

Document Detail

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Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>
Maillefer-PPCS 711-Manager Regulatory Affairs	Périne Roche	22-Sep-2015 12:16 pm GMT
Maillefer-Chef de projet	Selma Mefti	28-Sep-2015 5:18 pm GMT
REG administrator	Tiffany Domingues	29-Sep-2015 5:20 am GMT

Reference

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1450-RDT_Summary_A41	A41-Table of content	Master Document

Safety Data Sheet (SDS)

Revision: 03
Issued date: 22 feb. 2013
This document is electronically approved

Section n°1: Product and Company identification

Product Picture:	
Product Name:	GLYDE File Prep®
References:	A0901, A0902, A0903, A0904, A0905
Use of the substance/preparation:	Lubricate removing debris with hypochlorite.
Company:	MAILLEFER INSTRUMENTS HOLDING Sàrl Chemin du verger 3, 1338 Ballaigues Switzerland
Contact information:	DENTSPLY Maillefer North America 608 Rolling Hills Drive Johnson City, TN 37604 Http://www.dentsply.com ☎ 1-800-924-7393 (Product Information)
Emergency contact:	☎ 1-800-924-7393 ✉ chemtrec@chemtrec.com

Section n°2: Hazard Identification

 WARNING May intensify fire; oxidizer Keep away from heat. Keep away from clothing and combustible materials. Take any precaution to avoid mixing with combustible materials. Wear protection gloves/eye protection/face protection.	 WARNING CAUSES SKIN IRRITATION Wash hands thoroughly after handling. Wear protective gloves. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.
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Section n°3: Composition / Informations on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Ethylenediaminetetraacetic acid	60-00-4	Not Established	< than 20
Carbamide peroxide	124-43-6	Not Established	< than 15

Section n°4: First-Aid Measures

Emergency Overview: Material is considered irritating. Material may cause burns on the skin, mucosa and severe lesions of

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cornea, visible after several days. Hazard indications; contains urea hydrogen peroxide.			
Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Material can cause severe irritation.	Single	Severe
Skin	Material may cause burns of the skin.	Single & Repeated	Moderate
Inhalation	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed.	Single	Mild
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			
Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.			
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No. All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.			
Potential Environmental Effects: Do not allow to enter sewers/ surface or ground water.			
NFPA Hazard Classification Ratings (Scale 0-4), Health = 3, Fire = 1, Reactivity = 0 Specific = Corrosive			

Section n°5: Fire-Fighting Measures

Flashpoint Method:	Not Applicable
Flammable (Explosive) Limits in Air	
LEL:	Not Applicable
UEL:	Not Applicable
Autoignition Temperature:	Not Applicable. Product will not autoignite.
Flame Propagation or Burning Rate (for Solids):	Not Applicable
Properties Contributing to Fire Intensity:	Not Applicable
Flammability Classification :	Not Applicable
Other:	Not Applicable
Extinguishing Media:	CO ₂ , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.
Extinguishing Media to Avoid:	Water with full jet.
Protection and Procedures for Firefighters:	Firefighters should wear self-contained respiratory protective devices.
Unusual Fire and Explosion Hazards:	When heated carbamide peroxide will decompose into ammonia.

Section n°6: Accidental Release Measures

Containment Techniques: Material is a gel and as such will not flow.	
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing, gloves and safety glasses. Scoop up bulk material and place in a labeled plastic or metal container. Avoid contact with skin and eyes to minimize irritation. Ensure adequate ventilation.	
Evacuation Procedures:	Not Applicable
Special Instructions:	Not Applicable
Reporting Requirements:	Not Applicable

Section n°7: Handling and Storage

Handling Practices and Warnings: Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Use with adequate ventilation. Avoid eye exposure. Avoid skin contact. Avoid breathing vapor, mist, or fumes. Do not take internally. Contents may be under pressure, open carefully. Keep away from heat, sparks, open flame, pilot lights and other sources of ignition.	
Storage Practices and Warnings: Store in a well-ventilated place. Keep cool. Store only in the original package. Store out of direct sunlight. Keep package tightly sealed. Store away from food and beverages. Static electricity will accumulate and may ignite vapors. Keep container tightly closed.	

