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)

Date Issued: Document Number: 130150 Date Revised: 16 October 2014 Revision Number: 7

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® In-Office Tooth Whitener

Part/Item Number: 614055

1.1.2 Trade Name (as labeled): Captivate by NUPROTM In-Office Tooth Whitener

Part/Item Number: 614062

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 hydrogen peroxide 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: <u>ProfessionalMSDS@dentsply.com</u>

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

Part A

GHS Classification:		
Health	Environmental	Physical
Eye Damage Category 1 (H318)	Aquatic Acute Toxicity Category 3	Oxidizing Liquid Category 3
Skin Irritant Category 2 (H315)	Aquatic Chronic Toxicity Category 3	

Part B

GHS Classification:		
Health	Environmental	Physical
Skin Corrosive Category 1 (H314) Eye Damage Category 1 (H318)	Not Hazardous	Not Hazardous

EU Classification:

Part A: Harmful (Xn), Irritant (Xi) R22, R37/38, R41

Part B: Corrosive (C), R34

2.2 Label Elements:



Signal Word: Danger

Part A

Hazard Phrases	Precautionary Phrases
H271 May cause fire or explosion; strong oxidizer.	P210 Keep away from heat
H315 Causes skin irritation.	P220 Store away from clothing and combustible material
H318 Causes serious eye damage.	P221 Take any precaution to avoid mixing with
H412 Harmful to aquatic life with long lasting effects.	combustibles.
	P264 Wash thoroughly after handling.
	P273 Avoid release to the environment.
	P280 Wear protective gloves, protective clothing, 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.
	P302+P352 IF ON SKIN: Wash with plenty of soap and
	water.
	P332+P313 If skin irritation occurs: Get medical attention.
	P362 Take off contaminated clothing and wash before
	reuse.
	P370+P378 In case of fire: Use large amounts of water for
	extinction.
	P501 Dispose of contents and container in accordance with
	local and national regulations.

Part B

Hazard Phrases	Precautionary Phrases
H314 Causes severe skin burns and eye damage	P260 Do not breathe mists.
	P264 Wash thoroughly after handling.
	P280 Wear protective gloves, eye protection, and face
	protection.
	P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do
	not induce vomiting.
	P303 + P361 + P353 IF ON SKIN (or hair): Take off
	immediately all contaminated clothing. Rinse skin with
	water.
	P363 Wash contaminated clothing before reuse.
	P304 + P340 IF INHALED: Remove person to fresh air
	and keep comfortable for breathing.
	P310 Immediately call a POISON CENTER
	P305 + P351 + P338 IF IN EYES: Rinse cautiously with
	water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Part A

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Hydrogen Peroxide	7722-84-1	231-765-0	765-0 C, O, Xn R5, R8, R20/22, 45	
			R35	
			Oxid. Liq. Cat 1, H271	
			Acute Tox. Cat 4 (Oral),	
			H302, H332 (Inhalation)	
			Skin Corr. Cat 1A, H314	
			Eye Dam. Cat 1, H318	
			Aquatic Chronic Cat 3, H412	

Part B

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Glycerin	56-81-5	200-289-5	Not Applicable	80-90
Sodium Hydroxide	1310-73-2	231-765-0	C, R34 Met Corr 1, H290 Skin Corr 1, H314 Eye Dam 1, H318	<5

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 Descripti	on of First Aid Measures:
Eye	Part A: 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. Get immediate medical attention. Part B: Immediately flush eyes with plenty of water for at least 30 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get immediate medical attention.
Skin	Part A: Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation occurs and persists. Launder clothing before re-use. Part B: Immediately flush skin with plenty of water for 30 minutes while removing contaminated clothing and shoes. Get immediate medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	Part A: Immediately remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention. Part B: Immediately remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	 Part A: Do NOT induce vomiting unless directed to do so by medical personnel. If conscious, rinse mouth with a small amount of water and give one glass of water to dilute. Never give anything by mouth to an unconscious or drowsy person. Part B: Do NOT induce vomiting. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

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

Part A: May cause severe eye irritation with possible eye damage. May cause skin irritation with whitening of the skin. Inhalation of vapors may cause severe mucous membrane and respiratory irritation. If swallowed, may cause intestinal irritation and discomfort.

Part B: May cause severe eye and skin irritation and burns. If inhaled, may cause irritations and burns to upper respiratory tract. May be harmful if swallowed. May cause irritation and burns to mucous membranes and gastrointestinal tract.

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

Part A: Immediate medical attention is required for eye contact.

Part B: Immediate medical attention is required for all routes of contact.

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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use large quantities of water to extinguish fire.

