DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

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

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

1.1 Product Identifier:

1.1.1 Trade Name (as labeled):	**NUPRO® White Gold® Carbamide Peroxide (10% and 15%) Tooth Whitening Gel**
Part/Item Number:	**614056, 614057, 614059, 614060, 614061**
1.1.2 Trade Name (as labeled)	**Captivate by NUPRO™ Carbamide Peroxide (10% and 15%) Tooth Whitening Gel**
Part/Item Number:	**614064, 614065, 614066, 614067, 614068**

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

Recommended Use:	**Tooth Whitening Gel**
Restrictions on Use:	**For Professional Use Only. Do not use on persons hypersensitive to fluoride or other formula ingredients.**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	**DENTSPLY Professional**
Manufacturer/Supplier Address:	**1301 Smile Way**
	York, PA 17404
Manufacturer/Supplier Telephone Number:	**800-989-8826 or 717-767-8502 (Product Information)**
Email address:	**ProfessionalMSDS@dentsply.com**

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number:	**800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Eye Damage Category 1 (H318)	Not Hazardous	Not Hazardous

EU Classification: Irritant (Xi) R41

2.2 Label Elements:

Signal Word: Danger

Hazard Phrases	Precautionary Phrases
H318 Causes serious eye damage	P280 Wear eye protection and face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Glycerin	56-81-5	200-289-5	Not applicable	70-90
Carbamide Peroxide	124-43-6	204-701-4	C, O, R34, R8 Ox. Sol Cat 3 H272, Skin Corr. 1 H314	10-20
Sodium Fluoride*	7681-49-4	231-667-8	T, Xi R25, R32, R36/38 Acute Tox. Cat 3, H301 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315 EUH032	0.2

*** Only the 15% Carbamide Peroxide product contains sodium fluoride.**
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:	
Eye	Immediately flush eyes with plenty of water for at least 20 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Seek immediate medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation occurs. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if symptoms of exposure persist.
Ingestion	Do not induce vomiting. If conscious, give 8 ounces of water to dilute. Never give anything by mouth to an unconscious or convulsing person Get medical attention if symptoms develop.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
Direct contact may cause severe eye damage. May cause mild skin irritation. Inhalation may cause irritation of respiratory tract. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention is required for eye contact.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:
Decomposition may release oxides of carbon and nitrogen.

5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Use water to cool fire-exposed containers. Fight fire from safe distance or protected location.		
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Avoid contact with skin, eyes or clothing. Avoid breathing mists or vapors. Wear appropriate protective clothing.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

6.2 Environmental Precautions:
Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Report releases as required by local, state and federal 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 Handing:

Avoid contact with the eyes, skin, and clothing. Avoid breathing mists or vapors. Wear protective clothing and equipment. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Glycerin	United States	5 mg/m3 (Respirable fraction), 15 mg/m3 (Total Dust) TWA OSHA PEL (As mist)
	Germany	50 mg/m3 TWA 100 mg/m3 STEL DFG MAK (Inhalable)
	United Kingdom	10 mg/m3 TWA UK WEL
	European Union	Belgium: 10 mg/m3 TWA
Carbamide Peroxide	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Sodium Fluoride (As Flouride, F)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 TWA, 4 mg/m3 STEL DFG MAK (Inhalable, skin)
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL

Biological Exposure Limits:
Sodium Fluoride (as fluorides): Fluoride in urine, Prior to shift, 2 mg/L. Fluoride in urine, End of shift, 3 mg/L.

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles or safety glasses with side shields should be worn where splashing is possible.

