

## **SAFETY DATA SHEET**

Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, Ormco Bicuspids, High Retention Bands

### Section 1. Identification

Product identifier	: Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, Ormco Bicuspids, High Retention Bands
Product code	: Not available.
Other means of identification	: Not available.
Product type	: Solid.
Relevant identified uses of	the substance or mixture and uses advised against
Product use	<ul> <li>Dental product: Orthodontic Appliance This product, under the normal conditions of use, meets the definition of an "ARTICLE".</li> </ul>
Area of application	: Professional applications.
Manufacturer	: Ormco Corporation 1332 S. Lone Hill Avenue Glendora, CA 91740-5339 Telephone no.: 1-800-854-1741
e-mail address of person responsible for this SDS	: OrmcoCustCare@sybrondental.com
Emergency telephone number (with hours of operation)	: CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

### Section 2. Hazard identification

Classification of the substance or mixture	:	Not classified.
GHS label elements		
Signal word	:	No signal word.
Hazard statements	1	No known significant effects or critical hazards.
Precautionary statements		
Prevention	1	Not applicable.
Response	1	Not applicable.
Storage	1	Not applicable.
Disposal	1	Not applicable.
Supplemental label elements	:	Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 19%
Other hazards which do not result in classification	:	If dust or fumes are generated during processing (e.g., brazing, cutting, grinding, sawing, and welding) hazardous chemicals could be released.

#### Section 3. Composition/information on ingredients

#### Substance/mixture

### Other means of identification

- : Mixture
- : Not available.

Ingredient name	% (w/w)	CAS number
nickel	13	7440-02-0
manganese	2	7439-96-5
silicon	1	7440-21-3

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

#### Section 4. First-aid measures

Description of necess	ary first aid measures
Eye contact	: No special measures are required. Get medical attention if symptoms occur.
Inhalation	: No special measures required. Get medical attention if symptoms occur.
Skin contact	: No special measures required. Get medical attention if symptoms occur.
Ingestion	: If swallowed then seek immediate medical assistance.

#### Most important symptoms/effects, acute and delayed

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Potential acute health effe	<u>cts</u>
Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.
<u>Over-exposure signs/sym</u>	<u>otoms</u>
Eye contact	: No specific data.
Inhalation	: No specific data.
Skin contact	: No specific data.
Ingestion	: No specific data.
Indication of immediate me	dical attention and special treatment needed, if necessary
Notes to physician	<ul> <li>Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.</li> </ul>
Specific treatments	: No specific treatment.
Protection of first-aiders	: In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

### Section 5. Fire-fighting measures

#### Extinguishing media

Suitable extinguishing media	: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: Do not use water jet.

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### Section 5. Fire-fighting measures

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Specific hazards arising from the chemical	: No specific fire or explosion hazard.
Hazardous thermal decomposition products	: Decomposition products may include the following materials: metal oxide/oxides
Special protective actions for fire-fighters	: In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	<ul> <li>Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.</li> </ul>

### Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures				
For non-emergency personnel	: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely			
For emergency responders	: Low release. See also the information in "For non-emergency personnel".			
Environmental precautions	: No special measures are required.			
Methods and materials for containment and cleaning up				
Small spill	: No special measures required.			

# Large spill : No special measures required. Section 7. Handling and storage

		•
Precautions for safe handling	L	
Protective measures	1	No special measures are required.
Advice on general occupational hygiene	:	No special measures are required.

**Conditions for safe storage,** : Store in accordance with local regulations. **including any incompatibilities** 

### Section 8. Exposure controls/personal protection

#### **Control parameters**

#### **Occupational exposure limits**

Ingredient name			Exposure limits
Nickel			<ul> <li>CA Saskatchewan Provincial (Canada, 7/2013).</li> <li>STEL: 3 mg/m<sup>3</sup> 15 minutes. Form: Inhalable fraction</li> <li>TWA: 1.5 mg/m<sup>3</sup> 8 hours. Form: Inhalable fraction</li> <li>CA Ontario Provincial (Canada, 7/2015).</li> <li>TWA: 1 mg/m<sup>3</sup> 8 hours. Form: Inhalable fraction.</li> <li>CA Alberta Provincial (Canada, 4/2009).</li> <li>8 hrs OEL: 1.5 mg/m<sup>3</sup> 8 hours.</li> <li>CA British Columbia Provincial (Canada, 5/2015).</li> <li>TWA: 0.05 mg/m<sup>3</sup>, (as Ni) 8 hours.</li> </ul>
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### Section 8. Exposure controls/personal protection

