

Safety Data Sheet

RC-Prep® - Root Canal Preparation Cream

1. Identification

Product Identifier:

Trade name: RC-Prep®

Relevant identified uses of the substance or mixture and uses advised against: For dental professionals use only.

Product Description For Preparation of Root Canal

Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier:

Premier Dental Products Co.
1710 Romano Drive
Plymouth Meeting, PA 19462
Ph: 610-239-6000
Fx: 610-239-6171

Emergency telephone number: 610-239-6000

2. Hazard(s) Identification

Classification of the substance or mixture:



GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2B H320 Causes eye irritation.

Label elements:

GHS label elements

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

Hazard pictograms:



GHS07

Signal word: Warning

Hazard statements:

H315+H320 Causes skin and eye irritation.

Precautionary statements:

P264	Wash thoroughly after handling.
P280	Wear protective gloves.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

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
Reactivity = 0

HMIS-ratings (scale 0 - 4)

HEALTH	1
FIRE	0
REACTIVITY	0

Health = 1
Fire = 0
Reactivity = 0

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

3. Composition/Information on Ingredients

Chemical characterization: Mixtures

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

Dangerous Components:		
CAS: 57-55-6 RTECS: TY 2000000	Propylene Glycol	Not specified
CAS: 60-00-4 RTECS: AH 4375000	Edetic acid ⚠ Eye Irrit. 2A, H319	10-30%
CAS: 124-43-6 RTECS: YT 4850000	Carbamide Peroxide ⚠ Ox. Sol. 3, H272; ⚠ Skin Corr. 1B, H314; Eye Dam. 1, H318	1-10%
CAS: 36653-82-4 RTECS: MM 0225000	Cetyl alcohol ⚠ Skin Irrit. 2, H315; Eye Irrit. 2B, H320	1-10%

Additional information:

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.

4. First-Aid Measures

Description of first aid measures:

After inhalation: In case of unconsciousness place patient stably in side position for transportation.

After skin contact: If skin irritation occurs, consult a doctor.

After 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.

After swallowing: Rinse mouth with water.

Information for doctor:

Most important symptoms and effects, both acute and delayed: No further relevant information available.

Indication of any immediate medical attention and special treatment needed:

No further relevant information available.

5. Fire-Fighting Measures

Extinguishing media:

Suitable extinguishing agents: Use fire-fighting measures that suit the environment.

Special hazards arising from the substance or mixture: No further relevant information available.

Advice for firefighters:

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.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

Wear protective equipment. Keep unprotected persons away.

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

Methods and material 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 regulations.

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

7. Handling and Storage

Handling

Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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

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.

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 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.

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 of work.

Avoid contact with the eyes and skin.

Breathing equipment: Not required.

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.

Eye Protection:

Safety glasses

9. Physical and Chemical Properties**Information on basic physical and chemical properties****General Information****Appearance:**

Form:	Paste
Color:	White
Odor:	Odorless
Odor threshold:	Not determined.
pH-value:	Not applicable.

Change in condition

Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	≥185 °C (≥365 °F)

Flash point:	≥103 °C (≥217 °F)
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Flammability (solid, gaseous):	Not applicable.
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Ignition temperature:	Not applicable
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Decomposition temperature:	Not determined.
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Auto igniting:	Product is not self-igniting.
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Danger of explosion:	Product does not present an explosion hazard.
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Explosion limits:

Lower:	≥2.6 Vol %
Upper:	≤12.6 Vol %

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

Relative density:	Not determined.
Vapor density:	Not determined.
Evaporation rate:	Not determined.

Solubility in / Miscibility with:

Water:	Fully Soluble
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Partition coefficient (n-octanol/water):	Not determined.
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Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

Solvent content:

VOC content:	0.00 %
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Solids content:	61-95 %
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Other information:	No further relevant information available.
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10. Stability and Reactivity

Reactivity: No further relevant information available.

Chemical stability: Stable under normal conditions.

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

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: Avoid direct contact with sunlight and ultraviolet light.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

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	52,930 mg/l (Pimephales)
	Intravenous	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		
Oral	LD50	5,000 mg/kg (Rat)

Primary irritant effect:

On the skin:

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

On the eye:

Irritating effect. Corrosive effect.

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.

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.

Behavior in environmental systems:

Bioaccumulative potential: No further relevant information available.

Mobility in soil: 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.

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects: No further relevant information available.

13. Disposal Considerations

Waste treatment methods:

Recommendation:

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

Uncleaned packagings

Recommendation: Disposal must be made according to official regulations.

14. Transport Information

UN-Number:

DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

UN proper shipping name:

DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

Transport hazard class(es):

DOT, ADR/ADN, ADN, IMDG, IATA

Class: Non-Regulated Material

Packing group:

DOT, ADR/ADN, IMDG, IATA Non-Regulated Material

Environmental hazards:

Not applicable.

Special precautions for user:

Not applicable.

Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code:

Not applicable.

UN "Model Regulation":

Non-Regulated Material

15. Regulatory Information

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

SARA (Superfund Amendments and Reauthorization):

Section 355 (extremely hazardous substances):

None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

TSCA (Toxic Substances Control Act):

All ingredients are listed or exempt from listing.

California Proposition 65:

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 List:

25322-68-3	Polyethylene Glycol
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57-55-6	Propylene Glycol
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60-00-4	Edetic acid
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124-43-6	Carbamide Peroxide
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New Jersey Special Hazardous Substance List:

None of the ingredients are listed.

Pennsylvania Right-to-Know List:

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

GHS label elements

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

Hazard pictograms:

GHS07

Signal word: Warning**Hazard statements:**

H315+H320 Causes skin and eye irritation.

Precautionary statements:

P264 Wash thoroughly after handling.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
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P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

National regulations:

None of the ingredients are listed.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**16. Other Information****Premier's revision date:** 10/26/2017**Revision Number:** 11**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
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

· * **Data compared to the previous version altered.**

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Supplier's Number: 090117

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