

COMPANY INFORMATION

COMPANY NAME: ORTHO SPECIALTIES
COMPANY ADDRESS: 3820 OHIO AVE - SUITE 15
 ST. CHARLES, IL 60174
COMPANY PHONE: 630-443-0225
COMPANY FAX: 630-443-0224
COMPANY WEB ADDRESS: www.orthospecialties.com

NICKEL TITANIUM

DOCUMENT NUMBER:	SDS1
REVISION DATE:	09/26/2014
REVISION:	REV. E
NUMBER OF PAGES:	4

1 – PRODUCT IDENTIFICATION

PRODUCT NAME: Niti, Nickel Titanium
PRODUCT USE: Orthodontic Wires, Springs, Straights & Spools

2 – HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:
 These products are not hazardous unless processed (i.e. ground, welded) in a manner that generates dust or fumes. Dust and fumes may cause eye, skin and respiratory irritation. May cause skin and respiratory tract sensitization (allergic reaction). Prolonged inhalation of dust or fumes from this product may cause perforation of the nasal septum and lung damage.

EU PREPARATION:
CLASSIFICATION (1999/45/EC): Xn; R40, R43, R48/23

3 – COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No	Percent	EC Substance Classification (67/548/EEC)
Nickel	7440-02-0 / 231-111-4	45-60	Xn R40, R43, R48/23
Titanium	7440-32-6 / 231-142-3	40-50	Not Applicable

4 – FIRST AID MEASURES

No first aid required for contact with solid product. The following information applies to contact from processing.

EYE CONTACT:
 Flush with large quantities of water, holding the eyelids apart to assure that the material is washed out. Get medical attention if irritation persists.

SKIN CONTACT:
 Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops.

INGESTION:
 If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

INHALATION:
 If irritation or other symptoms develop, remove to fresh air. Get medical attention if symptoms persist.

5 – FIRE FIGHTING PROCEDURES

EXTINGUISHING MEDIA:
 This material is not combustible in solid form. Use media that is appropriate for the surrounding fire. For fires involving fine dust of filings, do not use water, CO2 or foam directly on the burning metal. Use dry sand, graphite powder, Lith-X powder, dry chemical or other media appropriate for a class D fire.

FIREFIGHTING PROCEDURES:
 Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus.

UNUSUAL FIRE/EXPLOSION HAZARDS:
 Fine powders or filings may burn with intense heat. Fine dust may present an explosion hazard. Dousing burning metal with water may generate explosive hydrogen gas.

KNOWN OR ANTICIPATED HAZARDOUS PRODUCTS OF COMBUSTION:
 Thermal decomposition or combustion products include oxides of the metals listed in Section 2 which may be highly toxic.

6 – ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:
 Pick up solid material for reuse or disposal. For spills of dust, wear respirator and protective clothing (see Section 8). Vacuum using an explosion-proof, HEPA vacuum and non-sparking tools. Do not breathe dust or allow it to contaminate skin or clothing. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

PERSONAL PRECAUTIONS:
 Avoid contact with eyes, skin or clothing. Do not breathe dust.

ENVIRONMENTAL PRECAUTIONS:
 Prevent entry into sewers and waterways.

7 – HANDLING & STORAGE

HANDLING:
 Do not breathe dust or fumes from processing. Avoid contact with dust. Wear protective clothing and equipment as described in Section 8. Process only with adequate ventilation. Keep containers closed when not in use. Do not eat, drink or smoke in the work area.

STORAGE:
 Store in a cool, well ventilated location away from incompatible materials.

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8 – EXPOSURE CONTROL/PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS:

Nickel (as metallic Nickel)	1 mg/m ³ TWA OSHA PEL 1.5 mg/m ³ TWA (inhalable) ACGIH TLV 0.5 mg/m ³ TWA UK WEL
Titanium	None Established

ENGINEERING CONTROLS:

None needed under normal use. If dust or fumes are generated during processing, use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

PERSONAL PROTECTIVE EQUIPMENT:

EYE PROTECTION:

Wear safety glasses or other eye protection consistent with industrial safety practice for the process being performed.