: 1 mg/m <sup>3</sup> 8 hours.
h Columbia Provincial (Canada,
2 mg/m³, (as Mn) 8 hours.
ta Provincial (Canada, 4/2009).
EL: 0.2 mg/m³, (as Mn) 8 hours.
rio Provincial (Canada, 7/2015).
2 mg/m³, (as Mn) 8 hours.
ec Provincial (Canada, 1/2014).
: 0.2 mg/m <sup>3</sup> , (as Mn) 8 hours. Form:
t.
atchewan Provincial (Canada,
.6 mg/m <sup>3</sup> , (measured as Mn) 15
2 mg/m³, (measured as Mn) 8
h Columbia Provincial (Canada,
mg/m <sup>3</sup> 8 hours. Form: Respirable
) mg/m³ 8 hours. Form: Total dust
ec Provincial (Canada, 1/2014).
: 10 mg/m <sup>3</sup> 8 hours. Form: Total
atchewan Provincial (Canada,
0 mg/m³ 15 minutes.
) mg/m³ 8 hours.

Appropriate engineering controls	: No special measures are required for small quantities under normal and intended conditions of product use.	I
Environmental exposure controls	: No special measures are required for small quantities under normal and intended conditions of product use.	I
Individual protection meas	<u>ires</u>	
Hygiene measures	: No special measures are required for small quantities under normal and intended conditions of product use.	I
Eye/face protection	: No special measures are required for small quantities under normal and intended conditions of product use.	1
Skin protection		
Hand protection	: No special protection is required.	
Body protection	: No special measures are required for small quantities under normal and intended conditions of product use.	1
Other skin protection	: No special measures are required for small quantities under normal and intended conditions of product use.	1
Respiratory protection	: No special measures are required for small quantities under normal and intended conditions of product use.	1

### Section 9. Physical and chemical properties

Appearance	
Physical state	: Solid. [Orthodontic Band]
Color	: Metallic. Gray.
Odor	: Odorless.
Odor threshold	: Not applicable.
рН	: Not applicable.
Melting point	: 482.22 to 1760°C (900 to 3200°F)
Boiling point	: Not applicable.
Flash point	: Not applicable.
Evaporation rate	: Not applicable.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not applicable.
Vapor pressure	: Not applicable.
Vapor density	: Not applicable.
Relative density	: Not applicable.
Solubility	: Insoluble in the following materials: cold water and hot water.
Partition coefficient: n- octanol/water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not applicable.
Viscosity	: Not applicable.
Flow time (ISO 2431)	: Not applicable.

### Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### Section 11. Toxicological information

#### Information on toxicological effects

Acute toxicity

### Section 11. Toxicological information

Product/ingredient name	Result		Specie	es	Dose		Exposure
manganese			ts Rat Rat		5.14 9 g/k	0	4 hours -
silicon	LD50 Oral		Rat			mg/kg	-
Conclusion/Summary	: Non-cytotoxic.						
rritation/Corrosion							
Product/ingredient name	Result	Sp	ecies	Scor	e	Exposure	Observation
manganese	Eyes - Mild irritan	t Ra	bbit	-		24 hours 50 milligrams	- 00
	Skin - Mild irritant	: Ra	bbit	-		24 hours 50 milligrams	- 00
silicon	Eyes - Mild irritan	t Ra	bbit	-		3 milligram	s -
Conclusion/Summary	•	I.					•
Skin	: Not available.						
Eyes	: Not available.						
Respiratory	: Not available.						
Sensitization							
Product/ingredient name	Route of exposure	Species			Resu	lt	
Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, Ormco Bicuspids	skin Guinea pig				Not s	ensitizing	
Conclusion/Summary							
Skin	: Not available.						
Respiratory	: Not available.						
<u>Mutagenicity</u>							
Conclusion/Summary	: Not available.						
Carcinogenicity							
Conclusion/Summary	: Not available.						
Reproductive toxicity							
Conclusion/Summary	: Not available.						
<u>Feratogenicity</u>							
Conclusion/Summary	: Not available.						
Specific target organ toxicit Not available.	ty (single exposur	<u>e)</u>					
Specific target organ toxicit	ty (repeated expos	<u>sure)</u>					

Name	Category	Route of exposure	Target organs
Nickel manganese	Category 1 Category 2	Inhalation Not determined	respiratory tract central nervous system (CNS) and lungs

#### **Aspiration hazard**

Not available.

