Trade Name: SNOOP Caries Detecting Dye

1.0	Commercial Product Name and Supplier			•
1.1	Commercial product name / designation	Snoop Caries Detecting Dye		
1.2	Application / Use	Dental material for use by dental professionals.		
1.2.2	SIC	851 Human health activity		
1.2.3	Use Category	55		
1.3	Manufacturer, Importer			
1.3.1	Manufacturer			
	Pulpdent Corporation 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA	Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: <u>Pulpdent@pulpdent.com</u>		
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)		
1.5	Authorized European Representative			
	International Business Solutions Ltd. 54 Mayfield Ridge, Hatch Warren, Basingstoke, RG22 4RS UK	Tel: 07989 407479 Fax: 01256 350330 Email: <u>s.williams5@btconnect.co.uk</u>		
2.0	Hazards Identification		Edgeloge Edgeloge	
2,1	Classification			
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement
		Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Irritant (Xi) R36 / 37 / 38		

2.2 Label Elements

Labeling according to Regulation (EC) No 1272/2008 [CLP]



Signal Word: WARNING

Restricted to use by dental professional only

Hazard Statements:

H319: Causes serious eye irritation. Category 2.

H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.

H315: Causes skin irritation, Category 2,

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Safety Data Sheet

Trade Name: SNOOP Caries Detecting Dye

Precautionary Statements:

P261: Avoid breathing fumes.

P280: Wear protective gloves / clothing and eye protection.

P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.

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3.0	Composition				
3.1	Chemical characterization of the preparation: Mixture of propylene glycol, water, colorant and emulsifier			glycol, water, colorant and emulsifier	
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
	57-55-6	Propylene glycol, USP	49.5%	Irritant (Xi) R36	Eye irritation, Category 2
	7732-18-5	Water	49.5%		
		Colorant	< 1.0%	frritant (XI) R36 / 37 / 38	Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.
		Emulsifier	< 5.0 %	frritant (XI) R36 / 37 / 38	Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.
4.0	First Aid Measures				
4,1	1		tissue and a Corneal inju this safety o	Not hazardous to health or environment. Snoop is a dye that will stain soft tissue and absorbent materials. May cause slight, temporary eye irritation. Corneal injury is unlikely. May cause mild skin or respiratory irritation. Show this safety data sheet to medical personnel. Seek medical attention in case of uncertainty.	
4,2	Eye Contact				running water for 15+ minutes, Remove inutes, Get medical advice or attention as
4,3	Skin Contact			Remove contaminated clothing. Immediately wash with soap and running water. Get medical attention for persistent irritation.	
4.4	Ingestion			Rinse mouth with water to minimize staining of soft tissue. No emergency medical treatment necessary.	
4.5	Inhalation	Inhalation Move to fresh air. If necessary, administer oxygen and/or a respiration; seek medical attention.			
4,6	Precautions for first responders		Wear safety	glasses and gloves.	

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4.7	Information for physicians	
	Symptoms	Contact with material may cause mild irritation in eyes, respiratory system or on skin. Skin and soft tissue may be stained.
	Hazards	May cause irritation.
	Treatment	Same as above under First Aid
5.0	Fire Fighting Measures	
5.1	Suitable extinguishing media	Decision should be based on surrounding fire.
5.2	Extinguishing media to avoid	Decision should be based on surrounding fire.
5.3	Special exposure hazards in a fire	None
5.4	Special protective equipment for fire-fighters	None
6.0	Accidental Release Measures	
6.1	Personal precautions.	Material will stain skin and clothing. Wear gloves, lab coat and/or apron and safety glasses.
6.2 6.3	Environmental precautions	Not hazardous to environment. Follow all government regulations.
0.0	Method for clean up	Absorb or wipe up spill with suitable material (paper towels or disposable cloths). Collect for disposal in a drip-proof plastic bag or container to prevent further staining of surroundings. Wash area of spill promptly with alcohol or soap and water, though discoloration of spill area may persist.
7.0	Handling and Storage	www.
7.1	Handling	Medical device for use only by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Re-cap container immediately to prevent spills.
7.2	Storage	Keep tightly capped in original container. Store at cool room temperature. Avoid extreme temperatures (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is two years from date of manufacture provided that the material has been stored properly.
7.3	Specific uses	Dental material
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	Not established
8.2	Exposure controls	
8,2.1	Occupational exposure controls	No special equipment or ventilation required under normal conditions of use in dental practice.
8.2.1.1	Respiratory protection	No special requirements under normal conditions of use.
8.2.1.2	Hand protection	No special requirements other than surgical gloves.