Specific Skin Protection: Wear impervious gloves such as natural rubber if needed to avoid skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved respirator with particulate cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear to slightly translucent gel	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Characteristic minty odor	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Vapor density:**	Not determined
pH:	5.7-6.5	**Relative density:**	1.2-1.25
Melting/freezing point:	Not determined	**Solubility(ies):**	Completely soluble in water
Initial boiling point and boiling range:	Not determined	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	Not applicable	**Auto-ignition temperature:**	Not applicable
Evaporation rate:	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not applicable	**Viscosity:**	<1,000,000 cps
Explosive Properties:	Not explosive	**Oxidizing Properties:**	Not an oxidizer

9.2 Other Information: None

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

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

10.4 Conditions to Avoid: Avoid excessive heat and moisture

10.5 Incompatible materials: Avoid oxidizing agents and reducing agents.

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Direct contact may cause severe irritation or burns with redness, pain and tearing with possible corneal damage.
Skin: May cause irritation with localized redness, pain, and dryness. In a clinical study on gum tissue with fifty seven subjects, this product showed to be an effective tooth whitening product when administered properly under the supervision of a dentist with commonly reported side-effects of transient tooth sensitivity and minimal gingival sensitivity. Little or no change in tissue health was noted.
Ingestion: Swallowing large amounts may cause gastrointestinal irritation or burns with nausea, vomiting and diarrhea. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.
Inhalation: Inhalation of mists may cause irritation to the nose, throat and upper respiratory tract.

Chronic Health Effects: Repeated excessive exposures to glycerin may cause increased fat levels in the blood and damage to the kidney and liver. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Irritation: Studies on gum tissue indicated that this product is not irritating to skin.

Corrosivity: Carbamide peroxide is classified as being corrosive to the skin and eyes, however, human test data involving application of this product to the gums did not cause significant change to tissue health. Therefore the product is not classified as being corrosive to skin.

Sensitization: No data available. This product is not expected to cause sensitization.

Carcinogenicity: Glycerin: No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg. Sodium Fluoride: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis. Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Glycerin: Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m3/1 hr

Carbamide Peroxide: No data available

Sodium Fluoride: Oral Rat LD50- 32 mg/kg

ATE: Oral: 7,462 mg/kg, Inhalation: >322 mg/m3, Dermal: >11,000

Reproductive Toxicity Data: Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg. Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):

Single Exposure: Glycerin: When place into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salvation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation. In a clinical study with fifty seven subjects, this product showed to be an effective tooth whitening product when administered properly under the supervision of a dentist with commonly reported side-effects of transient tooth sensitivity and minimal gingival sensitivity. Little or no change in tissue health was noted.

Repeated Exposure: Glycerin: In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed. Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Glycerin: 24 hr LC50 Goldfish - >5000 mg/L; 48 hr EC50 Daphnia magna -10,000 mg/L
Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L

12.2 Persistence and Degradability: Glycerin is readily biodegradable (96% in 24 hours). Biodegradability does not apply to inorganic compounds.

12.3 Bio-accumulative Potential: Glycerin is not expected to bioconcentrate in fish and aquatic organisms.

12.4 Mobility in Soil: Glycerin: Very high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: No adverse effects are expected.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: 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
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	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 has a Reportable Quantity (RQ) of 500,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 0.2%). 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:

Immediate Hazard:	Yes	**Pressure Hazard:**	No
Delayed Hazard:	No	**Reactivity Hazard:**	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

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

Components	C.A.S. #	WT %
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: This product is a medical device and not subject to chemical notification requirements.

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 – 3 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
C Corrosive
O Oxidizer
T Toxic
Xi Irritant
R8 Contact with combustible material may cause fire
R25 Toxic if swallowed
R32 Contact with acids liberates very toxic gas.
R34 Causes burns
R36/38 Irritating to eyes and skin.
R41 Risk of serious damage to eyes.

Acute Tox 3 Acute Toxicity Category 3
Eye Dam Cat 1 Eye Damage Category 1
Eye Irrit Cat 2 Eye Irritant Category 2
Ox Sol Cat 3 Oxidizing Solid Category 3
Skin Corr Cat 1 Skin Corrosive Category 1
Skin Irrit Cat 2 Skin Irritant Category 2
H272 All of the components of this product are listed on the TSCA inventory.
H301 Toxic if swallowed
H314 Causes severe skin burns and eye damage
H315 Causes skin irritation
H318 Causes serious eye damage
H319 Causes serious eye irritation.
EUH032 Contact with acids liberates very toxic gas.

Supersedes:-22 August2014
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Revision Summary: Add Captivate by NUPRO and part numbers to Section 1.1

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