

## Safety Data Sheet:

# Metal Brackets, Buccal Tubes & Lingual Sheaths

Date Revised: **10/12/2016**Revision Number: **2**Date Issued: **10/12/2016**

Document Number:

**0280-MSDS-0050**

### 1. PRODUCT IDENTIFICATION

<b>Trade Name (as labeled):</b>	<b>MicroArch+, OmniArch+, In-Ovation R, GAC Buccal Tubes, Lingual Sheaths</b>
<b><u>With Brazing Material</u> –</b>	MicroArch+, OmniArch+
<b><u>With Clip</u> –</b>	In-Ovation R
<b>Chemical Name/Classification:</b>	Stainless Steel Alloy
<b>Product Identifier (Part/Item Number):</b>	<b>Product classes J72, J77, J189, 268, 269, J21</b>
<b>U.N. Number:</b>	S-31600 & S-17400
<b>U.N. Dangerous Goods Classification:</b>	N/A
<b>Recommended Use:</b>	Orthodontic Bracket
<b>Restrictions on Use:</b>	Do not use outside of indicated use in orthodontics
<b>Manufacturer Name:</b>	<b>DENTSPLY GAC International</b>
<b>Manufacturer Address:</b>	One CA Plaza, Suite 100, Islandia, NY 11749
<b>Manufacturer Telephone Number:</b>	1-800-645-5530 (Product Information)
<b>24/7 Emergency Contact Number:</b>	<b>1-800-424-9300 (CHEMTREC, # CCN721860)</b>
<b>Manufacturer Email address:</b>	<a href="mailto:gac.info@dentsply.com">gac.info@dentsply.com</a>

### 2. HAZARD(s) IDENTIFICATION

**CAUTION**

#### Hazard/Danger Classification:

Health	Environmental	Physical
None	None	None

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**Associated Hazards:**

Hazard Statements	Precautionary Statements
None	None

**EU Classification:** Not classified as a dangerous preparation as sold. Dust or fumes generated from processing maybe harmful or dangerous to the environment.

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

**EU Risk (R) and Safety (S) Phrases:** Related only to the dust or fumes generated from processing: Harmful (Xn), Dangerous for the Environment (N), R40, R43, R48/23, R51/53.

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Component	C.A.S. # EC#	IUPAC Name	Substance Classification	WT % ( $\mu\text{g}/\text{m}^3$ )
<b>Bracket body &amp; hook/post</b>			<b>Alloy</b>	
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.
<b>Clip (where applicable)</b>			<b>Alloy</b>	
Carbon	7440-44-0	C	None	0 ~ 0.025
Manganese	7439-96-5	Mn	None	0 ~ 0.15
Silicon	7440-21-3	Si	None	0 ~ 0.15
Phosphorus	7723-14-0	P	None	0 ~ 0.015
Sulfur	7704-34-9	S	None	0 ~ 0.010
Chromium	7440-47-3	Cr	None	19.0 ~ 21.0
Nickel	7440-02-0	Ni	None	33.0 ~ 37.0
Molybdenum	7439-98-7	Mo	None	9.0 ~ 10.5

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Component	C.A.S. # EC#	IUPAC Name	Substance Classification	WT % ( $\mu\text{g}/\text{m}^3$ )
Iron	7439-89-6	Fe	None	0 ~ 1.0
Titanium	7440-32-6	Ti	None	0 ~ 1.0
Boron	7440-42-8	B	None	0 ~ 0.015
Cobalt	7440-48-4	Co	None	Bal.
<b>Bonding base</b>			<b>Alloy</b>	
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
<b>Brazing material (where applicable)</b>			<b>Alloy</b>	
Gold	7440-57-5	Au	None	20 ~ 50
Silver	7440-22-4	Ag	None	20 ~ 50
Copper	7440-50-8	Cu	None	Bal.

#### 4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
<b>Eye</b>	N/A
<b>Skin</b>	N/A
<b>Inhalation</b>	N/A
<b>Ingestion</b>	N/A
<b>Most important</b>	N/A

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<b>symptoms of exposure</b>	
<b>Other</b>	N/A
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> There are no required first aid measures for contact with the solid, finished product.	

## 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	The material is not combustible in its final, solid form. Use extinguishing media that is appropriate for the surrounding fire.		
<b>Fire Fighting Procedures:</b>	N/A		
<b>Specific Hazards Arising from the Chemical:</b>	N/A		
<b>Precautions for Fire Fighters:</b>	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.		
<b>Recommended Protective Equipment for Fire Fighters:</b>			
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. Use gloves to handle product that has come in contact with the patient.