Section n°8: Exposure Control / Personal Protection

Ventilation: None required during normal intended use of this product		
Other Engineering Controls: Local ventilation if large amounts are used.		
Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies

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Eye/Face	Safety Glasses 	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product. 	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection	Protective work clothing 	Not Applicable
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin. 		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

Section n°9: Physical and Chemical Properties

Appearance :	White gel.	Odor:	No Odor
Normal Physical State:	High Viscosity Liquid (Gel)	Melting Point:	Not Applicable
Specific Gravity:	1.0 g/cm ³	Solubility in Water:	Soluble in water and solvents.
pH:	Acidic, close to 3	Vapor Pressure (mm Hg):	Not Applicable
Vapor Density (AIR=1):	Not Applicable	Evaporation Rate (Butyl Acetate =1):	Not Applicable
Other:	Not Applicable		

Section n°10: Stability and Reactivity

Incompatibility (Materials to Avoid): Alkaline materials and heavy metals.
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. When heated carbamide peroxide will decompose into ammonia.
Hazardous Polymerization: ☐ May Occur ☒ May Not Occur
Stability? ☒ Stable ☐ Unstable
Conditions to Avoid: Heat greater than 60°C (140°F).

Section n°11: Toxicology Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Carbamide peroxide causes burns. Product is considered an irritant to the skin and mucous membranes. On the eye the product has an irritating effect.					
Emergency Overview: Material is considered irritating. Material may cause burns on the skin, mucosa and severe lesions of cornea, visible after several days. Hazard indications; contains urea hydrogen peroxide.					
Routes of	Signs and	Single, Repeated, or	Severity (Mild,	Acute and Chronic	Target

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Exposure	Symptoms	Lifetime Exposure	Moderate, Severe)	Health Effect(s)	Organ(s)
Eye	Material can cause severe irritation.	Single	Severe	Irritation and possible corneal damage	Not Applicable
Skin	Material may cause burns of the skin.	Single & Repeated	Moderate	Irritation.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Single	Mild	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.

Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No. All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects: Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0 Specific = Corrosive

Section n°12: Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard (Self-assessment): Slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system. In water solutions, Carbamide peroxide decomposes into urea and hydrogen peroxide. It is then rapidly reduced to water and oxygen.

Section n°13: Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

Section n°14: Transport Information

UN Identification Number: (3139)

UN Proper Shipping Name: 3139 - Oxidizing Liquid, N.O.S. (Contains Urea Hydrogen Peroxide)

Transport hazard class(es): 5.1

Packing Group: III

Special markings: Symbol Oxidizing Liquid



Section n°15: Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U. S. Federal Regulations: All chemical substances in this material are included on or exempted from listing on the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: 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. The CERCLA RQ for Carbamide peroxide is 5,000 pounds.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, **Section 313 (40 CFR 372):** None

Section 302 Extremely Hazardous Substances (TPQ): None

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EPA Toxic Substances Control Act (TSCA) Status:	All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations California Proposition 65:	This product does not contain any chemicals, which are on the California Proposition 65 list.
International Regulations: Canadian Environmental Protection Act:	This product is a medical device and not subject to chemical notification requirements.
European Community Labeling:	Hazard indications; contains urea hydrogen peroxide.
European Inventory of New and Existing Chemicals Substances (EINECS):	This product is a medical device and not subject to chemical notification requirements.
Other:	Not Applicable

Section n°16: Other Information

Disclaimer:	MAILLEFER INSTRUMENTS HOLDING Sàrl (hereafter "MAI") does not warrant the suitability for use of this Safety Data Sheet (hereafter "SDS") for any other material or product not specifically identified herein. MAI does not warrant the accuracy or authenticity of this SDS unless it has been obtained directly from MAI, or posted or viewed on MAI website. This SDS is based on information that is believed to be reliable and according to the best of our knowledge, but may be subject to change as new information becomes available. Because it is not possible to anticipate all conditions of use, additional safety precautions may be required. Since the use of this product is not under the MAI's control, each user has the sole responsibility for making their own determination as to the safe and proper handling of this product in their own particular use of this product. MAI makes no warranty of any kind, express or implied, concerning the safe use of this product. Users must meet all applicable safety and health standards. To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed natural rubber, or natural latex. All components are synthetically produced; none are derived from animal product. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship. The attached safety data sheet covers the dangers and measure to be taken when large quantities of material are released, for example due to accidents during transport or storage bay the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product of the product is given in the DFU.
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