Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006,
Regulation (EC) 1272/2008 and Regulation (EC) 2015/830

Date Issued: 17 March 2016
Document Number: EX21522
Date Revised: 12/28/2020
Revision Number: 4

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

1.1 Product Identifier:

Trade Name (as labeled):	PracticeProtect™ Instrument Disinfection and Cleaning Liquid - Glucprotamin
Part/Item Number:	EX21522FG

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

Recommended Use:	Instrument Disinfectant
Restrictions on Use:	For industrial and professional use.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Dentsply Sirona
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. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 Skin Corrosion Category 1B Eye Damage 1	Acute Aquatic Toxicity Category 1	Not Classified

2.2 Labeling Elements:

Signal Word: Danger!

Contains: Glucoprotamin, 2-phenoxyethanol

Hazard Statements	Precautionary Phrases

H302 + H332 Harmful if swallowed or if inhaled. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life.	P260 Do not breathe mists. P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves, eye protection and face protection. P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P310 Immediately call a POISON CENTER or doctor. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with soap and water. P363 Wash contaminated clothing before reuse. P310 Immediately call a POISON CENTER or doctor. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 Immediately call a POISON CENTER or doctor. 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. P391 Collect spillage. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards:

None known.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS # REACH Registration #	Classification	WT %
Glucoprotamin	164907-72-6	403-950-8 /	Acute Tox. 2 (H330) Acute Tox. 4 (H302) Skin Corr. 1B (H314) Eye Dam. 1(H318) Acute Aquatic 1 (H400)	>= 25 - < 30
2-phenoxyethanol	122-99-6	204-589-7 / 01-2119488943-21	Acute Tox. 4 (H302) Eye Irrit. 2 (H319)	>= 10 - < 20
2-(2-butoxyethoxy)ethanol	112-34-5	203-961-6 /	Eye Irrit. 2 (H319)	>= 10 - < 20
Fatty alcohol ethoxylates > 5EO	147993-63-3	639-700-1 /	Acute Aquatic 1 (H400) Skin Irrit. 2 (H315)	>= 5 - < 10

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical attention.

Skin	Wash off immediately with plenty of water for at least 15 minutes. Use a mild soap if available. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get immediate medical attention immediately.
Inhalation	Remove to fresh air. Treat symptomatically. Get immediate medical attention.
Ingestion	Rinse mouth with water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical attention.

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

Causes severe eye irritation and damage. Causes severe skin irritation and burns. Causes irritation respiratory tract if inhaled. Ingestion may cause severe gastro intestinal irritation and burns to mouth and throat.

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

Immediate medical attention is required for all routs of exposure.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Not flammable or combustible. Decomposition products may include the following materials: Carbon oxides.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Collect contaminated fire extinguishing water separately.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid inhalation, ingestion and contact with skin and eyes. Wear appropriate protective clothing; gloves and eye protection.

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Stop leak if safe to do so. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

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:

Do not ingest. Do not get in eyes, on skin, or on clothing. Do not breathe mist, vapors or spray. Use only with adequate ventilation. Wash hands thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage. Keep container tightly closed. Store in suitable labeled containers.

7.3 Specific End Use (s): Instrument Disinfectant.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Glucoprotamin	None established.
2-phenoxyethanol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
	200 ppm TWA, 400 ppm STEL Belgium WEL
	400 ppm STEL French WEL
	1 ppm TWA, 1 ppm STEL DFG MAK (inhalable)
	400 ppm TWA, 500 ppm STEL UK WEL
2-(2-butoxyethoxy)ethanol	10 ppm TWA ACGIH TLV (inhalable fraction and vapor)
	10 ppm TWA, 15 ppm STEL Belgium WEL
	10 ppm TWA, 15 ppm STEL DFG MAK (inhalable)
	10 ppm TWA, 15 ppm STEL French WEL
Fatty alcohol ethoxylates > 5EO	None established.

Biological Exposure Limits: None

8.2 Exposure Controls:

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

Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety glasses and face shield. In Europe follow EN 166.

Specific Skin Protection: Wear impervious gloves such as Nitrile rubber or Butyl-rubber. Consult glove supplier for thickness and breakthrough times. In Europe follow EN 374.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved respirator 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. In Europe follow EN 143, 14387.

Specific Thermal Hazards: None required.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light blue liquid	**Explosive limits:**	**LEL:** Not applicable. **UEL:** Not applicable.
Odor:	Perfumes, fragrances	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Vapor density:** (Air = 1)	Not determined
pH:	8.0-9.0	**Relative density:**	1.00 – 1.02
Melting/freezing point:	Not determined	**Solubility(ies):**	Soluble
Initial boiling point and range:	Not determined	**Partition coefficient: n-octanol/water:**	Not applicable.
Flash point:	Not applicable.	**Auto-ignition temperature:**	Not applicable.
Evaporation rate: (n-BuAc = 1)	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not applicable.	**Viscosity:**	Not determined
Explosive Properties:	None	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: No dangerous reaction known under conditions of normal use.
10.2 Chemical Stability: Stable under normal conditions
10.3 Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.
10.4 Conditions to Avoid: None known.
10.5 Incompatible materials: Avoid oxidizing agents and strong acids.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce Carbon oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects: Eyes: Causes severe eye irritation and damage. Skin: Causes severe skin irritation and burns. Ingestion: May cause severe gastro intestinal irritation and burns to mouth, throat, and digestive tract. Inhalation: May cause nose, throat, and lung irritation.
Chronic Health Effects: None expected under normal use.
Irritation: Causes severe eye irritation and damage. Causes severe skin irritation and burns.

