Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name:	Dual Rinse HEDP
Manufacturer:	Medcem GmbH
SDS Expiry:	19 July 2029
Supplier Details:	Healthcare Essentials Level 4/15 College Str Te Aro, Wellington 6011 New Zealand www.healthcareessentials.nz
Emergency Contacts:	Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police
HSNO Class/Category:	6.1D, 6.4A, 8.3A, 9.1D
HSNO Group Standard:	Dental Products Subsidiary Hazard Group Standard 2020 HSR002558
Statements/Pictograms:	As per attached Safety Data Sheet (SDS)
Date Prepared:	This coversheet was prepared – October 2026

This SDS coversheet has been produced by Healthcare Essentials and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

SAFETY DATA SHEET

According to Regulation (EC) 1907/2006 and Regulation (EU) 2020/878

Version 2
Revision Date 19.07.2024

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

1.1. Product identifier

Trade name: Dual Rinse® HEDP

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

- Application of the substance / the mixture: for treatment of root canals by a dentist
- Uses advised against: No further relevant information available

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

Address:

Medcem GmbH
Bahnhofstrasse 12
CH-8570 Weinfelden
Switzerland
Tel.: +41 71 620 04 21
Fax: +41 71 620 04 22
Email: info@medcem.ch

1.4. Emergency telephone number:

+41 71 620 04 21 8:00 – 18:00 (GMT + 1.00)

SECTION 2: Hazards information

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008

Acute Tox. 4	H302	Harmful if swallowed
Eye Irrit. 2	H319	Causes serious eye irritation
Eye Dam. 1	H318	Causes serious eye damage
Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life

Classification according to Directive 67/548/EWG or Directive 1999/45/EG

- Xn; Harmful
- R22: Harmful if swallowed
- Xi; Irritant
- R36: Irritating to eyes

2.2. Label elements

- Labelling according to Regulation (EC) Nr. 1272/2008

As this product is a medical device accoding to the Regulation (EU) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according ro regulation 1272/2008.

The product is classified and labelled according to the CLP regulation.

- Hazard pictograms




GHS05 GHS07

- Signal word: Warning
- Hazard-determining components of labelling:

  (1-hydroxyethylidene)bisphosphonic acid, sodium salt

- Hazard statements

H302	Harmful if swallowed
H319	Causes serious eye irritation
H318	Causes serious eye damage
H413	May cause long lasting harmful effects to aquatic life

- Precautionary statements

P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301+P313	IF SWALLOWED: Call a POISON CENTER/doctor/…/if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/ international regulations.l

2.3. Other hazards:

Results of PBT and vPvB assessment

PBT: Not applicable
vPvB: Not applicable

SECTION 3: Composition / information on ingredients

3.1. Substances

Dangerous components

CAS Nr.: 29329-71-3
EINECS Nr.: 249-559-4
Reg.nr.: 01-2119510382-52-0001

(1-hydroxyethylidene)bisphosphonic acid, sodium salt, 80 – 90 % Xn R22; Xi R36

Classification (Regulation (EC) No. 1272/2008)




• Acute Tox. 4	H302	Harmful if swallowed
• Eye Irrit. 2	H319	Causes serious eye irritation
• Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life
• Eye Dam. 1	H318	Causes serious eye damage

SECTION 4: First aid measures

4.1. Description of first aid measures

- after inhalation: Supply fresh air; consult doctor in case of complaints.
- after skin contact: Immediately rinse with water. If skin irriation persists, consult a doctor.
- after eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- after swallowing: Rinse out mouth and then drink plenty of water. Seek immediate medical advice.

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

No further relevant information available.
Information for doctor: No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents:

- Use fire fighting measures that suit the environment.

5.2.Special hazards arising from the substance or mixture:

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: No special measures required.

5.4. Further information

None

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Clean the affected area carefully; suitable cleaners are:
weak acid solution
Dispose of the material collected according to regulations.

6.4. Reference to other sections

See section 7 for information on safe handling.
See section 8 for information on personal protection equipment

See section 13 for disposal information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ensure good ventilation/suction at the workplace.
Wear suitable respiratory protective device when decanting larger quantities without extractor facilities.
Handling: Product is intended for dental use only.
Information about fire- and explosion protection: No special measures required

7.2. Conditions for safe storage, including any incompatibilities

Storage requirements to be met by storerooms and receptacles: Store only in the orginal receptable.
Information about storage in one common storage facility: Do not store together with acids.
Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
The product is hygroscopic.
Storage class 11

7.3. Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

- Not required

- DNELs
  The DNELs are those of the active acid.
  DNEL (oral, long-term, workers): 13 mg/kg/day
  DNEL (oral, long-term, consumers): 6,5 mg/kg/day
- PNECs
  The PNECs are those of the active acid.
  PNEC (aqua-freshwater): 0,136 mg/l
  PNEC (aqua-marine water): 0,0136 mg/l
  PNEC (marine-CHARM): 0,068 mg/l
  PNEC (sediment (freshwater)): 59 mg/kg sediment wwt
  PNEC (sediment (marine water)): 5,9 mg/kg sediment wwt
  PNEC (soil): 96 mg/kg wwt
  PNEC (sewage treatment plant): 20 mg/l
  PNEC (oral): 12 mg/kg food

Additional information: the lists vaild during the making were used as basis

8.2. Exposure controls:

- Personal protective equipment
- General protective and hygienic measures
  - The usual precautionary measures are to be adhered to when handling chemicals.
  - Keep away from foodstuffs, beverages and feed.
  - Wash hands before breaks and at the end of the work.
- Respiratory protection: Suitable respiratory protective device recommended.

