

## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product Identifier

**Product Name:**NiTi Wires, K-type, Ultra File, 3D Root, MFlex Taper/02, RT4, RT5, RT6, RT7, ST, MPilot, Opener, ReRoot, MM, MFlex Taper, MFlex Taper, MTurbo Rotary Files, MTurboBlue Rotary Files, MRoot, MRoot Next, MTaper Next, MTaper (RT8), RT2, MTaper(RT9), RT3, SF, MPro, MPro Blue, M-Flex, F-elastic, MSolo

**Common Name:**Orthodontic wires, Root canal instruments

**Material:**Nickel-Titanium (NiTi)

**Restrictions on Use:**Innovative Material and Devices, Inc' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. The law restricts this device to use by or on the order of a dentist or orthodontist.

**EC No.:** 231-111-4 (Nickel); 231-142-3 (Titanium)

**REACH Registration No.:**

01-2119438727-29-XXXX (Nickel)

01-2119484878-14-XXXX (Titanium)

**CAS No. / IUPAC:** See Below

### 1.2 Relevant Identified Uses/ Uses Advised Against

**Relevant identified uses:** Dental/Orthodontic use only

**Uses advised against:** Not for Consumer use. Please see "Restrictions on Use"

### 1.3 Details of the Supplier of the Safety Data Sheet

**Name:**Innovative Material and Devices, Inc

**Address:**Building #5, No.615, Fengdeng Road, Jiading District, Shanghai 201801,P.R. China

**SRN:** CN-MF-000002280

**Registered trade name(or registered trade mark):**NA

### 1.4 Emergency Telephone Number

86-21-59156556

Only available during office hours: 8:00AM – 5:00PM (Beijing Time)

Language of Phone Service: English/Chinese

## 2. HAZARDS IDENTIFICATION

### General Hazard Statement:

Solid metallic products are generally classified as "articles" and do not constitute a hazardous materials in solid form under the definitions of the OSHA Hazard Communication Standard (29 CFR 1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous. However some hazardous elements contained in these products can be emitted under

certain processing conditions such as but not limited to: burning, melting, cutting, sawing, brazing, grinding, machining, milling, and welding. Products in the solid state present no fire or explosion hazard. Small chips, fines, and dust may ignite readily, though. The following classification information is for the hazardous elements which may be released during processing.

## 2.1 Classification of the substance or mixture

Serious Eye Damage/Irritation - Category 2B

Respiratory Sensitizer - Category 1

Skin Sensitizer - Category 1

Germ Cell Mutagenicity - Category 2

Carcinogenicity - Category 1B

Toxic to reproduction - Category 1B

Specific target organ toxicity - Single exposure - Category 1 (kidneys, respiratory system)

Specific target organ toxicity - Repeated exposure - Category 1 (respiratory system, skin)

Hazardous to aquatic environment - Acute Hazard - Category 1

Hazardous to aquatic environment - Chronic Hazard - Category 1

## 2.2 Label Elements

*Labelling according to Regulation (EC) No 1272/2008 [CLP]*

### Hazard Pictogram(s)



**Signal Word(s): Danger**

Hazard Statements:

Causes eye irritation

May cause allergy or asthma symptoms or breathing difficulties if inhaled

May cause an allergic skin reaction

Suspected of causing genetic defects

Suspected of causing cancer

Causes damage to organs (kidneys, respiratory system)

Causes damage to organs through prolonged or repeated exposure (respiratory system)

Very toxic to aquatic life

Very toxic to aquatic life with long lasting effects

Supplemental Hazard information (EU):

Do not breathe dust/fume/gas/mist/vapors/spray.

In case of inadequate ventilation wear respiratory protection

Contaminated work clothing should not be allowed out of the workplace.  
Wash thoroughly after handling  
Wear protective gloves  
Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Use personal protective equipment as required  
Do not eat, drink or smoke when using this product.  
Avoid release to the environment

**Response**

IF exposed or concerned: Get medical advice/attention  
IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice/attention.  
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.  
If exposed or concerned: Get medical advice/attention.  
Collect spillage

**Storage**

Store locked up

**Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Ingredient(s)	CAS No.	EC No.	Wt. % Content (or Range)
Nickel, Ni	7440-02-0	231-111-4	54.5-56.3
Titanium, Ti	7440-32-6	231-142-3	other

Other trace elements may also be present in minute amounts. These small quantities (less than 0.1%) are frequently referred to as “trace” or “residual” elements; generally they originate in the raw mat.

**4. FIRST-AID MEASURES****4.1 Description of 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 AND EXPLOSION HAZARDS**

### **5.1 Extinguishing Media**

This material is not combustible in solid form. Use media that is appropriate for the surrounding fire. Suitable extinguishing media are:

- Dry sand
- Graphite powder
- Lith-A powder
- Dry chemical or other media appropriate for a Class D fire.