5.2 Special Hazards Arising from the Substance or Mixture:

This product contains hydrogen peroxide which is a strong oxidizer and may increase the flammability of combustible or flammable materials or powdered metals. Hydrogen peroxide will not burn but decomposes to release oxygen which supports combustion. Contamination can cause rapid decomposition and an explosive pressure rupture of the container if not properly vented. Decomposition may release oxides of carbon, oxygen, and water.

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	Do not enter fire area without	proper protection. Firefighters	should wear full emergency	
Fighters:	equipment and an approved positive pressure self-contained breathing apparatus.			
	Recommended Protective E	quipment for Fire Fighters:		
EYES/FACE	HANDS RESPIRATORY THERMAL			
CY				

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Wear appropriate protective clothing. Ventilate area. Prevent contact with flammable or combustible material. Keep away from heat, flames and high temperatures.

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:

Contain and absorb with an inert, non-combustible material and place in appropriate containers for disposal. Do not return to the original container. Keep containers away from combustible materials. Vent containers of recovered gel to prevent pressurization and rupture of containers. 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 vapors. Wear protective clothing and equipment. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep in vented, closed containers. Protect product from contamination. Keep away from flammable and combustible materials.

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, well-ventilated area away from heat, clothing and incompatible materials. Avoid light and heat and keep in a closed but vented container to prevent evaporation and contamination. Do not store on wooden shelves or floors. Recommended storage is refrigeration.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:				
Occupational Exposure Limits:				
Hydrogen Peroxide	United States	1 ppm TWA ACGIH TLV 1 ppm TWA OSHA PEL		
	Germany	0.5 ppm TWA, 0.5 ppm STEL DFG MAK		
	United Kingdom	1 ppm TWA, 2 ppm STEL UK WEL		
	European Union	Belgium: 1 ppm TWA		
Glycerin	United States	15 mg/m3 (total dust), 5 mg/m3 (respirable fraction)		
- 3	Germany	50 mg/m3 DFG MAK		
	United Kingdom	10 mg/m3 UK WEL		
	European Union	Belgium: 10 mg/m3 TWA		

Sodium Hydroxide	United States	2 mg/m3 STEL ACGIH TLV, 2 mg/m3 TWA OSHA PEL	
	Germany	None Established	
	United Kingdom	2 mg/m3 STEL UK WEL	
	European Union	Belgium: 2 mg/m3 TWA	
Biological Exposure Limits: None Established			

8.2 Exposure Controls:

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

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles and a face shield are recommended where splashing is possible..

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

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved 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.

Specific Therman Traze	Specific Thermal Hazarass (vone 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:	Part A: Colorless liquid Part B: Green liquid	Explosive limits:	LEL: Not determined UEL: Not determined
Odor:	Part A: Pungent odor Part B: Characteristic odor	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not determined
рН:	Part A: <4 Part B: >13	Relative density:	1.15
Melting/freezing point:	Not determined	Solubility(ies):	Soluble in water.
Initial boiling point and boiling range:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Not flammable	Auto-ignition temperature:	Not determined
Evaporation rate:	Not determined	Decomposition temperature:	Not determined

Flammability (solid, gas):	Not applicable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	Oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

- 10.1 Reactivity: None known.
- 10.2 Chemical Stability: Stable under normal storage and handling conditions. Unstable when exposed to heat and contaminants.
- **10.3 Possibility of Hazardous Reactions:** Oxidizers may react violently with many other materials, particularly flammable and combustible organic materials. Elevated temperatures can increase the decomposition of the product. Contact with organic substances may cause fire or explosion.
- **10.4 Conditions to Avoid:** Avoid excessive heat. Avoid light and heat and keep in a closed but vented container to prevent evaporation (concentration) and contamination.
- 10.5 Incompatible materials: Avoid acids, bases, metal powders and combustible materials.
- 10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon, oxygen and water.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Part A:

Eyes: Direct contact may cause severe irritation with redness, pain and tearing with possible corneal damage.

Skin: May cause irritation with redness and pain. Prolonged contact may cause bleaching of the skin.

<u>Ingestion:</u> Swallowing large amounts may cause gastrointestinal irritation, stomach distention, nausea, vomiting and diarrhea.

<u>Inhalation:</u> No adverse effects are expected under normal use conditions.

Part B:

Eyes: Causes severe irritation or burns with redness, tearing, pain and burns. Corneal damage may occur.

Skin: Causes severe skin irritation and possible burns.

