

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Tanzo™
Common Name: Orthodontic Wires
Material: Copper-Nickel-Titanium
Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal 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 (Section 3)

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

Company Name:
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com
National Contact: Safety Department

1.4 Emergency Telephone Number

Emergency Response Number:
 920-457-5051
 Only available during office hours: 8:00AM – 5:00PM (Central Time)
 Language of Phone Service: English

2. HAZARDS IDENTIFICATION

General Hazard Statement:

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

This product is classified as "articles" and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

However some hazardous elements contained in these products may be emitted under certain processing conditions. Products in the solid state present no fire or explosion hazards. The following classification information is for the hazardous elements which may be released during processing.

2.1 Classification of the substance or mixture

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

Carcinogenicity: Health Hazard Category 2 (Carc. 2, H351)

Skin Sensitization: Hazard Category 1B (Skin Sens. H317)

2.1.2 Classification according to Directive 67/548/EEC

Carc. Cat. 3; R40, R43 (Carcinogen Category 2; Skin Sensitization Category 1)

2.2 Label Elements

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

Hazard Pictogram(s)



GHS07



GHS08

Signal Word(s): Warning (Nickel)

Hazard Statements:

Suspected of causing cancer (H351)

May cause an allergic skin reaction (H317)

Precautionary Statements:

Obtain special instructions before use (P201)

Do not handle until all safety precautions have been read and understood (P202)

Use personal protective equipment as required (P281)

Avoid breathing dust/fume/gas/mist/vapors/spray (P261)

Contaminated work clothing should not be allowed out of the workplace (P272)

Wear protective gloves/protective clothing/eye protection/ face protection (P280)

If exposed or concerned: Get medical advice/attention (P308+P313)

If on skin: Wash with plenty of soap and water (P302+P352)

If skin irritation or rash occurs, get medical advice/attention (P333+P313)

Wash contaminated clothing before reuse (P363)

Dispose of Contents and Containers in accordance with applicable regulations. (P501)

2.3 Other Hazards

None

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Nickel, Ni	7440-02-0	231-111-4	45-55
Copper, Cu	7440-50-8	N/A	5.0-7.0
Chromium, Cr	7440-47-3	N/A	0-0.5
Titanium, Ti	7440-32-6	231-142-3	45-55

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 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
- CO₂
- 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 ³ TWA	1.5 mg/ m ³ TWA (inhalable)
Titanium	None Established	None Established
Copper	0.1 mg/ m ³ TWA	0.2 mg/ m ³ TWA (fume) 1.0 mg/ m ³ TWA (dust)
Chromium	1 mg/ m ³ TWA	0.5 mg/ m ³ TWA

Additional Information:

Nickel: 0.5mg /m³ 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/white solid
Odor:	None
OpH:	N/A
Melting Point/Freezing Point:	2264-2390°F /1240 -1310°C

9.2 Other Information

Specific Gravity:	6.4 to 9.0 g/cm ³
Volume Resistivity:	0.5 to 1.1 μΩ m

10. STABILITY AND REACTIVITY
10.1 Reactivity

Stable

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.
Sodium Chlorinate, Potassium Perchlorate, Peroxyformic Acid, Hydrogen Peroxide, Bromine
Pentaflourode, Ammonium Nitrate

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 federal, 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 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 3131 (40CFR372: Nickel (CASRN 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
3. *Revision Date:* 04/23/15

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. American Orthodontics, 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.**