SKIN PROTECTION:

Wear protective gloves if need to prevent cuts or other injuries.

RESPIRATORY PROTECTION:

None needed under normal use. If the occupational exposure limits are exceeded during processing, an approved respirator with high efficiency particulate filters may be used. For higher exposures (greater than 10 times the exposure limit) a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow OSHA 1910.134, ANSI Z88.2 or local authority regulations and good Industrial Hygiene practice.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT:

Use protective clothing consistent with industrial safety practice for the process being performed.

9 – PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE and ODOR: Silver or black wire with no odor.

BOILING POINT: Not Applicable.

FREEZING POINT: Not available.

SOLUBILITY IN WATER: Insoluble.

VAPOR PRESSURE (mmHg): Not Applicable.

EVAPORATION RATE: Not Applicable.

% VOLATILE BY VOLUME: None.

FLAMMABLE LIMITS IN AIR:

LEL: Not Applicable.
UEL: Not Applicable.

MELTING POINT: 1981°F

SPECIFIC GRAVITY: Not Available.

pH: Not Applicable.

VAPOR DENSITY: Not Applicable.

VISCOSITY: Not Applicable.

FLASHPOINT: Not Applicable.

AUTOIGNITION TEMPERATURE: Not Applicable.

10 – STABILITY AND REACTIVITY

STABILITY: Stable.

CONDITIONS TO AVOID: None known.

INCOMPATIBILITY WITH OTHER MATERIALS:

Acids, oxidizing agents, ammonium nitrate, sulfur, alkalis, selenium, nickel nitrate and sodium azide.

HAZARDOUS DECOMPOSITION PRODUCTS:

Toxic metal fumes and oxides are emitted when product is heated above the melting point.

11 – TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS:

EYES:

Dust or fines may cause mechanical irritation.

SKIN:

Dust may cause skin irritation. May cause allergic skin reaction (sensitization).

INGESTION:

No acute effects expected from swallowing small amounts.

INHALATION:

Dust or fumes may cause irritation of the mucous membranes and upper respiratory tract. May cause allergic respiratory reaction (sensitization).

CHRONIC HEALTH EFFECTS:

Prolonged or repeated skin contact 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.

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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".

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Individuals with pre-existing skin disorders may be at increased risk from exposure.

ACUTE TOXICITY DATA:

Nickel: No data available
 Titanium: No data available

12 – ECOLOGICAL INFORMATION

No data is available at this time.

13 – DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

14 – TRANSPORT INFORMATION

DOT SHIPPING NAME: Not Regulated
 DOT HAZARD CLASS: N/A
 UN NUMBER: N/A
 DOT LABELS REQUIRED (49CFR172.101): N/A

IATA SHIPPING NAME: Not Regulated
 IATA HAZARD CLASS: N/A
 UN NUMBER: N/A
 IATA HAZARD LABELS REQUIRED: N/A

IMDG SHIPPING NAME: Not Regulated
 IMDG CLASS: N/A
 UN NUMBER: N/A
 IMDG LABEL: N/A

15 – REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA: This product has a Reportable Quantity (RQ) of 166 lbs. based on the RQ for Nickel of 100 lbs. Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:
 Hazard Category For Section 311/312:
 Not hazardous unless processing creates dusts or fumes.

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SECTION 313 TOXIC CHEMICALS:

This product contains the following chemicals subject to Annual Release Reporting Requirements. UNDER SARA TITLE III, SECTION 313 (40 CFR 372):

Nickel 7440-02-0 45-60

SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (TPQ): None

EPA TOXIC SUBSTANCES CONTROL ACT (TSCA) STATUS:

This product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS:

CALIFORNIA PROPOSITION 65:

This product contains the following substances known to the State of California to cause cancer: Nickel.