<u>Ingestion:</u> Ingestion may cause mucous membrane and gastrointestinal burns

<u>Inhalation:</u> <u>Inhalation of vapors may cause mucous membrane and respiratory irritation with a burning sensation of the nose and throat, watering of the eyes, and difficulty in breathing.</u>

Chronic Health Effects: None known.

<u>Irritation:</u> Hydrogen Peroxide: In a study with 10% aqueous solution of hydrogen peroxide, the results showed that the solution was not irritating to rabbit skin and extremely irritating to rabbit eyes.

Corrosivity: This product is classified as corrosive to the eyes.

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

<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Hydrogen peroxide has tested positive for mutagenicity in some test systems.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Hydrogen Peroxide: Oral rat LD50 >225 mg/kg; Skin rabbit >6.5 g/kg; Inhalation rat LC50 >0.17 mg/L

Glycerin: Oral Rat LD50 – 17,000-27,200 mg/kg; Skin Rabbit LD50 - >10,000 mg/kg

Sodium Hydroxide: No data available

ATE: Part A: Oral: >500mg/kg, Dermal: > 14,492 Part B: Oral: >18867, Dermal: >11,000

Reproductive Toxicity Data: Hydrogen Peroxide: In a 90 day reproductive oral study with mice, hydrogen peroxide showed no effects in the reproductive organs in both males and females mice. It was presumed that the rapid degeneration of hydrogen peroxide on absorption and due to local effects, studies would be unlikely to reveal any specific developmental effects.

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Hydrogen Peroxide: Oral rat LD50 >225 mg/kg; Skin rabbit >6.5 g/kg; Inhalation rat LC50 >0.17 mg/L

Glycerin: Oral Rat LD50 – 17,000-27,200 mg/kg; Skin Rabbit LD50 - >10,000 mg/kg

Sodium Hydroxide: No data available

- 12.2 Persistence and Degradability: Hydrogen peroxide rapidly degrades in the environment.
- **12.3 Bio-accumulative Potential:** Hydrogen peroxide is decomposed by enzymatic action and does not accumulate in cell systems.
- **12.4 Mobility in Soil:** Hydrogen peroxide degrades in soil to form oxygen and water.
- 12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: None

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

Part A

	14.1 UN	14.2 UN Proper Shipping	14.3	14.4 Packing	14.5 Environmental
	Number	Name	Hazard	Group	Hazards
			Class(s)		
DOT	UN2014	Hydrogen Peroxide Solution	5.1 (8)	III	Not applicable
ADR/RID	UN2014	Hydrogen Peroxide Solution	5.1 (8)	III	Not applicable
IMDG	UN2014	Hydrogen Peroxide Solution	5.1 (8)	III	Not applicable
IATA/ICAO	UN2014	Hydrogen Peroxide Solution	5.1 (8)	III	Not applicable

Part B

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	UN1824	Sodium Hydroxide Solution	8	II	Not applicable
ADR/RID	UN1824	Sodium Hydroxide Solution	8	II	Not applicable
IMDG	UN1824	Sodium Hydroxide Solution	8	II	Not applicable
IATA/ICAO	UN1824	Sodium Hydroxide Solution	8	II	Not applicable

14.6 Special Precautions for User: Part A: Forbidden By Air

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 20,000 lbs. based on the RQ for Sodium Hydroxide of 1,000 lbs. Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

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:	Yes		

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): Cosmetics are not subject to WHMIS.

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.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 3 Flammability – 0 Physical Hazard – 1

Full text of Classification abbreviations used in Section 2 and 3:

C Corrosive

O Oxidizer

Xi Irritant

Xn Harmful

R5 Heating may cause an explosion.

R8 Contact with combustible material may cause fire.

R20/22 Harmful by inhalation and if swallowed.

R22 Harmful if swallowed.

R35 Causes severe burns.

R41 Risk of serious damage to eyes.

Acute Tox. Cat 4 Acute Toxicity Category 4

Aq Acute Cat 3 Aquatic Acute Toxicity Category 3

Aq Chronic Cat 3 Aquatic Chronic Toxicity Category 3

Eye Dam. Cat 1 Eye Damage Category 1

Oxid. Liq. Cat 1 Oxidizing Liquid Category 1

Met Corr Cat 1 Corrosive to Metals Category 1

Skin Corr. Cat 1A Skin Corrosion Category 1

Skin Irrit. Cat 2 Skin Irritation Category 2

H271 May cause fire or explosion; strong oxidizer.

H272 May intensify fire; oxidizer.

H290 Corrosive to metals

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Cause skin irritation.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H402 Harmful to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

Supersedes: 26 August 2014 Date Revised: 16 October 2014

Revision Summary: Add Captivate by NUPRO and part number to Section 1.1 Product Identifier

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.