

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

1.1 Product Name:	Opuscem				
Product Code:	055				
Application:	Glass Ionomer Luting Cement (Anhydrous)				
1.2 Relevant identified uses of the substance or mixture and uses advised against;	Professional Uses (SU20) Health Services Restricted Use – Private Households				
1.3 Company:	Davis Schottlander & Davis Ltd Fifth Avenue, Letchworth Garden City Herts SG6 2WD UK Tel: +44 (0)1462 480848 Fax: +44 (0)1462 482802 msds@schottlander.co.uk www.schottlander.com				
Revision Date:	17.2.22	V3.0	Previous Revision	24.11.2015	V2.0

2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture	
2.1.2. Classification - EC 1272/2008	Eye Irrit. 2: H319;
2.2 Label Elements	
Hazard pictograms	
Signal Word	Warning
Hazard Statement	Eye Irrit. 2: H319 - Causes serious eye irritation.
Precautionary Statement: Prevention	P280 - Wear protective gloves/protective clothing/eye protection/face protection
Precautionary Statement: Response	P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention
2.3 Other Hazards	
Other Hazards	PBT. vPvB. Not applicable.
Further Information	
	Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures						
EC 1272/2008						
Chemical Name	Index No.	CAS No	EC No	REACH Registration Number	Conc (%w/w)	Classification
L(+) Tartaric Acid		87-69-4	201-766-0	01-2119537204-47		Eye Dam. 1: H318;

4. FIRST AID MEASURES

4.1 Description of First Aid Measures	
Inhalation:	Move the exposed person to fresh air
Eye Contact:	Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin Contact:	Wash off immediately with plenty of soap and water. Remove contaminated clothing
Ingestion:	Do NOT induce vomiting
4.2 Most Important Symptoms and effects, both acute and delayed	
Inhalation:	May cause irritation to mucous membranes
Eye Contact:	Causes serious eye irritation
Skin Contact:	May cause irritation to skin
Ingestion:	May cause irritation to mucous membranes
4.3. Indication of any immediate medical attention and special treatment needed	
Inhalation:	Seek medical attention if irritation or symptoms persist
Eye Contact:	Seek medical attention if irritation or symptoms persist
Skin Contact:	Seek medical attention if irritation or symptoms persist
Ingestion:	Seek medical attention if irritation or symptoms persist
General Information	
	If you feel unwell, seek medical advice (show the label where possible).

5. FIRE FIGHTING MEASURES

5.1 Extinguishing Media	
	Use extinguishing media appropriate to the surrounding fire conditions
5.2. Special hazards arising from the substance or mixture	
	Burning produces irritating, toxic and obnoxious fumes
5.3 Advice for firefighters	
	Wear suitable respiratory equipment when necessary

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures	
	Ensure adequate ventilation of the working area. Wear suitable protective equipment
6.2. Environmental precautions	
	Do not allow product to enter drains. Prevent further spillage if safe.
6.3. Methods and material for containment and cleaning up	

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	Avoid raising dust. Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water
6.4. Reference to other sections	
	See Section 13 for disposal information. See Section 8 for exposure controls/personal protection

7. HANDLING AND STORAGE

7.1. Precautions for safe handling	
	Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing
7.2. Conditions for safe storage, including any incompatibilities	
	Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in original container.
7.3. Specific end use(s)	
	See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters	
DNEL: derived no effect level	
Exposure Pattern - Workers	
L(+) Tartaric Acid	Long-term - inhalation - Systemic 5.2 mg/m ³ effects Long-term - dermal - Systemic 2.9 mg/kg effects
Exposure Pattern – General Population	
L(+) Tartaric Acid	Long-term - inhalation - Systemic 1.3mg/m ³ effects Long-term - dermal - Systemic 1.5 mg/kg Effects Long-term - dermal - Systemic 8.1 mg/kg effects
8.2 Exposure Controls	
	
8.2.1 Appropriate Engineering controls	Ensure adequate ventilation of the working area.
8.2.2 Individual Protection Measures	Wear chemical protective clothing
Eye / face protection	Approved safety goggles
Skin protection	Chemical resistant gloves
Hand Protection	
Respiratory Protection	Wear suitable respiratory equipment when necessary

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties	
Appearance	Powder
Colour	Not required
Odour	Odourless
Odour threshold	Not applicable
pH	No data available
Melting Point	No data available
Freezing Point	No data available
Initial Boiling Point	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, gas)	No data available
Vapour pressure	Not applicable
Vapour density	No data available
Relative Density	No data available
Fat Solubility	No data available
Partition Coefficient	No data available
Autoignition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Solubility	No data available
9.2. Other Information	
Conductivity	No data available
Surface tension	No data available
Gas Group	Not applicable
Benzene Content	No data available
Lead content	No data available
VOC (volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity	
	No data available
10.2 Chemical Stability	
	Stable under normal conditions
10.3 Possibility of hazardous reactions	
	No data available on this product
10.4 Conditions to Avoid	
	Heat Moisture
10.5 Incompatible Materials	
	Strong Acids. Strong bases
10.6 Hazardous decomposition products	
	No data available

11. TOXICOLOGY INFORMATION

11.1 Information on toxicological effects	
Acute toxicity	No data available
Skin Corrosion/Irritation	May cause irritation to skin
Serious eye damage/irritation	Causes serious eye irritation
Respiratory or skin sensitisation	May cause irritation to mucous membranes
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No carcinogenic effects reported.
Reproductive toxicity	No teratogenic effects reported.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	Irritating to respiratory system.
Repeated or prolonged exposure	Irritating to skin.
11.1.4 Toxicological Information	
L(+) Tartaric Acid	Oral Rat LD50: 2000 mg/kg Dermal Rabbit LD50: 2000 mg/kg

12. ECOLOGICAL INFORMATION

12.1 Toxicity	
L(+) Tartaric Acid	Daphnia EC50/48h: 93.1000 mg/l Algae IC50/72h: 51.4000 mg/l Fish LC50/96h: 100.0000 mg/l
12.2 Persistence and degradability	
	No data is available on this product
12.3 Bio accumulative potential	
	No data is available on this product
Partition coefficient	
	Glass Ionomer Luting Cement L(+) Tartaric Acid -1.91 log P No data available (Anhydrous)
12.4 Mobility in soil	
	No data is available on this product
12.5 Results of PBT and vPvB assessment	
	No data is available on this product
12.6 Other Adverse effects	
	No data is available on this product

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods	
	Dispose of in compliance with all. local and national regulations
General Information	
	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND /OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment

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	or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances
Disposal Methods	
	Do not empty into drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used
Disposal Packaging	
	Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling

14. TRANSPORT INFORMATION

14.1	UN number	
		The product is not classified as dangerous for carriage
14.2	UN proper shipping name	
		The product is not classified as dangerous for carriage
14.3	Transport hazard class(es)	
		The product is not classified as dangerous for carriage
14.4	Packing Group	
		The product is not classified as dangerous for carriage
14.5	Environmental hazards	
		The product is not classified as dangerous for carriage
14.6	Special precautions for use	
		The product is not classified as dangerous for carriage
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and IBC Code	
		The product is not classified as dangerous for carriage

15. REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation for the substance or mixture	
	Regulations	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
15.2	Chemical safety assessment	
		No data available

16. FURTHER INFORMATION

Other Information	
Revision	This document differs from the previous version in the following areas:. 2 - Precautionary Statement: Prevention
Text of Hazard Statements in Section 3	Eye Dam. 1: H318 - Causes serious eye damage

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.