INTERNATIONAL REGULATIONS:

CANADIAN WHMIS CLASSIFICATION:

Medical devices are not subject to WHMIS.

CANADIAN ENVIRONMENTAL PROTECTION ACT:

This product is a medical device and not subject to chemical notification requirements.

EUROPEAN COMMUNITY LABELING:

This product is a manufactured article as defined under REACH. No labeling is required for finished products. **The following applies only to dust and fumes generated from processing:**

Contains nickel



Harmful

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.

S36/37 Wear suitable protective clothing and gloves.

S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

S59 Refer to manufacturer/supplier for information on recovery/recycling.

S61 Avoid release to the environment. Refer to Safety data sheet.

EUROPEAN INVENTORY OF NEW AND EXISTING CHEMICALS SUBSTANCES (EINECS):

This product is a medical device and not subject to chemical notification requirements.

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES:

This product is a medical device and not subject to chemical notification requirements.



OrthoSpecialties

SAFETY DATA SHEET

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CHINA INVENTORY OF EXISTING CHEMICALS AND CHEMICAL SUBSTANCES:
 This product is a medical device and not subject to chemical notification requirements.

JAPANESE EXISTING AND NEW CHEMICAL SUBSTANCES:
 This product is a medical device and not subject to chemical notification requirements.

KOREAN EXISTING CHEMICALS LIST:
 This product is a medical device and not subject to chemical notification requirements.

PHILIPPINE INVENTORY OF CHEMICALS AND CHEMICAL SUBSTANCES:
 This product is a medical device and not subject to chemical notification requirements.

16 – OTHER INFORMATION

HMIS Hazard Rating:

Health –1* Fire Hazard – 1 Physical Hazard – 0
 * Chronic Health Hazard

EU CLASSES AND RISK PHRASES FOR REFERENCE (SEE SECTIONS 2 AND 3):

Xn Harmful
 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.

Revision Date: 4/22/2010
Supersedes: New MSDS

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BETA TITANIUM

DOCUMENT NUMBER:	SDS3
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NUMBER OF PAGES:	4

1 – PRODUCT IDENTIFICATION

PRODUCT NAME: *BIII™-CNA® Wire*
PRODUCT USE: Orthodontic Archwires and Straights

2 – HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

These products are not hazardous unless processed (i.e. ground, welded) in a manner that generates dust or fumes. Dust and fumes may cause eye, skin and respiratory irritation.

EU PREPARATION CLASSIFICATION (1999/45/EC):

Not a dangerous preparation

3 – COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Molybdenum	7439-98-7 / 231-107-2	10-20	N/A
Zirconium	7440-67-7 / 231-176-9	5-10	N/A
Tin	7440-31-5 / 231-141-8	1-5	N/A
Titanium	7440-32-6 / 231-142-3	60-85	N/A

4 – FIRST AID MEASURES

No first aid required for contact with solid product. The following information applies to contact from processing.

EYE CONTACT:

Flush with large quantities of water, holding the eyelids apart to assure that the material is washed out. Get medical attention if irritation persists.

SKIN CONTACT:

Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops.

INGESTION:

If conscious, wash mouth out with water. Do not induce vomiting. Never give any thing by mouth to an unconscious or convulsing person. Get medical attention.

INHALATION:

If irritation or other symptoms develop, remove to fresh air. Get medical attention if symptoms persist.

5 – FIRE FIGHTING PROCEDURES

EXTINGUISHING MEDIA:

This material is not combustible in solid form. Use media that is appropriate for the surrounding fire. For fires involving fine dust or filings, do not use water, CO2 or foam directly on the burning metal. Use dry sand, graphite powder, Lith-X powder, dry chemical or other media appropriate for a class D fire.

FIREFIGHTING PROCEDURES:

Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus.

UNUSUAL FIRE/EXPLOSION HAZARDS:

Fine powders or filings may burn with intense heat. Fine dust may present an explosion hazard. Dousing burning metal with water may generate explosive hydrogen gas.

