



## Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC)  
1907/2006, Regulation (EC) 1272/2008 and Regulation  
(EC) 453/2010)

Document Number: SDS-116.002  
Date Revised: 03/31/2016

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product Identifier:

Trade Name (as labeled):  
Product Form  
Part/Item Number:

Prophy Powder – Mint Flavored  
Mixture  
562-1100-002

#### 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:

In-office stain removal product and preparation of  
tooth surfaces for bonding/sealing procedures.

Restrictions on Use:

For Professional Use Only

#### 1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:  
Manufacturer/Supplier Address:

Prophy Choice, LLC  
2730 Spencer Road  
Rock Stream, NY

Manufacturer/Supplier Telephone Number:  
Email address:

888-776-7492 (Product Information)  
[Sales@ProphyChoice.com](mailto:Sales@ProphyChoice.com)

#### 1.4 Emergency Telephone Number:

Transportation Emergency Number:

Chemtrec  
800-424-9300 (USA)  
001-703-527-3887 (Outside USA)

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not a dangerous preparation.

#### 2.2 Label Elements: Signal

Word: None

Hazard Phrases	Precautionary Phrases
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None Required

None Required

**2.3 Other Hazards:** None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-Hazardous Ingredients (contains sodium bicarbonate)	Proprietary	Proprietary	Not Applicable	100

The exact concentration is being withheld as a trade secret. Refer to Section 16 for the full text of the GHS and EU Classifications.

### 4. FIRST AID MEASURES

#### 4.1 Description of First Aid Measures:

<b>Eye</b>	Flush victim's eyes with water, while holding the eyelids apart. Get medical attention if irritation occurs and persists.
<b>Skin</b>	Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
<b>Inhalation</b>	Remove victim to fresh air.
<b>Ingestion</b>	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if you feel unwell.

#### 4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Dust may cause mechanical irritation to skin and eyes. Inhalation of dust may cause upper respiratory tract irritation. If swallowed, may cause gastrointestinal irritation.

#### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is not required.

**Note to Physicians (Treatment, Testing, and Monitoring):** Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing Media:

Use water spray, carbon dioxide or dry chemical.





#### 5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release oxides of carbon.

#### 5.3 Advice for Fire-Fighters:

##### Fire Fighting Procedures:

Use water to cool exposed containers and structures.

<b>Precautions for Fire Fighters:</b>	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.		
<b>Recommended Protective Equipment for Fire Fighters:</b>			
<b>EYES/FACE</b>	<b>HANDS</b>	<b>RESPIRATORY</b>	<b>THERMAL</b>
			

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes and skin. Avoid breathing dust. Wear appropriate protective clothing as described in Section 8. For

dusty conditions wear suitable respiratory equipment.

#### Recommended Personal Protective Equipment for Containment and Clean-up:

<b>EYES/FACE</b>	<b>HANDS</b>	<b>RESPIRATORY</b>	<b>SKIN</b>

### 6.3 Methods and Material for Containment and Cleaning up:

Sweep or vacuum up, taking care not to generate airborne dust and place in appropriate container for use. Do not use compressed air.

### 6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

### 6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe Handling:

Avoid contact with eyes and skin. Avoid breathing dust. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation.

Empty containers retaining product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

### 7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a dry, well-ventilated area away from acids or other incompatible materials. Keep container closed when not in use.

### 7.3 Specific End Use (s): For professional use only.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control Parameters:

#### Occupational Exposure Limits:

Non-hazardous Ingredients (contains sodium bicarbonate)	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

**Biological Exposure Limits:** None Established

### 8.2 Exposure Controls:

**Appropriate Engineering Controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels.

#### Individual Protection Measures (PPE):

**Specific Eye/face Protection:** Not required under normal conditions of use.

**Specific Skin Protection:** Not required under normal conditions of use.

**Specific Respiratory Protection:** Not required under normal conditions of use. If the exposure limits are excessive, an approved respirator with dust/mist cartridges or supplied air respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

**Specific Thermal Hazards:** None required.

#### Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

<b>Appearance:</b>	White powder	<b>Explosive limits:</b>	<b>LEL:</b> Not applicable <b>UEL:</b> Not applicable
<b>Odor:</b>	Minty odor	<b>Vapor pressure (mmHg):</b>	Not applicable
<b>Odor threshold:</b>	Not determined	<b>Vapor density:</b>	Not applicable
<b>pH:</b>	8.2	<b>Relative density:</b>	2.2
<b>Melting/freezing point:</b>	Not determined	<b>Solubility(ies):</b>	8.6 g/100 ml @ 154.4°C (68°F)
<b>Initial boiling point and boiling range:</b>	Not applicable	<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Flash point:</b>	Not applicable	<b>Auto-ignition temperature:</b>	Not applicable
<b>Evaporation rate:</b>	Not applicable	<b>Decomposition temperature:</b>	35°C (95°F)
<b>Flammability (solid, gas):</b>	Not flammable	<b>Viscosity:</b>	Not determined
<b>Explosive Properties:</b>	Not explosive	<b>Oxidizing Properties:</b>	Not an oxidizer

**9.2 Other Information:** None available

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** None known.

