

Safety Data Sheet

[SDS]

Form 0280-FM-07-09 Rev 6

Date Issued: 5/22/2015

Date Revised: 5/22/15

Revision Number: 1

Product Identifier [Part/Item Number(s)]: Class 133

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Elation MB Plastic Brackets

Chemical Name/Classification: Plastic/Polymer

U.N. Number: None

U.N. Dangerous Goods Classification: N/A

Recommended Use: Orthodontic bracket

Restrictions on Use: N/A

Manufacturer/Supplier Name: DENTSPLY GAC

Manufacturer/Supplier Address: One CA Plaza, Suite 100
Islandia, NY 11749

Manufacturer/Supplier Telephone Number: 1-800-645-5530

Emergency Contact Telephone Number: 1-800-424-9300 (CHEMTREC, account number CCN721860)

Email address: gac.info@dentsply.com

2. HAZARD(S) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
No Health hazards known	Unknown	Unknown

Associated Hazards:

Hazard Statements	Precautionary Statements
Unknown	Unknown

EU Classification: Unknown

EU Risk (R) and Safety (S) Phrases: Unknown

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Component	C.A.S. # / EC#	IUPAC Name	Substance Classification	WT % ($\mu\text{g}/\text{m}^3$)
Bracket body			Polymer	
Bisphenol-A Polycarbonate	25037-45-0 / 607-501-9	Carbonic acid; 4-[2-(4-hydroxyphenyl) propan-2-yl] phenol	None	70 ~ 80
Polyethylene terephthalate	25038-59-9	poly(ethylene terephthalate)	None	10 ~ 20
Polybutylene terephthalate	24968-12-5	Poly(oxy-1,4-butanediylloxycarbonyl-1,4-phenylenecarbonyl)	None	5 ~ 10
Metal Insert			Alloy	
Carbon	7440-44-0	C	None	0 ~ 0.08
Silicon	7740-21-3	Si	None	0 ~ 1
Manganese	7439-96-5	Mn	None	0 ~ 2
Nickel	7740-02-0	Ni	None	8 ~ 10.5
Chromium	7740-47-3	Cr	None	18 ~ 20
Iron	7439-89-6	Fe	None	Bal.





Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	N/A
Skin	No adverse effects anticipated by this route of exposure incidental to proper handling however, if effects occur, consult a physician.
Inhalation	N/A
Ingestion	N/A
Most important symptoms of exposure	Unknown
Other	none
Note to Physicians (Treatment, Testing, and Monitoring) There are no required first aid measures for contact with the solid, finished product.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	The material is not combustible in its final, solid form. Use extinguishing media that is appropriate for the surrounding fire.
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Fire Fighting Procedures:	N/A		
Specific Hazards Arising from the Chemical:	N/A		
Precautions for Fire Fighters:	Thermal decomposition or combustion products included oxides of the metals listed in Section 3, which may be highly toxic. This product is not considered hazardous in its final, solid form.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Remove by mechanical means. Use appropriate PPE for the situation. Specific PPE is not required to handle or remove the solid, finished product.

Environmental Precautions: N/A

Methods and Materials for Containment and Clean-up: N/A

7. HANDLING AND STORAGE

Precautions for Safe Handling: Use good housekeeping procedures to minimize dust accumulation. Keep containers closed when not in use. Do not eat, drink or smoke in the work area. Always follow Universal Precautions when in contact with patients.

Conditions for Safe Storage: Store away from heat and moisture. Storage in hot and humid conditions over the long term causes deterioration of bond strength. Store in a cool, well ventilated area, away from incompatible materials.




8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Component	OSHA PEL (mg/m ³)	ACGIH TLV (mg/m ³)
Bisphenol-A Polycarbonate	None	None
Polyethylene terephthalate	15.0	10.0
Polybutylene terephthalate	10.0	5.0
Carbon (C)	N/A, present below 0.1% by weight.	N/A, present below 0.1% by weight.
Chromium (Cr)	1.0	0.5
Iron (Fe)	10.0	5.0
Nickel (Ni)	1.0	1.0
Manganese (Mn)	5.0	0.02
Silicon (Si)	15.0	10.0

Biological Exposure Limits: N/A

Appropriate Engineering Controls: Wear protective gloves, eye protection and respiratory covers as appropriate when in contact with patients. Always follow Universal Precautions.

