

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

Date Issued: 01/10/2013  
Date-Revised: 05/26/2015  
Revision No: 2

## SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

### MANUFACTURER

PAC-DENT INTERNATIONAL, INC.  
670 ENDEAVOR CIRCLE  
BREA, CA 92821  
Telephone: 909-839-0888  
Hours: Mon.- Fri. 9:00 am. - 5:30 pm. P.S.T.

**PRODUCT NAME:** 6-12%HP Take-Home Tooth Whitening Gel

**PRODUCT USE:** Tooth Whitening

*The following information is provided with regard to the toxicity and hazards the pure components present in this product.*

## SECTION 2 - HAZARDS IDENTIFICATION

### 2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

**CLASSIFICATION ACCORDING TO DIRECTIVE 1999/45/EC:** The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**DANGER SYMBOLS:** Xi

**R PHRASES:** R36/38

**CLASSIFICATION ACCORDING TO REGULATION (EC) No 1272/2008 [CLP]**

**HEALTH:** Eye Irritation, Category 2

Skin Irritation, Category 2

### 2.2. LABEL ELEMENTS

This mixture contains Hydrogen Peroxide, Potassium Nitrate, Sodium Hydroxide, and Sodium Fluoride. These materials are considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1819.1200)

**CLASSIFICATION ACCORDING TO DIRECTIVE 1999/45/EC**

**HAZARD PICTOGRAM(S):**



Irritant

**R&S STATEMENT(S):** R36/38: Irritating to eyes and skin.

**CLASSIFICATION ACCORDING TO REGULATION (EC) No 1272/2008 [CLP]**

**HAZARD PICTOGRAM(S)**



Exclamation  
mark

**SIGNAL WORD:** WARNING

**HAZARD STATEMENT(S):** H315: Causes skin irritation.

**PRECAUTIONARY STATEMENT(S)**

**PREVENTION:** P280: Wear protective gloves/protective clothing/eye protection/face protection.

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**RESPONSE:** P305: IF IN EYES:  
P351: Rinse cautiously with water for several minutes.  
P315: Get immediate medical advice/attention.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P332+P313: If skin irritation occurs: Get medical advice/attention.

**STORAGE:** P273: Avoid release to the environment.

**DISPOSAL:** P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

## 2.3. OTHER HAZARDS

**IMMEDIATE CONCERNS:** No other adverse human effects.

## SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

COMPONENT	C.A.S.	EINECS No.	%	CLASSIFICATION ACCORDING TO DIRECTIVE 67/548/EEC	CLASSIFICATION ACCORDING TO REGULATION (EC) No 1272/2008[CLP]
Hydrogen Peroxide	7722-84-1	231-765-0	<13.0	O, Xi; R41; R37/38	Oxid. Liq.,Cat. 1; Acute Tox. (O),Cat. 4; Skin Corr.,Cat. 1A; H271; H314; H302; H332
Potassium Nitrate	7757-79-1	231-818-8	<5	O, Xi; R36/37/38; R22	H271; H272; H302; H315; H319; H335; H361; H371; H373
Sodium Hydroxide	1310-73-2	215-185-5	<5	C; R34	Skin Corr.,Cat. 1A; Acute Tox. (D),Cat. 4; H302; H314
Sodium Fluoride	7681-49-4	231-667-8	0.1-1.0	T, Xi; R25; R32; R36/38	Acute Tox. (O),Cat. 3; Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; H301; H315; H319

## SECTION 4 - FIRST AID MEASURES

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. If irritation persists, seek medical attention.

**SKIN CONTACT:** Flush eyes with plenty of water for at least 15 minutes.

**INGESTION:** Do not induce vomiting. Give plenty of water. If abdominal discomfort persists, seek medical attention.

**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.

### **MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**

**EYE CONTACT:** Irritating to eyes.

**SKIN CONTACT:** May cause skin irritation.

**INGESTION:** Maybe harmful if swallowed in large quantities.

**INHALATION:** None expected for this product.

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## SECTION 5 - FIRE FIGHTING MEASURES

**FLASH POINT:** N.E. **FLAMMABLE LIMITS:** N.E.  
**EXTINGUISHING MEDIA:** Water spray, or carbon dioxide  
**SPECIAL FIRE FIGHTING PROCEDURES:** None  
**UNUSUAL FIRE AND EXPLOSION HAZARDS:** None  
**HAZARDOUS COMBUSTION PRODUCTS:** None

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**IN CASE OF RELEASE OR SPILL:** For small spills, collect material and dispose per federal, state and local regulations. For larger spills, isolate area which may present a slip hazard. Sweep or collect material and dispose per federal, state and local regulations.

