according to GHS

Trade name : Periomat Intra/C+ Developer concentrate

Revision date: 01.10.2019 **Version:** 1.0.0

Print date : 21.07.2020

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

1.1 Product identifier

Periomat Intra/C+ Developer concentrate

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

Special X-ray set for Dürr developers.

Products Category [PC]

PC 30 - Photo-chemicals

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 (manufacturer/importer/only representative/downstream user/distributor)

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 Australia:

DÜRR DENTAL SE, PO Box 2067, Woonona East New South Wales 2517, Australia, Louis Manera +61 (0)412 95 95 25

Importer/Distributor:

Ivoclar Vivadent Ltd, PO Box 303011, North Harbour, Auckland, 0751, Phone +64 9 914 9999 Fax+64 9 914 9990

1.4 Emergency telephone number

NZ: National Poison Centre (New Zealand) 0800 764 766 Poisons Hotline (24 hours/7days)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to GHS

Acute Tox. 5; H303 - Acute toxicity (oral): Category 5; May be harmful if swallowed.

Skin Irrit. 2; H315 - Skin corrosion/irritation: Category 2; Causes skin irritation.

Eye Irrit. 2; H319 - Serious eye damage/eye irritation: Category 2; Causes serious eye irritation.

Classification procedure

The classification was carried out according to the calculation method of GHS.

2.2 Label elements

Labelling according to GHS

Hazard pictograms



Exclamation mark (GHS07)

Signal word

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(EN / NZ)

according to GHS

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Warning

Hazard components for labelling

POTASSIUM CARBONATE; CAS No.: 584-08-7

Hazard statements

H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H303 May be harmful if swallowed.

Precautionary statements

P280 Wear protective gloves and eye/face protection.
P312 Call a POISON CENTER/doctor/... if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container to hazardous or special waste collection point.

Special rules for supplemental label elements for certain mixtures

EUH208 Contains 4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON.May produce an

allergic reaction.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description

Periomat Intra/C+ Developer concentrate contains potassium carbonate, potassium sulfite, complexing agents, stabilizers and auxiliary agents in aqueous solution.

Hazardous ingredients

POTASSIUM CARBONATE; REACH No.: 01-2119532646-36; EC No.: 209-529-3; CAS No.: 584-08-7

Weight fraction : \geq 10 - < 15 %

Classification 1272/2008 [CLP]: Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON; REACH No. : -; EC No. : 235-920-3; CAS No. : 13047-13-7

Weight fraction : $\geq 0.1 - < 0.5 \%$

Classification 1272/2008 [CLP]: Acute Tox. 4; H302 Skin Sens. 1; H317 Aquatic Chronic 2; H411

Additional information

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Remove contaminated, saturated clothing immediately. When in doubt or if symptoms are observed, get medical advice.

Following inhalation

Provide fresh air. In case of respiratory tract irritation, consult a physician.

In case of skin contact

Wash with plenty of water. In case of skin irritation, consult a physician.

After eye contact

Remove contact lenses, keep eyelids open. 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.

After ingestion

If swallowed, immediately drink: Water Never give anything by mouth to an unconscious person or a person with cramps. Do NOT induce vomiting. Call a physician immediately.

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according to GHS

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4.2 Most important symptoms and effects, both acute and delayed

May cause sensitisation especially in sensitive humans. Causes skin irritation. Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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.

5.3 Advice for firefighters

Adapt protective equipment to surrounding fire. Do not allow run-off from fire-fighting to enter drains or water courses.

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

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

Other information

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

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. Handle and open container with care. Provide adequate ventilation. Do not breathe vapour/aerosol.

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

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according to GHS

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Requirements for storage rooms and vessels

Keep/Store only in original container. Keep container tightly closed. Keep in a cool, well-ventilated place. Do not store in temperatures below 5 $^{\circ}$ C.

Hints on joint storage

Store the foodstuffs separately.

7.3 Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

DNEL-/PNEC-values

There are no data available on the preparation itself.

DNEL/DMEL

POTASSIUM CARBONATE; CAS No.: 584-08-7

Limit value type : DNEL Consumer (local)

 $\begin{array}{lll} \mbox{Exposure route:} & \mbox{Inhalation} \\ \mbox{Exposure frequency:} & \mbox{Long-term} \\ \mbox{Limit value:} & \mbox{10 mg/m}^3 \end{array}$

Limit value type : DNEL Consumer (local)

Exposure route : Dermal Exposure frequency : Long-term Limit value : 8 mg/cm²

Limit value type : DNEL worker (local)

 $\begin{array}{lll} \mbox{Exposure route:} & \mbox{Inhalation} \\ \mbox{Exposure frequency:} & \mbox{Long-term} \\ \mbox{Limit value:} & \mbox{10 mg/m}^3 \\ \end{array}$

Limit value type : DNEL worker (local)

Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 16 mg/cm²

8.2 Exposure controls

Personal protection equipment

Eye/face protection

Eye glasses with side protection DIN EN 166

Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337. Safety glasses with side shields

Skin protection

Hand protection

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. AUS/NZ: Wear impervious rubber gloves (AS2161).

Body protection

Body protection: not required.

Respiratory protection

Usually no personal respirative protection necessary.