KNOWN OR ANTICIPATED HAZARDOUS PRODUCTS OF COMBUSTION:

Thermal decomposition or combustion products include oxides of the metals listed in Section 2 which may be highly toxic.

6 – ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:

Pick up solid material for reuse or disposal. For spills of dust, wear respirator and protective clothing (see Section 8). Vacuum using an explosion-proof, HEPA vacuum and non-sparking tools. Do not breathe dust or allow it to contaminate skin or clothing. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

PERSONAL PRECAUTIONS:

Avoid contact with eyes, skin or clothing. Do not breathe dust.

ENVIRONMENTAL PRECAUTIONS:

Prevent entry into sewers and waterways.

7 – HANDLING & STORAGE

HANDLING:

Do not breathe dust or fumes from processing. Avoid contact with dust. Wear protective clothing and equipment as described in Section 8. Process only with adequate ventilation. Keep containers closed when not in use. Do not eat, drink or smoke in the work area.

STORAGE:

Store in a cool, well ventilated location away from incompatible materials.

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8 – EXPOSURE CONTROL/PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS:

Molybdenum	15 mg/m3 TWA OSHA PEL (total dust) 3 mg/m3 TWA ACGIH TLV (respirable fraction)
Zirconium	5 mg/m3 TWA OSHA PEL (as zirconium compounds) 5 mg/m3 TWA ACGIH TLV 2 mg/m3 TWA OSHA PEL 1 mg/m3 TWA DFG MAK 5 mg/m3 TWA UK WEL; 10 mg/m3 STEL UK WEL
Tin	2 mg/m3 TWA OSHA PEL 2 mg/m3 TWA ACGIH TLV 2 mg/m3 TWA UK, WEL, 4 mg/m3 STEL UK WEL (as tin inorganic compounds)
Titanium	None Established

ENGINEERING CONTROLS:

None needed under normal use. If dust or fumes are generated during processing, use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

PERSONAL PROTECTIVE EQUIPMENT:

EYE PROTECTION:

Wear safety glasses or other eye protection consistent with industrial safety practice for the process being performed.

SKIN PROTECTION:

Wear protective gloves if need to prevent cuts or other injuries.

RESPIRATORY PROTECTION:

None needed under normal use. If the occupational exposure limits are exceeded during processing, an approved respirator with high efficiency particulate filters may be used. For higher exposures (greater than 10 times the exposure limit) a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow OSHA 1910.134, ANSI Z88.2 or local authority regulations and good Industrial Hygiene practice.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT:

Use protective clothing consistent with industrial safety practice for the process being performed.

9 – PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Silver wire.
ODOR/FLAVOR: No odor.
BOILING POINT: Not applicable.
FREEZING POINT: Not available.
SOLUBILITY IN WATER: Insoluble.
VAPOR PRESSURE (mmHg): Not Applicable.
EVAPORATION RATE: Not Applicable.
% VOLATILE BY VOLUME: None.
FLAMMABLE LIMITS IN AIR: LEL: Not Applicable.
 UEL: Not Applicable.
MELTING POINT: 3050°F
SPECIFIC GRAVITY: Not Available.
pH: Not Applicable.
VAPOR DENSITY: Not Applicable.
VISCOSITY: Not applicable.
FLASHPOINT: Not applicable.
AUTOIGNITION TEMPERATURE: Not applicable.

10 – STABILITY AND REACTIVITY

STABILITY: Stable.
CONDITIONS TO AVOID: None known.
INCOMPATIBILITY WITH OTHER MATERIALS:
 Acids, alkalis, oxidizing agents, potassium nitrate and turpentine.
HAZARDOUS DECOMPOSITION PRODUCTS:
 Metal fumes and oxides are emitted when product is heated above the melting point.

11 – TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS:

EYES:
 Dust or fines may cause mechanical irritation.
SKIN:
 Dust may cause skin irritation.
INGESTION:
 No acute effects expected from swallowing small amounts.

