

MATERIAL SAFETY DATA SHEET

PRODUCT NAME: 22% Carbamide Peroxide Teeth Whitening Gel
June 15, 2015

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APPEARANCE AND ODOR Clear thick gel, slight orange mint odor	VAPOR PRESSURE 0.08 mm Hg @ 20° C
pH 5.0 - 6.0	SPECIFIC GRAVITY (WATER = 1) 1.063
BOILING POINT / BOILING RANGE 369° F (187° C)	SOLUBILITY IN WATER Complete
FLASH POINT 210° F (98.9° C)	VISCOSITY Gel
FLAMMABLE LIMITS LEL: 2.6% UEL: 12.5%	VAPOR DENSITY (AIR = 1) 2.62
AUTOIGNITION TEMPERATURE 779° F (415° C)	EVAPORATION RATE (WATER = 1) < 0.1

STABILITY	UNSTABLE: STABLE: XXX	CONDITIONS TO AVOID: Extreme temperatures
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INCOMPATIBILITY (MATERIALS TO AVOID): Strong alkalis, strong acids.

HAZARDOUS DECOMPOSITION OR BYPRODUCTS: Decomposition will not occur if handled and stored properly. In case of a fire, oxides of carbon, hydrocarbons, fumes or vapors, and smoke may be produced.

HAZARDOUS POLYMERIZATION	MAY OCCUR: WILL NOT OCCUR: XXX	CONDITIONS TO AVOID: None
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Hazardous Components	CAS # EINECS #	LD50 of Ingredient (Specify Species and Route)	LC50 of Ingredient (Specify Species)
1,2-Propylene glycol (a)	57-55-6 200-338-0	20,000 mg / kg Oral - rat	Not established
Glycerine (b)	56-81-5 200-289-5	17,000 - 27,000 mg / kg Oral - rat	> 570 mg / m ³ / 1H Inhalation - rat
Carbamide Peroxide	124-43-6 7204-701-4	2000 mg / kg Oral - Mouse	2000 mg / m / 4 hours Inhalation - Rat
Spearmint Oil (c)	8006-90-4 282-015-4	> 5000 mg / kg Oral - rat	Not established

No data are available on the adverse effects of this material on the environment. Neither COD nor BOD data are available. Based on the chemical composition of this product it is assumed that the mixture can be treated in an acclimatized biological waste treatment plant system in limited quantities. However, such treatment should be evaluated and approved for each specific biological system. None of the ingredients in this mixture are classified as a Marine Pollutant.

SECTION 13 - DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with Local, State, and Federal Regulations. Product is classified as non - hazardous, however, non-hazardous materials may become hazardous waste upon contact with other products. Refer to "40 CFR Protection of Environment Parts 260 - 299" for complete waste disposal regulations. Consult your local, state, or Federal Environmental Protection Agency before disposing of any chemicals. According to the European Waste Catalogue, waste codes are application specific and should be assigned by the user based on the application for which the product is used.

SECTION 14 - TRANSPORT INFORMATION

PROPER SHIPPING NAME: Non - Hazardous for Transport DOT HAZARD CLASS / Packaging Group: Not regulated REFERENCE: Not Applicable UN / NA IDENTIFICATION NUMBER: None LABEL: None Required HAZARD SYMBOLS: None	IATA HAZARD CLASS / Packaging Group: Not regulated IMDG HAZARD CLASS: Not regulated RID / ADR Dangerous Goods Code: Not regulated UN TDG Class / Packaging Group: Not regulated Hazard Identification Number (HIN): None
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Note: Transportation information provided is for reference only. Client is urged to consult CFR 49 parts 100 - 177, IMDG, IATA, EU, United Nations TDG, and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

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TSCA (USA - Toxic Substance Control Act)

All components of this product are listed on the U.S. Toxic Substances Control Act Chemical Inventory (TSCA Inventory) or are exempted from listing because a Low Volume or Polymer Exemption has been granted in accordance with 40 CFR 723.50.

SARA TITLE III (USA - Superfund Amendments and Reauthorization Act)

311/312 Hazard Categories
 None

313 Reportable Ingredients:
 None

CERCLA (USA - Comprehensive Response Compensation and Liability Act)

None

California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986

There are no chemicals present known to the state of California to cause cancer or reproductive toxicity.

