SAFETY DATA SHEET

Premier® IntegraBondTM Universal Light-cure Bonding Agent

1. Chemical Product and Company Identification

Product Name: Premier® IntegraBondTM Universal light-cure bonding agent

Premier® Dental Products Company

1710 Romano Drive

Plymouth Meeting, PA 19462

PH: 610-239-6000 FAX: 610-239-6171

Emergency Phone: 610-239-6000

Indications for Use

IntegraBondTM is a single-step, universal bonding agent indicated for all direct composite / compomer restorations including amalgam bonding, all indirect restorations including cementation of crown and bridge, inlays and onlays, posts and veneers.

Contraindications:

Do not use on patients with known sensitivity or allergy to resins. Wash exposed area completely to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.

2. Hazards Identification.

Acute Health Hazards: May cause eye, respiratory and skin irritation.

Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation.

Prolonged skin exposure can cause dryness.

Primary Routes of Exposure: Inhalation, skin contact, eye contact.

Carcinogenicity: NTP – no, OSHA – no, IARC – no.

Hazard symbols:

3. Composition / Information of Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phrases
Acetone	67-64-1	F: Highly Flammable, Irritant,
		R11/36/66/67
Urethandimethacrylate	72869-86-4	Irritant, R36/37/38
Triethyleneglycoldimethacrylate	109-16-0	Irritant
2-Hydroxyethylmethacrylate	868-77-9	Irritant, R36/38-43
Multifunctional dimethacrylates	24448-20-2	Irritant, R36/37/38
4-methacryloxyethyltrimellitic Anhydrid	70293-55-9	Xn; R22-36/38-43
Photoinitiators	10287-53-3	Irritant, R36/37/38
	10334-26-6	N/E
Ethanol	64-17-5	F, R11

Additional information: For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures in Cause of Inhalation

If irritation occurs, take victim to open air.

In case of skin contact: wash with soap and water.

In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.

In case of ingestion: Consult a physician.

5. Fire-Fighting Measures

Flash Point: N/E

Extinguishing Media: Carbon dioxide, water spray, dry chemical. **Special Fire Fighting Procedures:** Avoid a direct jet of water.

Unusual Fire and Explosion Hazards: None.

6. Accidental Release Measures

Environmental Precautions: Avoid seepage into suvers and water supplies.

Clean-Up Procedure: Contain spill and pick up material with a suitable absorbent material. Place absorbent into a container for later disposal. Clean spill area with detergent and water.

7. Handling and Storage

Handling: No special measures necessary if handled according to instructions.

Storage: Keep container tightly closed when not in use. Store in a cool, dry location, below 24°C. Keep material in original packaging.

8. Exposure Controls/ Personal Protection

Exposure Controls: Use only in well ventilated areas.

Hand and Skin Protection: Avoid unnecessary skin contact. Wear latex gloves when handling. **Hygiene Measures:** Remove spilled material from skin and clothing. Do not eat or drink when handling this material.

9. Physical and Chemical Properties

Appearance: Light yellow liquid.

Odour: Specific odour. Boling Point: N/A Flash Point: N/E

Solubility in Water: Insoluble **Vapor Density (Air = 1):** N/E **Vapor Pressure (mm Hg):** N/E

10. Stability and Reactivity

Stability: Stable if handled according to directions.

Hazardous Reactions: None if handled according to directions

Hazardous Polymerization: May occur. **Conditions to Avoid:** Heat; UV-light.

Incompatibility: Free radicals, reducing agents, heavy metal ions.

Hazardous Decomposition Products: Carbon dioxide, carbon monoxide, acrylic decomposition

products, depending on conditions of heating and burning.

11. Toxicological Information

Acute oral toxicity: LD50 (rat) > 500 mg/kg

Irritation of Skin: Dryness and Irritation possible upon prolonged exposure.

Allergic Effects: Methacrylate sensitive individuals may exhibit an allergic reaction.

12. Ecological Information

Do not discharge into sewers or water supplies.

Environmental persistence and degradability: No data available.

Ecotoxicity: No data available.

13. Disposal Considerations

May be disposed of in landfill or incinerator In accordance with local, state and federal regulations.

14. Transport Information

14.1 Transport at land	ADR	3	RID	3
	UN Number	1170	Kemler Number	
	Packing Group	III		
	Proper shipping name	Ethanol Solution		
14.2 Transport at sea	ADNR	3	IMDG	3
_	UN Number	1170		
	EMS	F-E, S-D	MFAG	
	Packing Group	III		
	Proper shipping name	Ethanol Solution		
14.3 Air transport	ICAO / IATA-DGR			
	UN Number	1170		
	Proper shipping name	Ethanol Solution		
	Subsidiary Risk			
	Labels	Ethanol Solution		
	Packing Group	III		

U.S. DOT: Shipping Name: Not Regulated **U.S. DOT:** Hazard Class: None U.N/ N.A.

Number: None

U.S. Dot Packing Group: None

Other: Not considered hazardous cargo.

15. Regulatory Information

This product requires classification according to the criteria of EC. The product is a medical device according to the EC-directive 93/42.

15.1 UN Number15.2 National regulations	1170
15.3 EU number	
15.4 Hazard symbols	<u>!</u>
15.5 Hazard designation	Irritant.
	F: Highly Flammable. Contains Ethyl Alcohol.
15.6 Risk phrases	
	R: 11, 36, 37/38, 43
	11 Highly flammable.
	36 Irritating to eyes.
	37/38 Irritating to respiratory system and skin.
	43 May cause sensitization by skin contact.
15.7 Safety phrases	

S: 2, 9, 16, 23, 26, 28, 24/25, 37/39

- 2 Keep out of the reach of children.
- 9 Keep container in a well-ventilated place.
- 16 Keep away from sources of ignition No smoking.
- 23 Do not breathe vapor.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.
- 28 After contact with skin, wash immediately with
- plenty of water and soap.
- 24/25 Avoid contact with skin and eyes.
- 37/39 Wear suitable gloves and eye/face protection.

<u>U.S. – O.S.H.A. Status:</u> This material is not hazardous under the criteria of the U.S. Federal Hazard Communication Standard.

16. Other Information

Premier's revision date: 09-16-2014

Revision Number: 4

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

Relevant R-phrases

11 Highly flammable.

22 Harmful if swallowed.

36 Irritating to eyes.

37/38 Irritating to respiratory system and skin.

43 May cause sensitisation by skin contact.

Xn Harmful.

Material should be maintained in original containers. Empty containers should not be re-used.

AN SI / NFPA 704 DATA

Fire = 3 Health = 1

Reactivity = 1 Specific Supplier date: 07-30-2014

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