


Safety Data SheetTrade Name: **WINK**

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	WINK	
1.2	Application / Use	Dental lubricant and release agent	
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	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262	
	Watertown, MA 02472 USA	Email: Pulpdent@pulpdent.com	
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative		
	International Business Solutions Ltd.	Tel: 07989 407479 / Fax: 01256 350330	
	54 Mayfield Ridge	Email: s.williams5@btconnect.co.uk	
	Hatch Warren, Basingstoke, RG22 4RS UK		
2.0 Hazards Identification			
2.1	Classification		
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u>
		Eye irritation	2
		Skin sensitization	1
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Irritant (Xi); R36-43	
2.2	GHS Label Elements		
	Hazard Pictograms		
			
	Signal Word: Warning		
	Restricted to use by dental professional only		
	Hazard Statements:		
	H319: Eye irritation. 2. May cause eye irritation.		
	H317: Skin Sensitization. 1. May cause an allergic skin reaction.		
	Precautionary Statements:		
	P305+P351: If in eyes, rinse cautiously with water for several minutes.		
	P302+P352: If on skin, wash with plenty of soap and water.		
3.0 Composition			
3.1	Chemical characterization of the preparation		

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3.2 Hazardous Ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
8029-76-3	Soy lecithin, de-oiled	20-25%	Irritant (Xi) / R36-43	H319, Category 2 H317, Category 1

4.0 First Aid Measures

4.1	General Information	WINK is non-hazardous. May be irritating to eyes on contact. May be an allergen for certain susceptible individuals.
	NOTE: Most soy allergies are only to the soy protein. Soy lecithin is not part of the soy protein and therefore does not usually cause allergic reactions. However, there are some very allergic patients that will have reactions to soy lecithin and may need to avoid it as well. Get medical attention in case of uncertainty.	
4.2	Inhalation	Move person to fresh air. If effects occur, seek medical attention.
4.3	Skin Contact	Wash skin thoroughly with soap and water.
4.4	Eye Contact	Keep eyelids apart, flush with running water for 15+ minutes. Remove contact lenses after several minutes. Consult an ophthalmologist for persistent irritation
4.5	Ingestion	Large amounts: contact Poison Control Center or physician. Induce vomiting only on medical advice. See NOTE above.
4.6	Precautions for first responders	Wear safety glasses and gloves.
4.7	Information for physicians	
	Symptoms	Mild irritation/redness in eyes after contact.
	Hazards	May be irritating to eyes on contact. May be an allergen for certain susceptible individuals.
	Treatment	Same as above under First Aid.

5.0 Fire Fighting Measures

5.1	Suitable extinguishing media	Class B, carbon dioxide or dry chemical extinguishers. Water spray may be used to keep exposed containers cool.
5.2	Extinguishing media to avoid	Decision should be based on surrounding fire.
5.3	Special exposure hazards in a fire	Carbon monoxide and carbon dioxide may be generated.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire-fighting personnel.

6.0 Accidental Release Measures

6.1	Personal precautions.	Wear safety glasses, gloves, and lab coat.
6.2	Environmental precautions	Follow all government regulations.
6.3	Method for clean up	Absorb or wipe up spill with suitable material (paper towels or disposable cloths). Collect for disposal in a covered container. Wash area of spill with soap and water as it may remain slippery.

7.0 Handling and Storage

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7.1	Handling	Follow good hygiene practices. Wear gloves and safety glasses. Multi-dose syringes should either be encased in a fresh protective barrier for each patient or cleaned and disinfected between patients, as appropriate. Cap immediately after use
7.2	Storage	Keep container closed. Store product in original container at cool room temperature (< 25°C). Shelf life for unopened product is two years from date of manufacture, provided proper storage.
7.3	Specific uses	Dental lubricant and release agent.

8.0 Exposure Controls / Personal Protection

8.1	Exposure limit values	PEL: Not established. TLV: Not established.
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required.
8.2.1.1	Respiratory protection	None required under normal conditions of use of this product.
8.2.1.2	Hand protection	No special requirements under normal conditions of use.
8.2.1.3	Eye protection	Safety glasses
8.2.1.4	Skin protection	Good personal hygiene, lab coat and gloves. Wash hands after use.
8.2.1.5	Other controls	Emergency eye wash fountain should be close by and maintained.
8.2.2	Environmental exposure controls	Follow all government regulations.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	
9.1.1	Color	Tan, viscous liquid
9.1.2	Odor	Mild, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	Not determined
9.2.2	Boiling point	Not determined
9.2.3	Flash point	Not applicable
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not applicable
9.2.7	Vapor pressure	Not determined
9.2.8	Specific gravity	Not determined
9.2.9	Solubility in water	Soluble
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

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10.0	Stability and reactivity	
10.1	Conditions to avoid	Temperatures >27°C / 80°F
10.2	Materials to avoid	Strong oxidizing agents
10.3	Hazardous decomposition products	Carbon monoxide, carbon dioxide
10.4	Further information	Stable material
11.0	Toxicological information	
11.1	Acute toxicity	Not toxic. Soy lecithin is food grade.
11.2	Irritation and corrosiveness	May be irritating to eyes on contact.
11.3	Sensitization	May be an allergen for certain susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	None known
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	WINK has been on the market for about three years. There have been no reports of adverse events during that time.
12.0	Ecological Information	
12.1	Ecotoxicity	Not toxic. Follow all government regulations.
13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations.
14.0	Transport Information	
14.1	Restrictions	Non-hazardous material / Not regulated.
15.0	Regulatory Information	
15.1	EU	Class I Medical Device
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, Irritating to eyes. R43, May cause sensitization by skin contact.
16.2	Hazard Statements	H319: May cause eye irritation. Category 2. H317: May cause an allergic skin reaction. Category 1
16.3	Precautionary Statements	P305+P351: If in eyes, rinse cautiously with water for several minutes. P302+P352: If on skin, wash with plenty of soap and water.
16.4	Restrictions on use	Puldent products are for use by dental professionals only.

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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 the 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.