**10.2 Chemical Stability:** Stable under normal condition.

**10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**10.4 Conditions to Avoid:** Product will begin to decompose at temperatures greater than 95°F (35°C) releasing carbon dioxide.

**10.5 Incompatible materials:** Avoid acids.

**10.6 Hazardous Decomposition Products:** Thermal decomposition may release oxides of carbon.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

#### **Potential Health Effects:**

Eyes: Dust may cause mild irritation with redness and tearing.

Skin: Prolonged or repeated contact with moist skin may cause mild irritation.

Ingestion: Ingestion of large amounts may cause gastric distension, flatulence and nausea.

Inhalation: Inhalation of dust may cause slight irritation of the nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.

**Chronic Health Effects:** Prolonged ingestion of large amounts may cause systemic alkalosis.

**Irritation:** Sodium bicarbonate is slightly irritating to rabbit skin and eyes.

**Corrosivity:** No data available. Product is not expected to be corrosive.

**Sensitization:** Product is not known to cause sensitization.

#### **Carcinogenicity:**

None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

**Mutagenicity:** No data available.

#### **Medical Conditions Aggravated by Exposure:**

Individuals with pre-existing eye and respiratory disorders may be at increased risk from exposure.

#### **Acute Toxicity Data:**

Sodium Bicarbonate: Oral rat LD50: >4000 mg/kg; Inhalation rat LC50: >4.74 mg/L/air/4.5hr

**Reproductive Toxicity Data:** No data available.

#### **Specific Target Organ Toxicity (STOT):**

Single Exposure: No data available.

Repeated Exposure: No data available.

## 12. ECOLOGICAL INFORMATION

### **12.1 Toxicity:**

Sodium Bicarbonate: Lepomis macrochirus 96hr LC50: 7100 mg/L; Daphnia magna 48hr EC50: 4100 mg/L

**12.2 Persistence and Degradability:** No data is currently available

**12.3 Bio-accumulative Potential:** No data is currently available

**12.4 Mobility in Soil:** No data is currently available

**12.5 Results of PBT and vPvB Assessment:** Not applicable.

**12.6 Other Adverse Effects:** None

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste Treatment Methods:

<b>Regulations:</b> Dispose in accordance with all national and local regulations.
<b>Properties (Physical/Chemical) Affecting Disposal:</b> Empty containers retaining product residues and can be hazardous. Follow all SDS precautions when handling empty containers.
<b>Waste Treatment Recommendations:</b> Dispose in accordance with national and local regulations.

### 14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
<b>DOT</b>	None	Not Regulated	None	None	Not applicable
<b>ADR/RID</b>	None	Not Regulated	None	None	Not applicable
<b>IMDG</b>	None	Not Regulated	None	None	Not applicable
<b>IATA/ICAO</b>	None	Not Regulated	None	None	Not applicable

**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.

### 15. REGULATORY INFORMATION

#### 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

##### U.S. Federal Regulations

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

**Toxic Substances Control Act (TSCA):** This product is a medical device and not subject to chemical notification requirements.

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act.

##### **Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

##### **SARA Section 311/312 (40 CFR 370) Hazard Categories:**

<b>Immediate Hazard:</b>	No	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	No	<b>Reactivity Hazard:</b>	No

<b>Fire Hazard:</b>	<b>No</b>
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**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
None		

**State Regulations**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
None		

**International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Medical devices are not subject to WHMIS.

**Canadian Environmental Protection Act:** This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

**European Inventory of Existing Chemicals (EINECS):** This product is a medical device and not subject to chemical notification requirements.

**EU REACH:** All components requiring registration have been pre-registered.

**Australian Inventory of Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**China Inventory of Existing Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Japanese Existing and New Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Korean Existing Chemicals List:** This product is a medical device and not subject to chemical notification requirements.



**Philippine Inventory of Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**15.2 Chemical Safety Assessment:** None required.

## 16. OTHER INFORMATION

HMIS Hazard Rating:

Health: 1		Flammability: 0	Reactivity: 0
Health Hazard	1		
Fire Hazard	0		
Reactivity	0		

Supersedes: September 30, 2014

Date updated: March 31, 2016

Change Control Document #: DCN4720

Revision Summary: March 31, 2016: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Manufacturer disclaimer:

FOR DENTAL USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