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INHALATION:

Dust or fumes may cause irritation of the mucous membranes and upper respiratory tract.

CHRONIC HEALTH EFFECTS:

Prolonged inhalation of dust may cause lung damage, fibrotic lung disease, and effects on the cardiovascular system. Chronic exposure to tin oxide dusts and fumes may result in stannosis (benign pneumoconiosis). Repeated skin contact with zirconium compounds may cause allergic skin sensitization.

CARCINOGENICITY:

None of these components are listed as carcinogens by IARC, NTP, ACGIH, OSHA or the EU Directive.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Individuals with pre-existing skin disorders may be at increased risk from exposure.

ACUTE TOXICITY DATA:

MOLYBDENUM : No data available
 ZIRCONIUM: No data available
 TIN: No data available
 TITANIUM : No data available

12 – ECOLOGICAL INFORMATION

No data is available at this time.

13 – DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

14 – TRANSPORTATION INFORMATION

DOT SHIPPING NAME: Not Regulated
 DOT HAZARD CLASS: N/A
 UN NUMBER: N/A
 DOT LABELS REQUIRED (49CFR172.101): N/A
 IATA SHIPPING NAME: Not Regulated
 IATA HAZARD CLASS: N/A

UN NUMBER: N/A
 IATA HAZARD LABELS REQUIRED: N/A
 IMDG SHIPPING NAME: Not Regulated
 IMDG CLASS: N/A
 UN NUMBER: N/A
 IMDG LABEL: N/A
 pH: Not Applicable.
 VAPOR DENSITY: Not Applicable.
 VISCOSITY: Not applicable.
 FLASHPOINT: Not applicable.
 AUTOIGNITION TEMPERATURE: Not applicable.

15 – REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA: This product is not regulate under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:
 HAZARD CATEGORY FOR SECTION 311/312:
 Not hazardous unless processing creates dusts or fumes.

SECTION 313 TOXIC CHEMICALS: This product contains the following chemicals subject to Annual Release Reporting Requirements. UNDER SARA TITLE III, SECTION 313 (40 CFR 372): NONE

SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (TPQ): None

EPA TOXIC SUBSTANCES CONTROL ACT (TSCA) STATUS:
 This product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS:

CALIFORNIA PROPOSITION 65:
 This product contains the following substances known to the State of California to cause cancer: None

INTERNATIONAL REGULATIONS:

CANADIAN WHMIS CLASSIFICATION:

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Medical devices are not subject to WHMIS.

CANADIAN ENVIRONMENTAL PROTECTION ACT:

This product is a medical device and not subject to chemical notification requirements.

EUROPEAN COMMUNITY LABELING:

This product is a manufactured article as defined under REACH. No labeling is required for finished products.

EUROPEAN INVENTORY OF NEW AND EXISTING CHEMICALS SUBSTANCES (EINECS):

This product is a medical device and not subject to chemical notification requirements.

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES:

This product is a medical device and not subject to chemical notification requirements.

CHINA INVENTORY OF EXISTING CHEMICALS AND CHEMICAL SUBSTANCES:

This product is a medical device and not subject to chemical notification requirements.

JAPANESE EXISTING AND NEW CHEMICAL SUBSTANCES:

This product is a medical device and not subject to chemical notification requirements.

KOREAN EXISTING CHEMICALS LIST:

This product is a medical device and not subject to chemical notification requirements.

PHILIPPINE INVENTORY OF CHEMICALS AND CHEMICAL SUBSTANCES:

This product is a medical device and not subject to chemical notification requirements.

16 – OTHER INFORMATION

HMIS Hazard Rating:

Health –1 Fire Hazard – 1 Physical Hazard – 0

* Chronic Health Hazard

EU CLASSES AND RISK PHRASES FOR REFERENCE (SEE SECTIONS 2 AND 3): None listed

Revision Date: 4/22/2010

Supersedes: New MSDS