## SECTION 7 - HANDLING AND STORAGE

**HANDLING:** Avoid contact with eyes, skin and clothing. Use suitable protective equipment.  
**STORAGE:** Keep container in a cool, well-ventilated area. Keep container closed when not in use. Keep away from heat. Avoid exposure to direct sunlight.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**ENGINEERING CONTROLS:** Not applicable.  
**RESPIRATORY PROTECTION:** Not required.  
**VENTILATION:** Not required.  
**PROTECTIVE GLOVES:** Disposable vinyl gloves recommended.  
**EYE PROTECTION:** Safety glasses recommended.  
**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N.A.  
**WORK/HYGIENIC PRACTICE:** Observe good hygienic work practices.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

<b>BOILING POINT:</b>	N.E.	<b>SPECIFIC GRAVITY:</b>	>1 (H <sub>2</sub> O=1)
<b>VAPOR PRESSURE:</b>	N.E.	<b>MELTING POINT:</b>	N.E.
<b>VAPOR DENSITY:</b>	N.E.	<b>EVAPORATION RATE:</b>	N.E.
<b>SOLUBILITY IN WATER:</b>	Miscible	<b>APPEARANCE AND ODOR:</b>	Translucent to waxy gel with mint odor
<b>PERCENT VOLATILE BY VOLUME:</b>	N.E.		

## SECTION 10 - STABILITY AND REACTIVITY

**STABILITY:** Stable when stored and handled under recommended conditions.  
**CONDITIONS TO AVOID:** Avoid strong bases, Metals. Excess heat, exposure to moist air or water.  
**INCOMPATIBILITY (Materials to Avoid):** Strong caustics, most metals.

## SECTION 11 - TOXICOLOGICAL INFORMATION

**ROUTE OF ENTRY:** Skin contact, eye contact, ingestion.  
**SENSITIZATION:** Not defined.  
**EFFECTS AND SYMPTOMS OF SHORT-TERM EXPOSURE:** Skin: irritation; eyes: irritation; ingestion: irritation  
**CHRONIC EFFECTS AND SYMPTOMS OF LONG-TERM EXPOSURE:** Skin: irritation; eyes: irritation; ingestion: irritation

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## SECTION 12 - ECOLOGICAL INFORMATION

**AQUATIC TOXICITY (ACUTE):** Do not allow to enter sewers or drains that may lead to waterways.

**PERSISTENCE/DEGRADABILITY:** There is no environmental stability data for any component of this product at this time.

**BIOACCUMULATION/ACCUMULATION:** There is no accumulation data for any component of this product at this time

## SECTION 13 - DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL METHOD:** Dispose of container in accordance with local, state and federal guidelines.

## SECTION 14 - TRANSPORT INFORMATION

### ROAD AND RAIL (ADR/RID)

<b>PROPER SHIPPING NAME:</b>	Not Dangerous Goods
<b>UN NUMBER:</b>	N/A
<b>HAZARD CLASS:</b>	N/A
<b>PACKAGING GROUP:</b>	N/A

### AIR (ICAO/IATA)

<b>PROPER SHIPPING NAME:</b>	Not Dangerous Goods
<b>UN/NA NUMBER:</b>	N/A
<b>PRIMARY HAZARD CLASS/DIVISION:</b>	N/A
<b>PACKAGING GROUP:</b>	N/A

### VESSEL (IMO/IMDG)

<b>PROPER SHIPPING NAME:</b>	Not Dangerous Goods
<b>UN/NA NUMBER:</b>	N/A
<b>PRIMARY HAZARD CLASS/DIVISION:</b>	N/A
<b>PACKAGING GROUP:</b>	N/A

## SECTION 15 - REGULATORY INFORMATION

**RoHS:** Please refer to Regulation 1223/2009 on Cosmetics

## SECTION 16 - OTHER INFORMATION

### RELEVANT R-PHRASES AND/OR H-STATEMENTS (NUMBER AND FULL TEXT):

R25: Toxic if swallowed.  
R32: Contact with acids liberates very toxic gas.  
R34: Causes burns.  
R36/37/38: Irritating to eyes, respiratory system and skin.  
R36/38: Irritating to eyes and skin.  
R36: Irritating to eyes. Skin Irr., Cat. 2: Skin Irritation, Category 2  
H226: Flammable liquid and vapour.  
H272: May intensify fire; oxidizer.  
H290: May be corrosive to metals.  
H301: Toxic if swallowed.  
H302: Harmful if swallowed.  
H312: Harmful in contact with skin.

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H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

H340: May cause genetic defects .

H350: May cause cancer .

H400: Very toxic to aquatic life.

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**N.A. = NOT APPLICABLE**

**N.E. = NOT ESTABLISHED**

**FOR DENTAL USE ONLY: Use as directed.**

*This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use.*

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