

PREMIER DENTAL PRODUCTS COMPANY

Safety Data Sheet

Premier® RC-Prep® - Root Canal Preparation Cream

SECTION 1: Identification

1.1 GHS Product identifier

Product name: Premier® RC-Prep® - Root Canal Preparation Cream
Brand: RC-Prep®

1.2 Product description:

RC-Prep Root Canal Preparation Cream is a water-based paste, white in color, formulated to soften, lubricate, whiten, and deodorize the dental canals. RC-Prep can be dispensed by the end user using a multitude of different methods.

1.3 Recommended use of the chemical and restrictions on use

For Preparation of Root Canal. For dental professionals use only.

1.4 Manufacturer's/Supplier's details:

Name Premier Dental Products Company
Address 1710 Romano Drive
Plymouth Meeting PA 19462
USA

Telephone 610-239-6000
Fax 610-239-6171
Email regulatory@premierdentalco.com

1.5 Emergency phone number: 610-239-6000

SECTION 2: Hazard identification

General hazard statement

Unknown acute toxicity:

This value refers to knowledge of known, established toxicological or ecotoxicological values.
20 % of the mixture consists of component(s) of unknown toxicity.

Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

NFPA ratings (scale 0 - 4)

Health = 1
Fire = 0

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Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 1
Fire = 0
Reactivity = 0

2.1 Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)



GHS07

- Skin corrosion/irritation, Cat. 2
- Eye damage/irritation, Cat. 2B

2.2 GHS label elements, including precautionary statements.

Label elements: GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Pictograms



GHS07

Signal word: Warning

Hazard statement(s)

H315

Causes skin irritation.

H320

Causes eye irritation.

Precautionary statement(s)

P264

Wash ... thoroughly after handling.

P280

Wear protective gloves.

P302+P352

IF ON SKIN: Wash with plenty of water.

P321

Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

P332+P313

If skin irritation occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before reuse.

P305+P351+P338

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

P337+P313

If eye irritation persists: Get medical advice/attention.

2.3 Other hazards which do not result in classification.

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Hazard(s) not otherwise classified (HNOC): None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical characterization: Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Hazardous components

1. Propylene Glycol

Concentration Not specified, Proprietary.

CAS no.: 57-55-6

RTECS: TY 2000000

2. Edetic Acid

Concentration 10 - 30 % (weight), Proprietary

CAS no.: 60-00-4

RTECS: AH 4375000



Eye Irrit. 2A, H319

3. Carbamide Peroxide

Concentration 1 - 10 % (weight), Proprietary

CAS no.: 124-43-6

RTECS: YT 4850000



Ox. Sol. 3, H272



Skin Corr. 1B, H314; Eye Dam. 1, H318

4. Cetyl Alcohol

Concentration 1 - 10 % (weight), Proprietary

CAS no.: 36653-82-4

RTECS: MM 0225000



Skin Irrit. 2, H315; Eye Irrit. 2B, H320

Trade secret statement (OSHA 1910.1200(i))

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

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- If inhaled:** In case of unconsciousness place patient stably in side position for transportation.
- In case of skin contact:** If skin irritation occurs, consult a doctor.
- In case of eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor. If easy to do so, remove contact lenses if worn.
- If swallowed:** Rinse mouth with water.

Information for doctor:

Wear eye protection in addition to wearing protective clothing.

4.2 Most important symptoms/effects, acute and delayed.

No further relevant information available.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

No further relevant information available.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Use fire-fighting measures that suit the environment.

5.2 Specific hazards arising from the chemical

No further relevant information available.

5.3 Special protective actions for fire-fighters

Protective equipment:

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).

Use neutralizing agent.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to local and federal regulations.

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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.

Protective Action Criteria for Chemicals

PAC-1:		
CAS# 57-55-6	Propylene Glycol	30 mg/m ³
CAS# 60-00-4	Edetic acid	4.1 mg/m ³
CAS# 124-43-6	Carbamide Peroxide	1.2 mg/m ³
CAS# 36653-82-4	Cetyl alcohol	1.6 mg/m ³
PAC-2:		
CAS# 57-55-6	Propylene Glycol	1,300 mg/m ³
CAS# 60-00-4	Edetic acid	45 mg/m ³
CAS# 124-43-6	Carbamide Peroxide	13 mg/m ³
CAS# 36653-82-4	Cetyl alcohol	18 mg/m ³
PAC-3:		
CAS# 57-55-6	Propylene Glycol	7,900 mg/m ³
CAS# 60-00-4	Edetic acid	200mg/m ³
CAS# 124-43-6	Carbamide Peroxide	79 mg/m ³
CAS# 36653-82-4	Cetyl alcohol	110 mg/m ³

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities.

Storage

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Keep receptacle tightly sealed.

Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see section 7.

Control parameters:

Components with occupational exposure limits:

The following constituents are the only constituents of the product which have a PEL, TLV or other

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recommended exposure limit.

At this time, the other constituents have no known exposure limits.

57-55-6 Propylene Glycol	
WEEL	Long-term value: 10 mg/m ³

Additional information: The lists that were valid during the creation of this SDS were used as basis.

Eye/face protection



Safety glasses

Body protection

Wear protective clothing.

Protection of Hands



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Select glove material based on penetration times, rates of diffusion and degradation.

Material 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. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

Respiratory protection

Not required.

Exposure controls:

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing and wash before reuse.

Wash hands before breaks and at the end.

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Avoid contact with the eyes and skin.

