

Safety Data Sheet

Perfecta[®] (Unflavored) Carbamide Peroxide (11% to 21%)

1. Identification

Product Name: Perfecta[®] Dental Tooth Whitening Gel
Premier[®] Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA 19462
Phone: 610-239-6000 Fax: 610-239-6171
Emergency Phone: 610-239-6000

Recommended Use: Tooth Whitening Gel

Restrictions for Use: Not recommended for pregnant or lactating women

2. Hazard Identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

Danger symbols: Xi

R phrases: R36/38

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s)



Irritant

R&S statement(s): R36/38: Irritating to eyes and skin.

2.3. Other hazards

3. Composition/Information on Ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC
Carbamide Peroxide	000124-43-6	204-701-4	< 25	Xi; R36
[Tris(Hydroxymethyl) Aminomethane]	77-86-1	201-064-4	< 5	Xi; R36/37/38

For full text of H-statements and R-phrases: see SECTION 16.

4. First-Aid Measures

4.1. Description of first aid measures

Following eyes: Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

Following skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion: If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects both acute and delayed

Eyes: Irritating to eyes.

Skin: May cause skin irritation.

Ingestion: May be harmful if swallowed in large quantities.

Inhalation: None Expected.

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

5. Fire-Fighting Measures

5.1. Extinguishing media

Extinguishing media: Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Explosion hazards: Not Determined

Fire explosion: Not Determined

Sensitive to static discharge: Not Determined

Sensitivity to impact: Not Determined

5.3. Advice for firefighters

Fire fighting procedures: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

Fire-fighting equipment: Water spray only.

6. Accidental Release Measures

6.1. Personal precautions protective equipment and emergency procedures

General procedures: Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill: Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill: Wipe up with cloth, soap and water.

Large spill: Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections: Not Applicable

7. Handling and Storage

7.1. Precautions for safe handling

General procedures: Avoid contact with eyes, skin and clothing.

Handling: Use suitable protective equipment.

Storage: Keep refrigerated.

7.2. Conditions for safe storage including any incompatibilities

Shelf life: See product labeling

7.3. Specific end use(s)

Specific end use(s): Dental Teeth Whitening Gel

8. Exposure Controls/Personal Protection

8.1. Control parameters

Control parameters: Not Determined

8.2. Exposure controls

Eye/face protection: Wear eye protection

Skin protection: S36/37: Wear suitable protective clothing and gloves.

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state: Clear gel

Color: Colorless

Odor: Flavor dependent

pH: 5.4 to 7.2

Solubility in water: Partially Soluble

9.2. Other information

Percent volatile: Not Determined

10. Stability and Reactivity

10.1. Reactivity

Stable: Yes

10.2. Chemical stability

Chemical stability: Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization: No

10.4. Conditions to avoid

Conditions to avoid: Avoid strong bases, metals. Excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials: Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products: None known.

11. Toxicological Information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀: Not Determined

Oral LD₅₀: Not Determined

Inhalation LC₅₀: Not Determined

12. Ecological Information

12.1. Toxicity

Toxicity: Not yet Determined

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

96-hour LC₅₀: Not Determined

48-hour EC₅₀: Not Determined

96-hour EC₅₀: Not Determined

12.2. Persistence and degradability

Persistence and degradability: Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential: Not Determined

12.4. Mobility in soil

Mobility in soil: Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: Not Determined

12.6. Other adverse effects

Environmental data: Not Available

13. Disposal Considerations

13.1. Waste treatment methods

Disposal method: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

14. Transportation Information

14.1. UN number

UN number: N/A

14.2. UN proper shipping name

UN proper shipping name: Not classified

14.3. Transport hazard class(es)

Primary hazard class/division: N/A

14.4. Packing group

14.5. Environmental hazards

Marine pollutant #1: N/A

14.6. Special precautions for user

ADR – road: N/A

RID – rail: N/A

IMDG – sea: N/A

IATA – air: N/A

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk: N/A

15. Regulatory Information

15.1. Safety health and environmental regulations/legislation specific for the substance or mixture

RoHS: Please refer to Regulation 1223/2009 on Cosmetics

15.2. Chemical safety assessment

Chemical safety assessment: Not Determined

16. Other Information

Relevant R-phrases and/or Hstatements(number and full text):

R36/37/38: Irritating to eyes, respiratory system and skin.

R36: Irritating to eyes.

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