Individual Protection Measures (PPE) Specific Eye/face Protection: as appropriate and consistent with industry standards Specific Skin Protection: as appropriate and consistent with industry standards Specific Respiratory Protection: as appropriate and consistent with industry standards Specific Thermal Hazards: N/A			
Recommended Personal Protective Equipment; Not required			
EYES/FACE	SKIN	RESPIRATORY	
			
Environmental Exposure Controls: N/A			
General Hygiene Considerations and Work Practices: Universal Precautions and Dental/Orthodontic Industry Standards			
Protective Measures During Repair and Maintenance of Contaminated Equipment: N/A			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, transparent solid	Explosive limits:	N/A
Odor:	Odorless / None	Vapor pressure:	N/A
Odor threshold:	N/A	Vapor density:	N/A
pH:	N/A	Relative density:	N/A
Melting/freezing point:	N/A	Solubility:	N/A
Initial boiling point and range:	N/A	Partition coefficient: n-octanol/water:	N/A
Flash point:	N/A	Auto-ignition temperature:	N/A
Evaporation rate:	N/A	Decomposition temperature:	N/A
Flammability:	N/A	Viscosity:	N/A
Explosive Properties:	N/A	Oxidizing Properties:	N/A

10. Stability and Reactivity

Reactivity: Non-reactive under normal, ambient and atmospheric conditions.

Chemical Stability: Stable under normal, ambient and atmospheric conditions.
Possibility of Hazardous Reactions: None known
Conditions to Avoid: Avoid temperatures above 797 °F, 425 °C. Product can decompose at elevated temperatures.
Incompatible materials: May react with strong acids (hydrogen, oxides of nitrogen) and strong oxidizers (high pH).
Hazardous Decomposition Products: At temperatures exceeding melt temperature polymer fragments can occur. Hazardous decomposition products may include and are not limited to bisphenol A.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects: In the product's solid and final form, stainless steel alloys do not present inhalation, absorption or ingestion hazards. Eyes: None known Skin: None known Ingestion: None known Inhalation: None known
Chronic Health Effects: Prolonged or repeated skin contact with Nickel (Ni) may cause sensitization.
Carcinogenicity: Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as "Reasonably Anticipated to be a Carcinogen". None of the other components is listed as a carcinogen by IARC, NTP, ACGIH or OSHA.
Mutagenicity: None known
Medical Conditions Aggravated by Exposure: This product should not be used in individuals with a known Nickel sensitivity or allergy. Use of this product should be discontinued in those individuals whom develop a Nickel sensitivity/allergy after prolonged contact. Individuals with pre-existing skin disorders may be at increased risk from exposure.
Acute Toxicity Data: None known
Reproductive Toxicity Data: None known
Specific Target Organ Toxicity (STOT): None known Single Exposure: None known Repeated Exposure: None known

12. ECOLOGICAL INFORMATION

Toxicity: None known / No data available
Persistence and Degradability: None known / No data available
Bio-accumulative Potential: None known / No data available
Mobility in Soil: None known / No data available
Other Adverse Effects: None known / No data available

Results of PBT/vPvB Assessment: None known / No data available

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose of used product in accordance with national and local regulations. Consider selling or recycling unused product through authorized parties, following all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: N/A

Waste Treatment Recommendations: None known

14. TRANSPORT INFORMATION

UN Identification Number: N/A

UN Proper Shipping Name: N/A

Transport hazard class(es): Not classified

Packing Group: N/A

Special precautions for user: N/A, product is non-hazardous and Not Regulated by DOT. Special labeling for transport is not required.

15. REGULATORY INFORMATION

This product is manufactured using Good Manufacturing Practices (GMP). The product is regulated as a Class I Medical Device in the United States by the Food and Drug Administration (FDA). The product is regulated as a Class II Medical Device by Health Canada (CMDR), and as a Class IIa Medical Device in the European Community (MDD 93-42 EEC).

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): N/A

Toxic Substances Control Act (TSCA): N/A.

Clean Water Act (CWA): N/A

Clean Air Act (CAA): N/A

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: This product does not contain any chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372).

Immediate Hazard:	N/A	Pressure Hazard:	N/A
Delayed Hazard:	N/A	Reactivity Hazard:	N/A
Fire Hazard:	N/A		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Chromium (Cr)	7440-47-3	18.0-20.0
Nickel (Ni)	7440-47-3	8.0-10.5
Manganese (Mn)	7439-96-5	0-2.0

State Regulations

California Proposition 65: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm (if blank, the product does not contain Proposition 65 regulated chemicals): Nickel.

International Regulations

Canadian Environmental Protection Act: N/A

Canadian Workplace Hazardous Materials Information System (WHMIS): N/A

European Inventory of Existing Chemicals (EINECS): N/A

European Chemical Agency (ECHA) REACH (Registration, Evaluation, Authorization and Restriction of Chemicals): N/A

Australian Inventory of Chemical Substances: N/A

China Inventory of Existing Chemicals and Chemical Substances: N/A

Japanese Existing and New Chemical Substances: N/A

Korean Existing Chemicals List: N/A

Philippine Inventory of Chemicals and Chemical Substances: N/A

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: N/A

Date of SDS Preparation/Revision: 05/22/2015, Revision 1

Data Sources:

- 1) GHS – Globally Harmonized System of Classification and Labeling of Chemicals (2007).
- 2) OSHA – Occupational & Health Safety Administration, Permissible Exposure Limits [PEL] (2004).
- 3) ACGIH – Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2008).
- 4) Appropriate published regulations, i.e. California Prop 65, CWA, CAA, CERCLA, etc.
- 5) Supplier's MSDS Specification