### Information on the likely routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation.

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### Section 11. Toxicological information

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Potential acute health effects		
Eye contact	lo known significant effects or critical hazards.	
Inhalation	lo known significant effects or critical hazards.	
Skin contact	lo known significant effects or critical hazards.	
Ingestion	lo known significant effects or critical hazards.	
Symptoms related to the phy	, chemical and toxicological characteristics	
Eye contact	lo specific data.	
Inhalation	lo specific data.	
Skin contact	lo specific data.	
Ingestion	o specific data.	
Delayed and immediate effec	d also chronic effects from short and long term ex	posure
<u>Short term exposure</u>		
Potential immediate effects	lot available.	
Potential delayed effects	lot available.	
<u>Long term exposure</u>		
Potential immediate effects	lot available.	
Potential delayed effects	lot available.	
Potential chronic health effe		
<b>Conclusion/Summary</b>	lot available.	
General	lo known significant effects or critical hazards.	
Carcinogenicity	lo known significant effects or critical hazards.	
Mutagenicity	lo known significant effects or critical hazards.	
Teratogenicity	lo known significant effects or critical hazards.	
<b>Developmental effects</b>	lo known significant effects or critical hazards.	
Fertility effects	lo known significant effects or critical hazards.	

#### Numerical measures of toxicity

Acute toxicity estimates

Not available.

### Section 12. Ecological information

#### **Toxicity**

Product/ingredient name	Result	Species	Exposure
Nickel	Acute EC50 2 ppm Marine water	Algae - Macrocystis pyrifera - Young	4 days
	Acute EC50 450 µg/l Fresh water	Aquatic plants - Lemna minor	4 days
	Acute EC50 1000 µg/l Marine water	Daphnia - Daphnia magna	48 hours
	Acute IC50 0.31 mg/l Marine water	Crustaceans - Americamysis bahia - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 47.5 ng/L Fresh water	Fish - Heteropneustes fossilis	96 hours
	Chronic NOEC 100 mg/l Marine water	Algae - Glenodinium halli	72 hours
	Chronic NOEC 3.5 µg/l Fresh water	Fish - Cyprinus carpio	4 weeks
manganese	Acute EC50 31000 µg/l Fresh water	Aquatic plants - Lemna minor	4 days
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#### Section 12. Ecological information

Acute LC50 29000 μg/l Acute LC50 28 mg/l Fresh water Chronic NOEC 1.7 mg/l Fresh water	Daphnia - Daphnia magna Fish - Pimephales promelas Daphnia - Water Flea- Ceriodaphnia dubia	48 hours 96 hours 8 days
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**Conclusion/Summary** 

: Not available.

#### Persistence and degradability

**Conclusion/Summary** : Not available.

#### **Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
silicon	57 to 77	-	high

#### **Mobility in soil**

Soil/water partition	: Not available.
coefficient (Koc)	

Other adverse effects : No known significant effects or critical hazards.

#### Section 13. Disposal considerations

**Disposal methods** 

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

### Section 14. Transport information

	TDG Classification	DOT Classification	ADR/RID	IMDG	ΙΑΤΑ
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-	-
Transport hazard class(es)	-	-	-	-	-
Packing group	-	-	-	-	-
Environmental hazards	No.	No.	No.	No.	No.
Additional information	-	-	-	-	-

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according : Not available. to Annex II of MARPOL and the IBC Code

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#### Section 15. Regulatory information

<u>Canadian lists</u>	
Canadian NPRI	: The following components are listed: Nickel (and its compounds); Chromium (and its compounds); Manganese (and its compounds)
CEPA Toxic substances	: None of the components are listed.
Canada inventory	: All components are listed or exempted.
International regulations	
Chemical Weapon Conver	ntion List Schedules I, II & III Chemicals
Not listed.	
Montreal Protocol (Annexe Not listed.	<u>es A, B, C, E)</u>
Stockholm Convention on Not listed.	<u>Persistent Organic Pollutants</u>
Rotterdam Convention on Not listed.	Prior Informed Consent (PIC)
UNECE Aarhus Protocol o	n POPs and Heavy Metals

Not listed.

### Section 16. Other information

#### **History**

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Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Internediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) UN = United Nations HPR = Hazardous Products Regulations

#### Procedure used to derive the classification

Classification	Justification
Not classified.	

#### References

: HPR = Hazardous Products Regulations

Indicates information that has changed from previously issued version.

#### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the abovenamed supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

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