SECTION 9: Physical and chemical properties

Appearance	Paste
Color	White
Odor	Odorless
Odor threshold	Not determined.
pH-Value	Not applicable.
Melting point and freezing point	Not determined.
Initial boiling point and boiling range	≥185 °C (≥365 °F)
Flash point	≥103 °C (≥217 °F)
Evaporation rate	Not determined.
Flammability, in the case of solids and gases	Not applicable.
Upper and lower flammability or explosive limits	Not applicable.
Vapor pressure	≤0.1 hPa (≤0 mm Hg) @ 20°C (68 °F)
Vapor density	No Data available
Relative density	No Data available
Solubility	Fully Soluble in water.
Partition coefficient — n-octanol/water	Not determined.
Auto-ignition temperature	Product is not self-igniting.
Decomposition temperature	Not determined.
Viscosity	Not determined.

Additional properties

Physical state

Explosive properties

Product does not present an explosion hazard.

Supplemental information regarding physical hazard classes

Explosion limits:

Lower: ≥2.6 Vol %

Upper: ≤12.6 Vol %

Vapor pressure @ 20°C (68 °F): ≤0.1 hPa (≤0 mm Hg)

Density:

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

Solvent content:

VOC content: 0.00 %

Solids content: 61-95 %

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Other information: No further relevant information available.

Further safety characteristics (supplemental)

No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid.

Avoid direct contact with sunlight and ultraviolet light.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:		
57-55-6 Propylene Glycol		
Oral	LD50	20,000 mg/kg (Rat)
Dermal	LD50	20,800 mg/kg (Rabbit)
Inhalative	LC50/96 hours Intravenous	52,930 mg/l (Pimephales)
		6,630 mg/kg (Mouse)
		6,423 mg/kg (Rat)
		6,500 mg/kg (Rabbit)
60-00-4 Edetic acid		
Oral	LD50	4,500 mg/kg (Rat)
36653-82-4 Cetyl alcohol		
	LD50	5,000 mg/kg (Rat)

Primary irritant effect:

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Skin corrosion/irritation

Corrosive effect on skin and mucous membranes. Corrosive to skin and mucous membranes.

Serious eye damage/irritation

Irritating effect. Corrosive effect.

Additional information

Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Corrosive

Swallowing will lead to a corrosive effect on mouth and throat and to the danger of perforation of esophagus and stomach.

Carcinogenic categories:

IARC (International Agency for Research on Cancer): None of the ingredients are listed.

NTP (National Toxicology Program): None of the ingredients are listed.

OSHA-Ca (Occupational Safety & Health Administration): None of the ingredients are listed.

SECTION 12: Ecological information

Toxicity:

Aquatic toxicity:	
57-55-6 Propylene Glycol	
EC50	>10,000 mg/l (Daphnia)

Persistence and degradability

No further relevant information available.

Bioaccumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

Results of PBT and vPvB assessment

Not applicable.

Other adverse effects

No further relevant information available.

Additional ecological information:

General notes:

Do not allow product to reach ground water, water course or sewage system. Must not reach bodies of water or drainage ditch undiluted or unneutralized. Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal considerations

Disposal methods

Product disposal

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Observe all federal, state, and local environmental regulations when disposing of this material.

Packaging disposal

Observe all federal, state, and local environmental regulations when disposing of this material.

Uncleaned packaging's

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

DOT (US) or use alt. title:

UN Number: Non-Regulated Material

Class: Non-Regulated Material

Packing Group:

Proper Shipping Name: Non-Regulated Material

Reportable quantity (RQ):

Marine pollutant:

Poison inhalation hazard:

IMDG

UN Number: Non-Regulated Material

Class: Non-Regulated Material

Packing Group:

EMS Number:

Proper Shipping Name:

IATA

UN Number: Non-Regulated Material

Class: Non-Regulated Material

Packing Group: Non-Regulated Material

Proper Shipping Name:

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

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

SARA (Superfund Amendments and Reauthorization):

SARA 313 Components

None of the ingredients are listed.

Section 355 (extremely hazardous substances)

None of the ingredients are listed.

Toxic Substances Control Act (TSCA) Inventory

All ingredients are listed or exempt from listing.

California Proposition 65:

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Chemicals known to cause cancer: None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients are listed.

Chemicals known to cause developmental toxicity: None of the ingredients are listed.

New Jersey Right To Know Components

25322-68-3	Polyethylene Glycol
57-55-6	Propylene Glycol
60-00-4	Edetic Acid
124-43-6	Carbamide Peroxide

New Jersey Special Hazardous Substance List:

None of the ingredients are listed.

Pennsylvania Right To Know Components

25322-68-3	Polyethylene Glycol
57-55-6	Propylene Glycol
60-00-4	Edetic Acid

Pennsylvania Special Hazardous Substance List:

60-00-4	Edetic Acid
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Carcinogenic categories:

EPA (Environmental Protection Agency):

None of the ingredients are listed.

TLV (Threshold Limit Value established by ACGIH):

None of the ingredients are listed.

NIOSH-Ca (National Institute for Occupational Safety and Health):

None of the ingredients are listed.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

National regulations: None of the ingredients are listed.

SECTION 16: Other information

Premier's revision date: 05-OCTOBER-2023

Revision #:

Abbreviations and acronyms:

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

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

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DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Ox. Sol. 3: Oxidizing solids – Category 3

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B

16.1 Further information/disclaimer

The information contained herein is based on our present knowledge. However, this information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Premier Dental Products Company makes no warranties, express or implied with respect to, and assumes no responsibility or liability for, the accuracy or completeness of the information contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

16.2 Preparation information

Manufacturer's/Supplier's Number: 090117