- Protection of hands: the glove material has to be impermeable and resistant to the product/ the substance/the preparation. Due to missing tests no recommendation to the glove material can be given to the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- Materials of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. The resistance of the glove material has to be checked prior to the application.
- Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Body protection: Protective work clothing
- Eye protection:



Tightly sealed goggles.

SECTION 9:Physical and chemical properties

9.1. Information on basic physical and chemical properties

General information:

• Appearance:	
• Form:	solid, granulate
• Colour:	white
• Odour:	undistinguishable
• Odour threshold:	not determined
• pH-value (10g/L):	11.5
• Change in condition:	
• Melting point/Melting range:	< 250°C
• Boiling point/Boiling range:	not determined
• Flash point:	not applicable
• Flammability (solid, gaseous):	not determined
• Ignition temperature:	540°C Minimum ignition energy > 10000 mJ
• Decomposition temperature:	not determined
• Self-igniting:	Product is not selfigniting.
• Danger of explosion:	Product does not present an explosion hazard.
• Explosion limits:	
• Lower:	not determined
• Uper:	not determined
• Vapour pressure:	not applicable
• Density:	not determined
• Bulk density at 20 °C:	0.7 – 1.1 g/cm^3
• Vapour density:	not applicable
• Evaporation rate:	not applicable
• Solubility in /Miscibility with water:	soluble
• Partition coefficient : (n-octanol/water)	not determined
• Viscosity:	
• dynamic:	not applicable
• kinematic:	not applicable
• Solvent content:	
• Organic solvents:	0,0%
• Solids content:	100%

9.2. Other information:

No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity: No further relevant information available

10.2. Chemical stability
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. To avoid thermal decomposition do not superheat.

10.3. Possibility of hazardous reactions: No dangerous reactions known

10.4. Conditions to avoid: No further relevant information available

10.5. Incompatible materials: No further relevant information available

10.6. Hazardous decomposition products:

In case of fire : Carbon monoxide (CO), Phosphin (PH_3)

SECTION 11: Toxicological information

11.1. Informations on toxicological effects
Acute toxicity:
LD/LC50 values that are relevant for classification: LD50 oral: 1100 mg/kg (rat)

Primary irritant effect:

- on the skin: no irritating effect
- on the eye: irritating effect
- Sensitization: No sensitizing effects known.

Additional toxicological information:
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity:

LC 50 (Salmo gairdneri)	> 100 mg/L 96h
EC 50 (Daphnia magna)	> 170 mg/L 96h

12.2. Persistence and degradability: No further relevant information available

12.3. Bioaccumulative potential: No further relevant information available

12.4. Mobility in soil: No further relevant information available

Additional ecological information :

General notes:
Water hazard class 2 (German Regulation) (Self-assessment): hazardous to water.
Do not allow product to reach ground water, water course or sewage system. Danger to drinking water even if small quantities leak into the ground.

12.5. Results of PBT and vPvB assessment:

- PBT: Not applicable
- vPvB: Not applicable

12.6. Other adverse effects: No further relevant information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recommendation:



After prior treatment product has to be disposed of in a dump for hazardons waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.

Waste disposal key:

According to the EAK decree,the specification of the waste disposal key code shall be specific to the respective industrial section and the application process.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1. UN-Number

- ADR, IMDG, IATA void

14.2. UN proper shipping name

- ADR, IMDG, IATA void

14.3. Transport hazard class(es)

- ADR, IMDG, IATA
- Class void

14.4. Packing group

- ADR, IMDG, IATA void

14.5. Environmental hazards

- Marine pollutant: No

14.6. Special precautions for user: Not applicable

14.7. Transport in bulk according to Annex II
of Marpol 73/78 and the IBC Code: Not applicable

UN „Model Regulation“: -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific of the substance or mixture:
Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.

15.2. Chemical safety assessment:

A chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage the product is given in the DFU.

Relevant phrases

- H302 Harmful if swallowed.
- H319 Causes serious eye irritation.
- H413 May cause long lasting harmful effects to aquatic life
- H318 Causes serious eye damage

- R22 Harmful if swallowed.
- R36 Irritating to eyes.

Department issuing MSDS: Safety officer development

Contact: Hotline for urgent technical support: +41 71 620 04 21

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 Harmonised 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 (division of the American Chemical Society)
- Eye Irrit. 1: Serious eye damage/eye irritation. Hazard Category 2
- Acute Tox. 4: Acute – Toxicity, Hazard Category 4
- DNEL: Derived No-Effect Level (REACH)
- PNEC: Predicted No-Effect Concentration (REACH)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- EC50: Effective concentration, 50 percent