Dentsply Sirona Orthodontics

Date Revised: **04/27/2017**
Revision Number: **2**
Date Issued: **02/09/2017**
Document Number:
0280-MSDS-0064

Safety Data Sheet: In-Ovation X Brackets

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**In-Ovation X Brackets**
Chemical Name/Classification:	**Stainless Steel Alloy**
U.N. Number:	**S-31600 & S-17400**
U.N. Dangerous Goods Classification:	**N/A**
Recommended Use:	**Orthodontic bracket**
Restrictions on Use:	**N/A**
Manufacturer/Supplier Name:	**DENTSPLY-GAC**
Manufacturer/Supplier Address:	**1 CA Plaza, Suite 100, Islandia, NY - 11749**
Manufacturer/Supplier Telephone Number:	**1-631-419-1700 (Product Information)**
24/7 Emergency Contact Telephone Number:	**1-800-424-9300 (CHEMTREC)**
Email address:	**gac.info@dentsply.com**

2. HAZARD(s) IDENTIFICATION

This product is considered a stable material under normal storage and handling conditions. Stainless steel products in their normal, solid state are not generally classified as hazardous.

Hazard/Danger Classification:

Health	Environmental	Physical
None	None	None

Associated Hazards: **Signal Word:**

Hazard Statements	Precautionary Statements
None	None

EU Classification: not listed

EU Risk (R) and Safety (S) Phrases: N/A

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 % (µg/ m^3)
Bracket body & hook/post			**Alloy**	
Carbon	7440-44-0	C	None	0 ~ 0.07
Manganese	7439-96-5	Mn	None	0 ~ 1
Nickel	7440-02-0	Ni	None	3 ~ 5
Chromium	7440-47-3	Cr	None	15 ~ 17.5
Copper	7440-50-8	Cu	None	3 ~ 5
Niobium	7440-03-1	Nb	None	0.15 ~ 0.45
Silicon	7440-21-3	Si	None	0 ~ 1
Iron	7439-89-6	Fe	None	Bal.
Clip			**Alloy**	
Carbon	7440-44-0	C	None	≤0.03%
Manganese	7439-96-5	Mn	None	0 ~ 0.5
Silicon	7440-21-3	Si	None	0 ~ 0.1
Chromium	7440-47-3	Cr	None	19.5 ~ 20.5
Nickel	7440-02-0	Ni	None	31.4 ~ 33.4
Molybdenum	7439-98-7	Mo	None	9.5 ~ 10.5
Iron	7439-89-6	Fe	None	1.1 ~ 2.1
Titanium	7440-32-6	Ti	None	0.3 ~ 0.7
Niobium	7440-03-1	Nb	None	0.8 ~ 1.2
Cobalt	7440-48-4	Co	None	Bal.

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

Component	C.A.S. # EC#	IUPAC Name	Substance Classification	WT % (µg/ m^3)
Bonding base			**Alloy**	
Carbon	7440-44-0	C	None	0 ~ 0.030
Manganese	7439-96-5	Mn	None	0 ~ 2.0
Nickel	7440-02-0	Ni	None	12.0 ~ 15.0
Chromium	7440-47-3	Cr	None	16.0 ~ 18.0
Molybdenum	7439-98-7	Mo	None	2.0 ~ 3.0
Silicon	7440-21-3	Si	None	0 ~ 1.0
Phosphorus	7723-14-0	P	None	0 ~ 0.045
Sulfur	7704-34-9	S	None	0 ~ 0.030

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	N/A
Skin	N/A
Inhalation	N/A
Ingestion	N/A
Most important symptoms of exposure	N/A
Other	N/A

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.
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. The product is not considered hazardous in its final, solid form.

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPRIATORY	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

Recommended Personal Protective Equipment for Containment and Clean-up: N/A

7. HANDLING AND STORAGE

Precautions for Safe Handing: 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 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)
Carbon (C)	N/A, present below 0.1% by weight.	N/A, present below 0.1% by weight.
Chromium (Cr)	1.0	0.5
Cobalt (Co)	0.1	1.5
Copper (Cu)	1.0	1.0
Gold (Au)	None	None
Iron (Fe)	10.0	5.0
Manganese (Mn)	5.0	0.02
Molybdenum (Mo)	15.0	10.0
Nickel (Ni)	1.0	1.0
Phosphorus (P)	N/A, present below 0.1% by weight.	N/A, present below 0.1% by weight.
Silicon (Si)	15.0	10.0
Silver (Ag)	0.01	1.0
Sulfur (S)	N/A, present below 0.1% by weight.	N/A, present below 0.1% by weight.
Titanium (Ti)	None	None

Biological Exposure Limits: N/A

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

Appropriate Engineering Controls: Wear protective gloves while handling stainless steel products to prevent cuts and skin abrasions, as well as to reduce the risk of sensitization from skin contact. 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

EYES/FACE	SKIN	RESPRIATORY

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:	Varying from dull to very light grey, to shiny metallic light grey, to bright mirror-finish	**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

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

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: None known
Incompatible materials: May react with strong acids (hydrogen, oxides of nitrogen) and strong oxidizers (high pH).
Hazardous Decomposition Products: None known

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. Long-term exposures to Copper (Cu) may cause respiratory, liver and/or kidney effects.
Carcinogenicity: Nickel compounds (may be formed in welding) are classified by IARC as known human carcinogens (Group 1) and by NTP as "Known Human Carcinogens". Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as "Reasonably Anticipated to be a Carcinogen" in its raw and pure form. None of the other components are 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: No data available
Reproductive Toxicity Data: No data available
Specific Target Organ Toxicity (STOT): None known **Single Exposure:** No data available **Repeated Exposure:** No data available

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

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): N/A
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).

This document contains proprietary information. It may not be reproduced or disclosed without prior written approval

U.S. Federal Regulations

This product does not contain any known hazardous materials in reportable levels as defined by OSHA Hazard Communication Standard, 29 CFR 1910.1200 or as defined under SARA § 311 and § 312.

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 contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): *Exempt; components not hazardous unless processing creates dusts or fumes.*

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): *Not Applicable; product is stable and non-toxic/non-hazardous when used in its final, solid form.*

State Regulations

California Proposition 65: This product does not contain any ingredients known to the State of California to cause cancer, birth defects or other reproductive harm.

International Regulations

This material or all of its components are listed on the Inventory of Existing Chemical Substances under: the Toxic Substance Control Act (TSCA), the Canadian Domestic Substances List (DSL), or considered as having been notified under the European Inventory of Existing Chemical Substances (EINECS). Other inventory lists: Japan (ENCS), Korea, Australia, China (Draft), Philippines (PICCS).

Canadian Environmental Protection Act:

Canadian Workplace Hazardous Materials Information System (WHMIS): This MSDS has been prepared according to the hazard criteria of the control Products Regulations (CPR) and contains all of the information required.

European Inventory of Existing Chemicals (EINECS): The components used to make this product are EU listed.

REACH: N/A

16. OTHER INFORMATION

The data in this Safety Data Sheet relates only to the specific material designated herein. It does not relate to use in combination with any other material or in any process.

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of DENTSPLY GAC International. The data on this sheet are related only to the specific material designated herein. DENTSPLY GAC International assumes no legal responsibility for use or reliance upon these data.

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

Date of SDS Preparation/Revision: 09Feb2017, rev. 1

Data Sources: DENTSPLY GAC International technical and design history file information, along with individual raw material safety data sheets and applicable hazard communication regulations.