

Section 1. Identification

GHS product identifier : Washbon® Bands, Trimline® Bands, Ultima® Bands, Stainless Steel Crowns, High Retention Bands, 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. Hazards identification

OSHA/HCS status : While this material is an article and exempted by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 19%

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Section 2. Hazards identification

Hazards not otherwise classified : 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	Other names	%	CAS number
Nickel	-	≥10 - ≤25	7440-02-0
manganese	-	≤3	7439-96-5
silicon	-	≤3	7440-21-3

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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 and hence require reporting in this section.

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.

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 manganese silicon	ACGIH TLV (United States, 3/2016). TWA: 1.5 mg/m ³ 8 hours. Form: Inhalable fraction NIOSH REL (United States, 10/2013). TWA: 0.015 mg/m ³ , (as Ni) 10 hours. OSHA PEL (United States, 6/2016). TWA: 1 mg/m ³ , (as Ni) 8 hours. OSHA PEL (United States, 6/2016). CEIL: 5 mg/m ³ , (as Mn) Form: Fume NIOSH REL (United States, 10/2013). TWA: 1 mg/m ³ , (as Mn) 10 hours. Form: Fume STEL: 3 mg/m ³ , (as Mn) 15 minutes. Form: Fume ACGIH TLV (United States, 3/2016). TWA: 0.1 mg/m ³ , (as Mn) 8 hours. Form: Inhalable fraction TWA: 0.02 mg/m ³ , (as Mn) 8 hours. Form: Respirable fraction OSHA PEL (United States, 6/2016). TWA: 5 mg/m ³ 8 hours. Form: Respirable fraction TWA: 15 mg/m ³ 8 hours. Form: Total dust NIOSH REL (United States, 10/2013). TWA: 5 mg/m ³ 10 hours. Form: Respirable fraction TWA: 10 mg/m ³ 10 hours. Form: Total

- 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.
Density	: Not available.
Solubility	: Insoluble in the following materials: cold water and hot water.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not applicable.
SADT	: Not available.
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

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	-

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

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Nickel	-	2B	Reasonably anticipated to be a human carcinogen.

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

Section 11. Toxicological information

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

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

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 manganese	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
	Acute EC50 31000 µg/l Fresh water	Aquatic plants - Lemna minor	4 days
	Acute LC50 29000 µg/l	Daphnia - Daphnia magna	48 hours
	Acute LC50 28 mg/l Fresh water	Fish - Pimephales promelas	96 hours
Chronic NOEC 1.7 mg/l Fresh water	Daphnia - Water Flea- Ceriodaphnia dubia	8 days	

Persistence and degradability

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

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-

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Section 14. Transport information

Transport hazard class (es)	-	-	-
Packing group	-	-	-
Environmental hazards	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

U.S. Federal regulations : **United States inventory (TSCA 8b):** All components are listed or exempted.
Clean Water Act (CWA) 307: Nickel; chromium

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Section 15. Regulatory information

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Nickel	≥10 - ≤25	No.	No.	No.	Yes.	Yes.
manganese	≤3	Yes.	No.	No.	Yes.	Yes.
silicon	≤3	Yes.	No.	No.	Yes.	No.

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	chromium	7440-47-3	≥10 - ≤25
	Nickel	7440-02-0	≥10 - ≤25
	manganese	7439-96-5	≤3
Supplier notification	chromium	7440-47-3	≥10 - ≤25
	Nickel	7440-02-0	≥10 - ≤25
	manganese	7439-96-5	≤3

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

- Massachusetts** : The following components are listed: NICKEL; NICKEL CATALYST; CHROMIUM; SILICON DUST; MANGANESE
- New York** : The following components are listed: Nickel; Chromium
- New Jersey** : The following components are listed: NICKEL; CHROMIUM; SILICON; MANGANESE
- Pennsylvania** : The following components are listed: NICKEL CATALYST; CHROMIUM COMPOUNDS; SILICON; MANGANESE COMPOUNDS

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Nickel	Yes.	No.	No.	No.

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

Hazardous Material Information System (U.S.A.)

Health	0
Flammability	0
Physical hazards	0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on SDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.)



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

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

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

References

: HCS (U.S.A.)- Hazard Communication Standard
 International transport regulations

Section 16. Other information

✔ 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.