General information

Keep away from food, drink and animal feedingstuffs. Avoid contact with skin, eyes and clothes. Remove contaminated, saturated clothing. Wash hands before breaks and after work. Separate storage of work clothes. When using do not eat, drink, smoke, sniff.

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Other protection measures

No particular measures required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Liquid
Colour: light yellow
Odour: odourless
Safety characteristics

Melting point/freezing point: (1013 hPa) not determined Initial boiling point and boiling (1013 hPa) not determined range: (1013 hPa) not determined Decomposition temperature : Flash point: not applicable Auto-ignition temperature : not applicable Lower explosion limit: not applicable Upper explosion limit: not applicable Vapour pressure : (50°C) not determined

Density: (20 °C) 1,173 - 1,182 g/cm³

Solvent separation test: (20 °C) < 3 %

Water solubility: (20 °C) 10,5 - 10,9

log P O/W: 10,5 - 10,9 not determined

Flow time : (20 °C) < 20 s DIN-cup 4 mm

Odour threshold: not applicable

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).

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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according to GHS

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Acute toxicity

Acute oral toxicity

Parameter: ATEmix calculated

Exposure route: Oral

Effective dose: 3849 mg/kg

Parameter: LD50 (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Exposure route : Oral Species : Rat

Effective dose: > 2000 mg/kg

Parameter: LD50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Exposure route: Oral
Species: Rat
Effective dose: 1300 mg/kg

Parameter: LD50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Exposure route : Oral
Species : Rat
Effective dose : 566 mg/kg

Parameter: ATE (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Exposure route : Oral
Effective dose : 500 mg/kg

Parameter: ATE (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Exposure route : Oral

Effective dose : 500 mg/kg

Practical experience/human evidence

May cause sensitisation especially in sensitive humans.

Acute dermal toxicity

Parameter : ATEmix calculated

Exposure route : Dermal Effective dose : not relevant

Parameter: LD50 (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Exposure route: Dermal
Species: Rabbit
Effective dose: > 2000 mg/kg

Acute inhalation toxicity

Parameter: ATEmix calculated
Exposure route: Inhalation (vapour)
Effective dose: not relevant

Parameter: LC50 (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Exposure route: Inhalation
Species: Rat

Effective dose : > 4,96 mg/kg

Exposure time: 4 h

Corrosion

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause sensitization by skin contact.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

11.5 Additional information

The classification was carried out according to the calculation method of GHS.

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according to GHS

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity

Parameter: LC50 (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Species: Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter: Acute (short-term) fish toxicity

Effective dose : 68 mg/l Exposure time : 96 h

Parameter: LC50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Species: Pimephales promelas (fathead minnow)

Evaluation parameter: Acute (short-term) fish toxicity

Effective dose: 1 - 10 mg/l

Parameter: LC50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON; CAS No.:

13047-13-7)

Species: Leuciscus idus (golden orfe)
Evaluation parameter: Acute (short-term) fish toxicity

Effective dose : 35 mg/l Exposure time : 48 h

Chronic (long-term) fish toxicity

Parameter: NOEC (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Species : Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter : Chronic (long-term) fish toxicity

Effective dose: 33 mg/l Exposure time: 96 h

Acute (short-term) toxicity to crustacea

Parameter : EC50 (POTASSIUM CARBONATE ; CAS No. : 584-08-7)

Species: Daphnia magna (Big water flea)
Evaluation parameter: Acute (short-term) daphnia toxicity

Effective dose: 200 mg/l Exposure time: 48 h

Parameter: EC50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Species: Daphnia magna (Big water flea)
Evaluation parameter: Acute (short-term) daphnia toxicity

Effective dose : 7,1 mg/l Exposure time : 24 h

Toxicity to microorganisms

Parameter: EC50 (4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-PYRAZOLIDIN-3-ON ; CAS No. :

13047-13-7)

Species: Pseudomonas putida
Evaluation parameter: Bacteria toxicity
Effective dose: 480 mg/l
Exposure time: 16 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

Distribution

There are no data available on the preparation itself.

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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 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Directive 2008/98/EC (Waste Framework Directive)

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. Waste codes 15 01 10*. Contact a specialist disposal company or the local waste regulator for advice. This should be done in accordance with 'The Hazardous Waste Act'. Can be eliminated with domestic garbage on condition it complies with local regulations.

Waste codes/waste designations according to EWC/AVV

Concentrate/larger quantities: 09 01 01* water based developer baths.

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 Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

$^{15.1}$ Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

EPA NZ Classes of hazardous properties class 8—corrosive substance

NZ HSNO Approval: HSR003645: Ascorbic acid, HSNO Approval: HSR003274: Potassium carbonate, HSNO Approval: HSR003789: Potassium bromide, HSNO Approval: HSR001586: Potassium hydroxide

Restrictions of occupation

According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented.

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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

None

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

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

 ${\sf OECD} = {\sf Organisation} \ {\sf for} \ {\sf Economic} \ {\sf Co-operation} \ {\sf and} \ {\sf Development}$

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

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).

Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).

Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

16.4 Classification for mixtures and used evaluation method according to GHS

The classification was carried out according to the calculation method of GHS.

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Safety Data Sheet according to GHS

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

H302 Harmful if swallowed. H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

16.6 Training advice

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

16.7 Additional information

Notice the directions 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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