

Section 1. Identification

Product identifier	: Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, Ormco Bicuspids
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	: Dental product: Orthodontic Appliance This product, under the normal conditions of use, meets the definition of an "ARTICLE".
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.
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GHS label elements

Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.
<u>Precautionary statements</u>	
Prevention	: Not applicable.
Response	: Not applicable.
Storage	: Not applicable.
Disposal	: 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 : Mixture
Other means of identification : 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 necessary 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

Potential acute health effects

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.

Over-exposure signs/symptoms

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
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.

Section 5. Fire-fighting measures

- 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** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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

- Protective measures** : No special measures are required.
- Advice on general occupational hygiene** : No special measures are required.

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

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Nickel	<p>CA Saskatchewan Provincial (Canada, 7/2013). STEL: 3 mg/m³ 15 minutes. Form: Inhalable fraction TWA: 1.5 mg/m³ 8 hours. Form: Inhalable fraction</p> <p>CA Ontario Provincial (Canada, 7/2015). TWA: 1 mg/m³ 8 hours. Form: Inhalable fraction.</p> <p>CA Alberta Provincial (Canada, 4/2009). 8 hrs OEL: 1.5 mg/m³ 8 hours.</p> <p>CA British Columbia Provincial (Canada, 5/2015). TWA: 0.05 mg/m³, (as Ni) 8 hours.</p>

Section 8. Exposure controls/personal protection

manganese	<p>CA Quebec Provincial (Canada, 1/2014). TWAEV: 1 mg/m³ 8 hours.</p> <p>CA British Columbia Provincial (Canada, 5/2015). TWA: 0.2 mg/m³, (as Mn) 8 hours.</p> <p>CA Alberta Provincial (Canada, 4/2009). 8 hrs OEL: 0.2 mg/m³, (as Mn) 8 hours.</p> <p>CA Ontario Provincial (Canada, 7/2015). TWA: 0.2 mg/m³, (as Mn) 8 hours.</p> <p>CA Quebec Provincial (Canada, 1/2014). TWAEV: 0.2 mg/m³, (as Mn) 8 hours. Form: Total dust.</p> <p>CA Saskatchewan Provincial (Canada, 7/2013). STEL: 0.6 mg/m³, (measured as Mn) 15 minutes. TWA: 0.2 mg/m³, (measured as Mn) 8 hours.</p>
silicon	<p>CA British Columbia Provincial (Canada, 5/2015). TWA: 3 mg/m³ 8 hours. Form: Respirable dust TWA: 10 mg/m³ 8 hours. Form: Total dust</p> <p>CA Quebec Provincial (Canada, 1/2014). TWAEV: 10 mg/m³ 8 hours. Form: Total dust.</p> <p>CA Saskatchewan Provincial (Canada, 7/2013). STEL: 20 mg/m³ 15 minutes. TWA: 10 mg/m³ 8 hours.</p>

Appropriate engineering controls : No special measures are required for small quantities under normal and intended conditions of product use.

Environmental exposure controls : No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures : No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection : No special measures are required for small quantities under normal and intended conditions of product use.

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.

Other skin protection : No special measures are required for small quantities under normal and intended conditions of product use.

Respiratory protection : No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state	: Solid. [Orthodontic Band]
Color	: Metallic. Gray.
Odor	: Odorless.
Odor threshold	: Not applicable.
pH	: 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	Species	Dose	Exposure
manganese	LC50 Inhalation Dusts and mists	Rat	5.14 mg/l	4 hours
	LD50 Oral	Rat	9 g/kg	-
silicon	LD50 Oral	Rat	3160 mg/kg	-

Conclusion/Summary : Non-cytotoxic.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
manganese	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
silicon	Eyes - Mild irritant	Rabbit	-	3 milligrams	-

Conclusion/Summary

Skin : Not available.

Eyes : Not available.

Respiratory : Not available.

Sensitization

Product/ingredient name	Route of exposure	Species	Result
Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, Ormco Bicuspid	skin	Guinea pig	Not sensitizing

Conclusion/Summary

Skin : Not available.

Respiratory : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

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.

Section 11. Toxicological information

Potential acute health effects

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.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: No specific data.
Inhalation	: No specific data.
Skin contact	: No specific data.
Ingestion	: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects	: Not available.
Potential delayed effects	: Not available.

Long term exposure

Potential immediate effects	: Not available.
Potential delayed effects	: Not available.

Potential chronic health effects

Conclusion/Summary	: Not available.
General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No 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 - <i>Macrocystis pyrifera</i> - Young	4 days
	Acute EC50 450 µg/l Fresh water	Aquatic plants - <i>Lemna minor</i>	4 days
	Acute EC50 1000 µg/l Marine water	Daphnia - <i>Daphnia magna</i>	48 hours
	Acute IC50 0.31 mg/l Marine water	Crustaceans - <i>Americamysis bahia</i> - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 47.5 ng/L Fresh water	Fish - <i>Heteropneustes fossilis</i>	96 hours
	Chronic NOEC 100 mg/l Marine water	Algae - <i>Glenodinium halli</i>	72 hours
	Chronic NOEC 3.5 µg/l Fresh water	Fish - <i>Cyprinus carpio</i>	4 weeks
manganese	Acute EC50 31000 µg/l Fresh water	Aquatic plants - <i>Lemna minor</i>	4 days

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	LogP _{ow}	BCF	Potential
silicon	57 to 77	-	high

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

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	IATA
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 to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

Canadian lists

- 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 Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

History

Date of issue/Date of revision : 22/11/2016

Date of previous issue : No previous validation

Version : 1

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 = Intermediate 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

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Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.