Corrosivity: Product is corrosive to eyes and skin.

Sensitization: Based on available data, the classification criteria are not met.

Carcinogenicity: None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU CLP.

Mutagenicity: Based on available data, the classification criteria are not met.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

ATE Oral: LD50 1818 mg/kg; Inhalation: Rat LC50 1.44 mg/l/4 hr.

Glucoprotamin: Inhalation rat LC50 0.3 mg/l/4 hr

2-phenoxyethanol: Oral rat LD50 2,000 mg/kg, Skin rabbit LD50 2,250 mg/kg

2-(2-butoxyethoxy)ethanol: Oral rat LD50 3,306 mg/kg, Skin rabbit LD50 2,764 mg/kg

Reproductive Toxicity Data: Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Single Exposure (STOT-SE): Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Based on available data, the classification criteria are not met

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Very toxic to aquatic life.

Glucoprotamin: 72 h EC50 Desmodesmus subspicatus: 0.039 mg/l

2-phenoxyethanol: 96 h LC50 Fish: > 220 mg/l

2-(2-butoxyethoxy)ethanol: 96 h LC50 Fish: 1,300 mg/l

12.2 Persistence and Degradability.

2-phenoxyethanol: Readily biodegradable. Glucoprotamin: Readily biodegradable.

The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC.

12.3 Bio-accumulative Potential:

No data available

12.4 Mobility in Soil:

No data available

12.5 Other Adverse Effects: The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC.

12.6 Results of PBT/vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste Treatment Methods:

Product:	The product should not be allowed to enter drains, water courses or the soil. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.
Contaminated packaging:	Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, state, and federal regulations.
European Waste Catalogue:	200129* - detergents containing dangerous substances

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
ADR/RID	UN3267	CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.(Glucoprotamin)	8	III	Yes
IMDG	UN3267	CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.(Glucoprotamin)	8	III	Yes
IATA/ICAO	UN3267	CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.(Glucoprotamin)	8	III	Yes

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

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

15. REGULATORY INFORMATION

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

According to Detergents Regulation EC 648/2004: 5 % or over but less than 15 %: Non-ionic surfactants
Contains: Disinfectants
glucoprotamin
Contains: Perfumes
Hexyl cinnamal
Citronellol

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Hazard class for water:	WGK 2 Classification according VwVwS, Annex 4
German storage class:	8B

15.2 Chemical Safety Assessment:

This product contains substances for which Chemical Safety Assessments are still required.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 3:

Acute Tox. 2 Acute Toxicity Category 2
Acute Tox. 4 Acute Toxicity Category 4
Aquatic Acute 1 Acute Aquatic Toxicity Category 1
Eye Dam. 1 Eye Damage Category 1
Eye Irrit. 2 Eye Irritant Category 2
Skin Corr 1B Skin Corrosion Category 1B
Skin Irrit. 2 Skin Irritation Category 2

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled
H400 Very toxic to aquatic life.

Supersedes: 11 August 2017

Date Updated: 28 December 2020

Revision Summary: Three year update. Changes to format, Company name, Sections - 1, 3, 4, 6, 7, 8, 9, 11, 12 & 16.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.

Skin Irrit. 2 (H315)

ANNEX: EXPOSURE SCENARIOS

DPD+ Substances:

The following substances are the lead substances that contribute to the mixture Exposure Scenario according to the DPD+ Rule:

Route	Substance	CAS-No.	EINECS-No.
Ingestion	glucoprotamin	164907-72-6	403-950-8
Inhalation	glucoprotamin	164907-72-6	403-950-8
Dermal	glucoprotamin	164907-72-6	403-950-8
Eyes	glucoprotamin	164907-72-6	403-950-8
Aquatic environment	glucoprotamin	164907-72-6	403-950-8

To calculate if your downstream Operating Conditions and Risk management Measures are safe, please calculate your risk factor at the website below:

www.ecetoc.org/tra

Short title of Exposure Scenario: **Medical devices. Dipping process**

Use Descriptors

Main User Groups:	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Sectors of end-use:	**SU22**: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Process categories:	**PROC13**: Treatment of articles by dipping and pouring. **PROC8a**: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
Product categories:	**PC35**: Washing and cleaning products (including solvent based products)
Environmental Release Categories:	**ERC8a**: Wide dispersive indoor use of processing aids in open systems.