

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### 1.1 Product identifier

**Product name** : Ni-Ti® Wire  
**Product code** : Not available.  
**Product type** : Solid.  
**Other means of identification** : Not available.

### 1.2 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.

### 1.3 Details of the supplier of the safety data sheet

#### Supplier/Manufacturer

Ormco Corporation  
1332 S. Lone Hill Avenue  
Glendora, CA 91740-5339  
Telephone no.: 1-800-854-1741

#### Distributor

ORMCO B.V.  
Basicweg, 20  
NL 3821 BR AMERSFOORT (HOLLAND)  
00-800-3032-3032

**e-mail address of person responsible for this SDS** : OrmcoCustCare@sybrondental.com

### 1.4 Emergency telephone number

#### National advisory body/Poison Centre

**Telephone number** : CHEMTREC® International (24 hours): +1 (703) 527-3887  
United Kingdom (UK) National advisory body/Poison Centre: +44 870 600 6266

#### Supplier

**Telephone number** : +39-340-1721884  
**Hours of operation** : 08.00-23.00, European time, GMT+1

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## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Product definition** : Mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]**

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 11 for more detailed information on health effects and symptoms.

### 2.2 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.

**Supplemental label elements** : Contains nickel. May produce an allergic reaction. Safety data sheet available on request.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

#### **Special packaging requirements**

**Containers to be fitted with child-resistant fastenings** : Not applicable.

**Tactile warning of danger** : Not applicable.

### 2.3 Other hazards

**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

**3.2 Mixtures** : Mixture

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### SECTION 3: Composition/information on ingredients

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
Nickel	EC: 231-111-4 CAS: 7440-02-0	≥50 - ≤75	Skin Sens. 1, H317 Carc. 2, H351 STOT RE 1, H372 (respiratory tract) (inhalation)	[1] [2]
copper	EC: 231-159-6 CAS: 7440-50-8	≥10 - ≤25	Aquatic Acute 1, H400 (M=1) Aquatic Chronic 3, H412  <b>See Section 16 for the full text of the H statements declared above.</b>	[1] [2]

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, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

#### Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII

[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

[5] Substance of equivalent concern

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

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

##### Over-exposure signs/symptoms

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

#### 4.3 Indication of any immediate medical attention and special treatment needed

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## SECTION 4: First aid measures

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

### 5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials: metal oxide/oxides

### 5.3 Advice for firefighters

- 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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

## SECTION 6: Accidental release measures

### 6.1 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".

- 6.2 Environmental precautions** : No special measures are required.

### 6.3 Methods and material for containment and cleaning up

- Small spill** : No special measures required.
- Large spill** : No special measures required.

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## SECTION 6: Accidental release measures

- 6.4 Reference to other sections** : See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

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

### 7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations.

### 7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits

Product/ingredient name	Exposure limit values
Nickel	<b>EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin.</b> TWA: 0.5 mg/m <sup>3</sup> , (as Ni) 8 hours.
copper	<b>EH40/2005 WELs (United Kingdom (UK), 12/2011).</b> STEL: 2 mg/m <sup>3</sup> , (as Cu) 15 minutes. Form: Dusts and Mists TWA: 1 mg/m <sup>3</sup> , (as Cu) 8 hours. Form: Dusts and Mists TWA: 0.2 mg/m <sup>3</sup> , (as Cu) 8 hours. Form: Fume

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

#### DNELs/DMELs

No DNELs/DMELs available.

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## SECTION 8: Exposure controls/personal protection

### PNECs

No PNECs available

### 8.2 Exposure controls

**Appropriate engineering 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.

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

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

**Physical state** : Solid. [Wire]

**Colour** : Metallic./Grey.

**Odour** : Odourless.

**Odour threshold** : Not applicable.

**pH** : Not applicable.

**Melting point/freezing point** : 1000°C

**Initial boiling point and boiling range** : Not applicable.

**Flash point** : Not applicable.

**Evaporation rate** : Not applicable.

**Flammability (solid, gas)** : Not available.

**Upper/lower flammability or explosive limits** : Not applicable.

**Vapour pressure** : Not applicable.

**Vapour density** : Not applicable.

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## SECTION 9: Physical and chemical properties

Relative density	: Not applicable.
Solubility(ies)	: Insoluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/ water	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not applicable.
Viscosity	: Not applicable.
Explosive properties	: Not available.
Oxidising properties	: Not available.

### 9.2 Other information

Solubility in water	: Not available.
Physical/chemical properties comments	: No additional information.

## SECTION 10: Stability and reactivity

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

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Conclusion/Summary : Non-cytotoxic.

#### Acute toxicity estimates

Not available.

#### Irritation/Corrosion

Conclusion/Summary : Not available.

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## SECTION 11: Toxicological information

### Sensitisation

Product/ingredient name	Route of exposure	Species	Result
Ni-Ti® Wire	skin	Guinea pig	Not sensitizing

**Conclusion/Summary** : Not available.

### Mutagenicity

**Conclusion/Summary** : No mutagenic effect.

### Carcinogenicity

**Conclusion/Summary** : Not available.

### Reproductive toxicity

**Conclusion/Summary** : Not available.

### Teratogenicity

**Conclusion/Summary** : Not available.

Not available.

### Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Nickel	Category 1	Inhalation	respiratory tract

### Aspiration hazard

Not available.

**Information on likely routes of exposure** : Not available.

### 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 as well as chronic effects from short and long-term exposure

#### Short term exposure



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## SECTION 11: Toxicological information

**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.

**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.

**Other information** : Not available.

## SECTION 12: Ecological information

### 12.1 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
copper	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
	Acute EC50 1100 µg/l Fresh water	Aquatic plants - <i>Lemna minor</i>	4 days
	Acute EC50 2.1 µg/l Fresh water	Daphnia - <i>Daphnia longispina</i> - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute IC50 13 µg/l Fresh water	Algae - <i>Pseudokirchneriella subcapitata</i> - Exponential growth phase	72 hours
	Acute IC50 5.4 mg/l Marine water	Aquatic plants - <i>Plantae</i> - Exponential growth phase	72 hours
	Acute LC50 0.072 µg/l Marine water	Crustaceans - Amphipoda - Adult	48 hours
Acute LC50 7.56 µg/l Marine water	Fish - <i>Periophthalmus waltoni</i> -	96 hours	

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## SECTION 12: Ecological information

	Chronic NOEC 2.5 µg/l Marine water	Adult Algae - Nitzschia closterium - Exponential growth phase	72 hours
	Chronic NOEC 7 mg/l Fresh water	Aquatic plants - Ceratophyllum demersum	3 days
	Chronic NOEC 0.02 mg/l Fresh water	Crustaceans - Cambarus bartonii - Mature	21 days
	Chronic NOEC 2 µg/l Fresh water	Daphnia - Daphnia magna	21 days
	Chronic NOEC 0.8 µg/l Fresh water	Fish - Oreochromis niloticus - Juvenile (Fledgling, Hatchling, Weanling)	6 weeks

**Conclusion/Summary** : Not available.

### 12.2 Persistence and degradability

**Conclusion/Summary** : Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Mobility** : Not available.

### 12.5 Results of PBT and vPvB assessment

**PBT** : Not applicable.

**vPvB** : Not applicable.

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

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product

**Methods of disposal** : The generation of waste should be avoided or minimised 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.

**Hazardous waste** : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

#### Packaging

**Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

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## SECTION 13: Disposal considerations

**Special precautions** : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

**14.6 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.

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

## SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
**EU Regulation (EC) No. 1907/2006 (REACH)**

**Annex XIV - List of substances subject to authorisation**

**Annex XIV**

None of the components are listed.

**Substances of very high concern**

None of the components are listed.

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## SECTION 15: Regulatory information

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

### Other EU regulations

**Europe inventory** : All components are listed or exempted.

**Industrial emissions (integrated pollution prevention and control) - Air** : Listed

**Industrial emissions (integrated pollution prevention and control) - Water** : Listed

### Ozone depleting substances (1005/2009/EU)

Not listed.

### Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

### Seveso Directive

This product is not controlled under the Seveso Directive.

### 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.

**15.2 Chemical safety assessment** : This product contains substances for which Chemical Safety Assessments are still required.

**15.3 Registration status** : Mixture. Information concerning the substance : Contact local supplier or distributor.

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## SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

**Abbreviations and acronyms** : ATE = Acute Toxicity Estimate  
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]  
DMEL = Derived Minimal Effect Level  
DNEL = Derived No Effect Level  
EUH statement = CLP-specific Hazard statement  
PBT = Persistent, Bioaccumulative and Toxic  
PNEC = Predicted No Effect Concentration  
RRN = REACH Registration Number  
vPvB = Very Persistent and Very Bioaccumulative

**Key literature references and sources for data** : Regulation (EC) No. 1272/2008 [CLP]; European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), concluded in Geneva on 30 September 1957 plus amendments (Uniform text: Journal of Laws 27/2009 pos. 162 plus amendments); Regulation for the transport of dangerous materials on the Rhine (ADN); Occupational exposure limits; International regulations

### Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

### Full text of abbreviated H statements

H317 H351 H372 (inhalation)	May cause an allergic skin reaction. Suspected of causing cancer. Causes damage to organs through prolonged or repeated exposure if inhaled.
H400 H412	Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

### Full text of classifications [CLP/GHS]

Aquatic Acute 1, H400 Aquatic Chronic 3, H412 Carc. 2, H351 Skin Sens. 1, H317 STOT RE 1, H372 (inhalation)	ACUTE AQUATIC HAZARD - Category 1 LONG-TERM AQUATIC HAZARD - Category 3 CARCINOGENICITY - Category 2 SKIN SENSITISATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE (inhalation) - Category 1
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**Training advice** : Ensure operatives are trained to minimise exposures. Training staff on good practice.

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

**Date of previous issue** : No previous validation

**Version** : 1

### Notice to reader

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## SECTION 16: Other information

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

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.