**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 in a cool, well ventilated area, away from incompatible materials.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits:

Component	OSHA PEL (mg/m <sup>3</sup> )	ACGIH TLV (mg/m <sup>3</sup> )
Boron (B)	N/A, present below 0.1% by weight.	N/A, present below 0.1% by weight.
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

**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:

**Specific Eye 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	RESPIRATORY
		
<b>Environmental Exposure Controls:</b> N/A		
<b>General Hygiene Considerations and Work Practices:</b> Universal Precautions and Dental/Orthodontic Industry Standards		
<b>Protective Measures During Repair and Maintenance of Contaminated Equipment:</b> N/A		

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Varying from dull to very light grey, to shiny metallic light grey, to bright mirror-finish	<b>Odor:</b>	Odorless / None
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## 10. STABILITY AND REACTIVITY

<b>Reactivity:</b> Non-reactive under normal, ambient and atmospheric conditions.
<b>Chemical Stability:</b> Stable under normal, ambient and atmospheric conditions.
<b>Possibility of Hazardous Reactions:</b> None known
<b>Conditions to Avoid:</b> None known
<b>Incompatible materials:</b> May react with strong acids (hydrogen, oxides of nitrogen) and strong oxidizers (high pH).
<b>Hazardous Decomposition Products:</b> None known

## 11. TOXICOLOGICAL INFORMATION

**Signs and Symptoms of Overexposure:** In the product's solid and final form, stainless steel alloys do not present inhalation, absorption or ingestion hazards.

**Emergency Overview:** If exposure occurs during industrial processing - Dust of fumes may cause eye and skin irritation or allergic reaction (sensitization). Exposure to nickel dust or fumes may cause irritation of the mucous membranes and upper respiratory tract. May cause allergic respiratory reaction

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(sensitization). Exposure to copper dust may cause cough, headache, shortness of breath, and eye, skin and respiratory irritation. Exposure to fumes may cause metal fume fever or skin and hair discoloration.

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
<b>Eye:</b>	Irritation	Single	Mild-moderate	Acute	Eye	No data available	No data available
<b>Skin:</b>	Irritation, Allergic Reaction	Single, Repeated	Mild – severe	Acute	Skin	No data available	No data available
<b>Inhalation:</b>	Irritation, Metal fume fever, Hair discoloration	Single, Repeated	Mild – severe	Acute	Mucous membranes, upper respiratory tract	No data available	No data available
<b>Ingestion:</b>	Irritation	Single	Mild-moderate	Acute	Eye	No data available	No data available
<b>Other:</b>	Irritation, Allergic Reaction	Single, Repeated	Mild – severe	Acute	Skin	No data available	No data available

**Chronic Exposure:** Prolonged or repeated skin contact to nickel may cause sensitization. Prolonged inhalation of dust may cause lung damage, fibrotic lung disease, and effects on the cardiovascular system. Prolonged inhalation of nickel dust or fumes may cause perforation of the nasal septum and lung damage. Long-term exposures to copper may cause respiratory, liver and kidney effects.

**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.

**Toxicity:** No acute effects expected from swallowing small amounts. Ingestion of large amounts of copper may cause abdominal pain, nausea or vomiting.

**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”. None of the other components is listed as a carcinogen by IARC, NTP, ACGIH or OSHA.

## 12. ECOLOGICAL INFORMATION

**Toxicity:** No data available at this time

**Persistence and Degradability:** No data available at this time

**Bio-accumulative Potential:** No data available at this time

**Mobility in Soil:** No data available at this time

**Other Adverse Effects:** No data available at this time

**Results of PBT/vPvB Assessment:** No data available at this time

### 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

**NFPA Rating: Health- 0**

**Flammability- 0**

**Physical Hazard- 0**

NFPA numeric hazard values: 0 =Minimal, 1 =Slight, 2 =Moderate, 3 =Serious, 4 =Severe

#### 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

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**Clean Air Act (CAA):** N/A

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:** N/A

**SARA Section 311/312 (40 CFR 370) Hazard Categories:** N/A, 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. However, components below are listed under SARA Section 313.

Components	C.A.S. #	WT % ( $\mu\text{g}/\text{m}^3$ )
Chromium (Cr)	7440-47-3	16.0-18.0
Cobalt (Co)	7440-48-4	33.0
Copper (Cu)	7440-50-8	3.0-5.0
Manganese (Mn)	7439-96-5	0-2.0
Nickel (Ni)	7440-02-0	3.0-37.0

### State Regulations

**California Proposition 65:** This product contains Nickel, which is known to the State of California to cause cancer.

### 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:** This product is a medical device and not subject to the chemical notification requirements.

**Canadian Workplace Hazardous Materials Information System (WHMIS):** This SDS 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:** There are not currently any chemical components of this product that have been included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006.

**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:

R40 Limited evidence of carcinogenic effect.

R43 May cause sensitization by skin contact.

R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation.

R51/53 Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

Date of SDS Preparation/Revision: 12OCT2016, rev. 2

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