8.2.1.3	Eye protection	No special requirements other than safety glasses.		
8.2.1.4	Skin protection	No special requirements other than good hygiene and safety practices to prevent contact with skin and subsequent staining.		
8.2.1.5	Other controls	Emergency eye wash fountain should be close by and maintained. Wash hands after use. Do not eat, drink or smoke.		
8.2.2	Environmental exposure controls	Follow all government regulations.		
9.0	Physical and Chemical Properties			
9,1	Appearance / Color			
9.1.1	Color	Very dark blue liquid		
9.1.2	Odor	None		
9.2	Important health, safety and environmental information			
9.2.1	ρН	Not determined		
9.2.2	Boiling point	Boiling Point: 220°F / 105°C		
9.2.3	Flash point	Not applicable		
9.2.4	Ignition temperature	Not applicable		
9.2.5	Explosive properties	Not applicable		
9.2.6	Odor threshold	Not applicable		
9.2.7	Vapor pressure	Not determined		
9.2.8	Specific gravity	1.060		
9,2,9	Solubility in water	Complete		
9.2.10	Partition coefficient	Not determined		
9.2.11	Viscosity	Not determined		
9.2.12	Vapor density	Not determined		
9.2.13	Evaporation rate	Not determined		
10.0	Stability and reactivity			
10.1	Conditions to avoid	None.		
10.2	Materials to avoid	None		
10.3	Hazardous decomposition products	None		
10.4	Further information	None		
11.0	Toxicological Information			
11.1	Acute toxicity	Not toxic. Minimal health hazard under normal conditions of use.		
11.2	Irritation and corrosiveness	May cause irritation/redness of eyes, skin or respiratory system.		
11,3	Sensitization	Not applicable.		
11,4	Sub-acute, sub-chronic and prolonged toxicity	Not toxic		
	4	4/6		
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11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not carcinogenic. No mutagenicity/ reproductive toxicity known.	
11.6	Empirical data	None available	
11.7	Clinical experience	Snoop has been sold to and used by dentists all over the world for about 15 years with no reported problems.	
12.0	Ecological Information		
12.1	Ecotoxicity	Not toxic. Follow good work practices and government regulations.	
13,0	Disposal Considerations		
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.	
14.0	Transport Information		
14.1	UN Number	Not applicable	
14.2	Technical name	Not applicable	
14.3	Packing group	Not applicable	
14.4	IATA class	Not applicable	
15.0	Regulatory information		
15.1	EU	Class IIA medical device under MDD 93/42/EEC.	
15.2	US FDA	Class II medical device	
15.3	Health Canada	Class II medical device	
16.0	Other information		
16,1	List of relevant R phrases	R36/37/38: Irritating to eyes, skin, and respiratory system.	
16.2	Hazard Statements	H319: Causes serious eye irritation. Category 2. H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. H315: Causes skin irritation. Category 2.	
16.3	Precautionary Statements	P261: Avoid breathing fumes. P280: Wear protective gloves / clothing and eye protection. P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.	
16.4	Restrictions on use	Pulpdent dental materials, such as Snoop are to be sold to and used by dental professionals only.	

16.5	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.6	Sources of key data	National Institute for Occupational Safety (NIOSH)
		US Occupational Safety and Health Administration (OSHA)
		Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).
		Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.7	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.