Extinguishing Media which should not be directly used for fires involving fine dust or filings:

- Water
- CO<sub>2</sub>
- Foam

### **5.2 Special Exposure Hazards from Substance/Mixture**

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.

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

### **5.3 Advice for Firefighters**

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

## **6. ACCIDENTAL RELEASE MEASURES**

### **6.1 Personal Precautions, Protective Equipment & Emergency**

#### **Procedures**

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

## 6.2 Environmental Precautions

Prevent entry into sewers and waterways

## 6.3 Methods & Material for Containment & Cleaning Up

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.

## 6.4 Reference to other sections (as applicable)

None

# 7. HANDLING AND STORAGE

## 7.1 Precautions for Safe-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.

## 7.2 Conditions for Safe Storage, Including Any

### Incompatibilities

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

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## 8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Nickel (as metallic Nickel)	1 mg/ m <sup>3</sup> TWA	1.5 mg/ m <sup>3</sup> TWA (inhalable)
Titanium	None Established	None Established

Additional Information:

Nickel: 0.5mg /m<sup>3</sup> TWA UK WEL

## 8.2 Exposure Controls

### 8.2.1 Appropriate 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.

### 8.2.2 Personal Protective Equipment

#### 8.2.2.1 Eye & Face Protection

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

#### 8.2.2.2 Skin Protection

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

#### 8.2.2.3 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.

#### 8.2.2.4 Thermal Hazards

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

Reference Section 5 for specific personal protective equipment advice

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Basic Physical & Chemical Properties

Appearance	Silver or Black Wire
Odor	None
pH	N/A
Melting Point/Freezing Point:	1981°F/ 1083°C
Flash Point	N/A
Evaporation Rate	N/A
Flammability (solid, gas)	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Relative Density	N/A
Solubility(ies)	Insoluble in H <sub>2</sub> O

### 9.2 Other Information

None

## **10. STABILITY AND REACTIVITY**

### **10.1 Reactivity**

None Known

### **10.2 Chemical Stability**

Stable

### **10.3 Conditions of Instability**

None Known

### **10.4 Possibility of Hazardous Reactions**

None Known

### **10.5 Conditions to Avoid**

None Known

### **10.6 Incompatible Materials**

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

### **10.7 Hazardous Decomposition Products**

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

### **10.8 Hazardous Polymerization**

None known

## **11. TOXICOLOGICAL INFORMATION**

This mixture has not been evaluated as a whole for health effects. Exposure effects listed are based on existing health data for the individual components which comprise the mixture.

### **11.1 Information on Toxicological Information**

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.

Serious Eye Damage/Irritation: Dust or fines may cause mechanical irritation

Respiratory/Skin Sensitization: Dust may cause skin irritation May cause allergic

skin reaction (sensitization).

Ingestion: No acute effects expected from swallowing small amounts

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”.

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

Medical Conditions Generally Aggravated by Exposure: Individuals with pre-existing skin disorders may be at increased risk from exposure.

#### **11.1.1 Acute Toxicity**

No data available

## **12. ECOLOGICAL INFORMATION**

No data available at this time.

## **13. DISPOSAL CONSIDERATIONS**

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable state/provincial and local regulations.

## **14. TRANSPORTATION INFORMATION**

None, not regulated for Transport of Dangerous Goods (DOT, IATA, IMDG)

## **15. REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

#### EU Regulations

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



Limited evidence of carcinogenic effect (R40)  
May cause sensitization by skin contact (R43)  
Toxic: danger of serious damage to health by prolonged exposure through inhalation (R48/23)  
Wear suitable protective clothing and gloves (S36/37)  
In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) (S45)  
Refer to manufacturer/supplier for information on recovery/recycling (S59)  
Avoid release to the environment. Refer to Safety data sheet. (S61)  
European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.

**National Regulations (USA):**

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 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 3131 (40CFR372: Nickel, 7440-02 EPA Toxic Substances Control Act (TSCA)  
Status: This product is a medical device and not subject to chemical notification requirements.  
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.

**15.2 Chemical Safety Assessment:**

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

**16. ADDITIONAL INFORMATION****16.1 Indication of changes/revision to SDS:**

1. New format
2. Inclusion of EC Requirements

**16.2 Abbreviations and acronyms:**

None

### **16.3 Key literature references and sources for data**

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

### **16.4 Classification and procedure used to derive classification**

#### **for mixtures according to Regulation (EC) 1272/2008[CLP]:**

None

---

---

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. Innovative Material and Devices, Inc, , however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**