Trade Name: SNOOP Caries Detecting Dve

1.0	Commercial Product Name and Supplier				
1.1	Commercial product name / designation	Snoop Caries	Detecting Dye		
1.2	Application / Use	Dental material for	r use by dental professio	onals.	
1.2.2	SIC	851 Human health	n activity		
1.2.3	Use Category	55			
1.3	Manufacturer				
	<b>Pulpdent Corporation</b> 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 (2	24 Hour / USA)		
1.5	Authorized European Representative	Advena Ltd. Pure Offices, Plate Warwick, CV34 6\ United Kingdom			
2.0	Hazards Identification				
2.1	Classification				
2.1.1	Classification according to Regulation	Hazard Class	Hazard Category	Hazard Statement	
	(EC) No. 1272/2008 [CLP]	Eye irritation	2	H319	
		STOT SE	3	H335	

#### 2.2 **GHS Label Elements**

2.1.2

Hazard Pictograms



Signal Word: WARNING

#### Restricted to use by dental professional only

Classification according to Directive 67/548/EEC

#### **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.

Skin irritation

2

Irritant (Xi) R36 / 37 / 38 (See SECTION 16 for full text of risk phrases)

H315

H315: Causes skin irritation. Category 2.

#### **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.

#### 3.0 Composition 3.1 Chemical characterization of the preparation: Mixture of propylene glycol, water, colorant and emulsifier

Trade Name: SNOOP Caries Detecting Dye

### 3.2 Hazardous ingredients

		,				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (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%	Irritant (Xi) R36 / 37 / 38	Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.	
		Emulsifier	< 5.0 %	Irritant (Xi) R36 / 37 / 38	Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.	
4.0	First Aid Mea	sures				
4.1	General Inforr	mation	tissue and a Corneal inju this safety of	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			Keep eyelids apart, flush with running water for 15+ minutes. Remove contact lenses after several minutes. Get medical advice or attention as indicated.		
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			Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention.		
4.6	Precautions for first responders		Wear safety	glasses and gloves.		
4.7	Information fo	r 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 i	May cause irritation.		
	Treatment		Same as ab	Same as above under First Aid		
5.0	Fire Fighting	Measures				
5.1	Suitable extinguishing media		Decision s	Decision should be based on surrounding fire.		
5.2	Extinguishing media to avoid		Decision s	Decision should be based on surrounding fire.		
5.3	Special expos	Special exposure hazards in a fire		None		
5.4	Special protect	ctive equipment for fire-fighte	ers None			
6.0	Accidental R	elease Measures				
6.1	Personal prec	autions.	Material wand safety		thing. Wear gloves, lab coat and/or apron	

9.2.8

Specific gravity

Trade Name: SNOOP Caries Detecting Dye 6.2 Environmental precautions Not hazardous to environment. Follow all government regulations. 6.3 Method for clean up Absorb or wipe up spill with 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** 7.1 Handling Medical device for use only by trained dental professionals. Follow good hygiene practices. Re-cap container immediately to prevent spills. 7.2 Store tightly capped at cool room temperature. Avoid temperature Storage extremes (>27°C/80°F, <5°C/40°F). Shelf life for properly stored, unopened product is two years from date of manufacture. 7.3 Dental material Specific uses 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 No special requirements other than surgical gloves. Hand protection Eye protection 8.2.1.3 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. 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 Characteristics 9.1.1 Appearance / Color / Physical state Very dark blue liquid 9.1.2 Odor None 9.2 Important health, safety and environmental information 9.2.1 pΗ Not determined **Boiling point** 9.2.2 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

1.060

Trade	Name: <b>SNOOP Caries Detecting Dye</b>		
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	
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 regulated	
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	

Trade Name: SNOOP Caries Detecting Dye

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 res in a position comfortable for breathing.
		P305+P351+P338: If in eyes, rinse cautiously with water fo 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 Pulpden 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.

Revision Date: May 28, 2019