CPR (Canadian Controlled Products Regulations)

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations. WHMIS Classification: Not controlled

IDL (Canadian Ingredient Disclosure List)

Components of this product identified by CAS number and listed on the Canadian Ingredient Disclosure List are shown in Section 2.

DSL / NDSL (Canadian Domestic Substances List / Non-Domestic Substances List)

Components of this product identified by CAS number are listed on the DSL or NDSL, or are otherwise in compliance with the New Substances Notification (NSN) regulations. Only ingredients classified as "hazardous" are listed in Section 2 unless otherwise indicated.

EINECS (European Inventory of Existing Commercial Chemical Substances)

Components of this product identified by CAS numbers are on the European Inventory of Existing Commercial Chemical Substances.

WGK Water Quality Index: 1

VbK Index: A III

RISK PHRASES:

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

SYMBOL(S) REQUIRED FOR LABEL

Irritant



SAFETY PHRASES:

S2 Keep out of the reach of children.
 S25 Avoid contact with eyes.

SECTION 16 - OTHER INFORMATION

Notes & full R-Phrase text

R10 Flammable.
 R36/37/38 Irritating to eyes, respiratory system and skin.
 R43 May cause sensitization by skin contact.

HMIS HAZARD RATINGS

HEALTH	1	* = Chronic Health Hazard	2 = MODERATE
FLAMMABILITY	1	0 = INSIGNIFICANT	3 = HIGH
PHYSICAL HAZARD	0	1 = SLIGHT	4 = EXTREME
PERSONAL PROTECTIVE EQUIPMENT	A	None required	

REVISION SUMMARY:

This MSDS has been revised in the following sections: No revisions available

MSDS Prepared by: Comprehensive Data Base, Inc.
 P.O. Box 5604
 Lakeland, FL 33807 USA (863) 644 - 3298 www.compdatabase.com

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of need that information is current, applicable and suited to the circumstances of use. Vendor assumes no responsibility for injury to vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, vendor assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Any questions regarding this product should be directed to the manufacturer of the product as described in Section 1.



PSC Research Institute

Ethical Independent Clinical Studies

Certificate of Analysis

WHITENING RX 22% CARBAMIDE PEROXIDE TEETH WHITENING GEL

Manufactured in Delray Beach, FL USA

100% VEGAN CERTIFIED KOSHER/KOFK

GMO-FREE & GLUTEN-FREE

22% CP TEETH WHITENING GEL / SERUM

Lot CP22 1025

Date of Manufacture

10/05/2015

Date of Expire

10/25/2017

Lot Size

96 lbs.

DESCRIPTION

pH	6.75
Appearance	Thick Translucent Gel
Stability	2 Years
Color	Clear
Odor	Characteristic
Flavor	Characteristic
% Peroxide Concentration	11.85% (Equivalent to 35% Carbamide Peroxide)
% Potassium Nitrate	5.0%
Solubility	100% in Water

MICROBIOLOGICAL ANALYSIS

	<u>Specification Limits</u>	<u>Results</u>	<u>Unit of Measure</u>	<u>Test Method</u>
Total Bacterial Count	<100,000	982	CFU/grn	FDA-BAM 3.01 8 th Ed.
E. Coll	<10 Negative	<4 Negative	CFU/grn	PH. EUR. CAT 3B
S. Aureus	<10 Negative	<10 Negative	CFU/grm	PH. EUR. CAT 3B
P. Aeruginos	<10 Negative	Negative	per 25 gm	PH. EUR. CAT 3B
Yeast	<500	<300	CFU/grn	PH. EUR. CAT 3B
Mold	<500	<100	CFU/gm	PH. EUR. CAT 3B

EACH LOT TESTED FOR

Chloroform	0.05 ppm	None Detected	ppm	HPLC
Fluoride	1100 ppm	1100 ppm	ppm	HPLC
Diethyl Glycol	0.05 ppm	None Detected	ppm	HPLC
Sodium Carbonate	10,000 ppm	None Detected	ppm	HPLC

HEAVY METALS

Arsenic (As)	0.05 ppm	None Detected	ppm	ICP-MS
Cadmium (Cd)	0.05 ppm	None Detected	ppm	ICP-MS
Lead (Pb)	0.1 ppm	None Detected	ppm	ICP-MS
Chromium (Cr)	0.01 ppm	None Detected	ppm	ICP-MS

Date Reported: 10/25/2015

Signature:

Martin Giniger, DMD, PhD
Laboratory Manager
PSC Research Inc.