS No. : 64-17-5 )
Species: Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter: Acute (short-term) fish toxicity

Effective dose: 11200 mg/l

Parameter: LC50 ( ETHANOL ; CAS No. : 64-17-5 )
Species: Pimephales promelas (fathead minnow)
Evaluation parameter: Acute (short-term) fish toxicity

Effective dose : > 15000 mg/l

Exposure time : 96 h

Chronic (long-term) fish toxicity

Parameter: NOEC (ETHANOL; CAS No.: 64-17-5)

Species: Ceriodaphnia spec

Evaluation parameter: Acute (short-term) daphnia toxicity

Effective dose : 9,6 mg/l **Acute (short-term) toxicity to crustacea** 

Parameter: EC50 ( ETHANOL ; CAS No. : 64-17-5 )
Species: Daphnia magna (Big water flea)
Evaluation parameter: Acute (short-term) daphnia toxicity

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Effective dose: 9200 - 14300 mg/l

Exposure time: 48 h

Parameter: EC50 (ETHANOL; CAS No.: 64-17-5)

Species: Ceriodaphnia spec

Evaluation parameter: Acute (short-term) daphnia toxicity

Effective dose: 1806 mg/l

#### Acute (short-term) toxicity to algae and cyanobacteria

Parameter: EC50 (ETHANOL; CAS No.: 64-17-5)

Species: Chlorella vulgaris

Evaluation parameter: Acute (short-term) algae toxicity

Effective dose: 275 mg/l

Parameter: EC50 (ETHANOL; CAS No.: 64-17-5)

Species : Selenastrum capricornutum

Evaluation parameter : Acute (short-term) algae toxicity

Effective dose: 440 mg/l

Parameter: IC50 (ETHANOL; CAS No.: 64-17-5)

Species: Scenedesmus subspicatus
Evaluation parameter: Acute (short-term) algae toxicity

Effective dose : > 100 mg/l

Parameter: ErC50 ( ETHANOL ; CAS No. : 64-17-5 )
Species: Pseudokirchneriella subcapitata
Evaluation parameter: Acute (short-term) algae toxicity

Effective dose : > 4800 mg/l
Exposure time : 72 h
Method : OECD 201

#### Sewage treatment plant

Parameter: EC50 (ETHANOL; CAS No.: 64-17-5)

Inoculum: Effects in sewage plants

Effective dose : 5800 mg/l Exposure time : 4 h

#### 12.2 Persistence and degradability

#### **Biodegradation**

No data available.

# 12.3 Bioaccumulative potential

No information available.

# 12.4 Mobility in soil

#### **Distribution**

No data available

## 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.

#### 12.6 Endocrine disrupting properties

The mixture contains < 0.15 % substances with potential endocrine disrupting properties.

## 12.7 Other adverse effects

No information available.

## 12.8 Additional ecotoxicological information

No ecological problems are expected when used and handled properly.

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

**Directive 2008/98/EC (Waste Framework Directive)** 

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#### After intended use

#### Disposal operations

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

#### **Recovery operations**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself

# **SECTION 14: Transport information**

#### 14.1 UN number

No dangerous good in sense of these transport regulations.

#### 14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

#### 14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

#### 14.4 Packing group

No dangerous good in sense of these transport regulations.

#### 14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

## 14.6 Special precautions for user

None

#### 14.7 Maritime transport in bulk according to IMO instruments

not applicable

## **SECTION 15: Regulatory information**

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

**EU** legislation

Authorisations and/or restrictions on use

**Restrictions on use** 

Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)

Use restriction according to REACH annex XVII, no.: 40, 75

#### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has not been carried out.

## **SECTION 16: Other information**

## 16.1 Indication of changes

02. Classification of the substance or mixture ` 02. Label elements ` 02. Labelling according to Regulation (EC) No. 1272/2008 [CLP] · 02. Special rules for supplemental label elements for certain mixtures · 03. Hazardous ingredients · 11. Acute toxicity · 11. Corrosion · 11. Respiratory or skin sensitisation · 11. Carcinogenicity · 11. Germ cell mutagenicity · 11. Reproductive toxicity · 11. STOT-single exposure · 11. STOT-repeated exposure · 11. Aspiration hazard · 12. Aquatic toxicity · 15. Restrictions on use

#### 16.2 Abbreviations and acronyms

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimates

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CMR = Carcinogen, Mutagen or Reproductive toxicant

 $CO_2$  = Carbon dioxide

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DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EC = European Commission

EC50 = Half maximal effective concentration

EN = European Standard (Norm)

EU = European Union

EUH statement = CLP-specific Hazard statement

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

H statement = GHS Hazard statement

IATA = International Air Transport Association ICAO-TI = International Civil Aviation Organization-Technical Instructions

IMDG = International Maritime Dangerous Goods

LC50 = Median lethal concentration

LD50 = Median lethal dose

LogPow = Logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol

of 1978. ("Marpol" = marine pollution)

NOEC/NOEL = No observed effect concentration/level

OECD = Organisation for Economic Co-operation and Development

PBT = Persistent, Bioaccumulative and Toxic

PNEC = Predicted No Effect Concentration

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation [Regulation (EC) No.

1907/2006]

RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail

RMM = Risk Management Measure

RRN = REACH Registration Number

STOT-RE = Specific Target Organ Toxicity - Repeated Exposure

STOT-SE = Specific Target Organ Toxicity - Single Exposure

SVHC = Substances of Very High Concern

TLV/STEL = Threshold limit value/short-term exposure limit

TLV/TWA = Threshold limit value/time weighted average

UN = United Nations

VOC = Volatile Organic Compound

vPvB = Very Persistent and Very Bioaccumulative

# 16.3 Key literature references and sources for data

None

# Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

#### 16.5 Relevant H- and EUH-phrases (Number and full text)

H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation.

## 16.6 Training advice

None

#### 16.7 Additional information

Follow the instructions for use on the label.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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