

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Gold-Nickel Alloy Braze
Common Name: Orthodontic Supplies - Gold-Nickel Alloy
Material: Gold-Nickel Alloy
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)
REACH Registration No. : 01-2119438727-29-XXXX (Nickel)
CAS No. / IUPAC: 7440-57-5 (Gold); 7440-02-2 (Nickel)

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only; for brazing and other metallurgical processes.
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

NOTE: Hazards identification below pertains to the element Nickel.

2.1 Classification of the substance or mixture

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

Nickel:
 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

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

2.1.3 Additional information:

None

2.2 Label Elements

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

Hazard Pictogram(s)

(Nickel)



Signal Word(s): Warning (Nickel)

Hazard Statements:

Suspected of causing cancer (H351)

May cause an allergic skin reaction (H317)

Precautionary Statements:

Prevention:

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)

Storage: Store locked up (P405)

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

Supplemental Hazard information (EU):

Not applicable

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>
Gold, Au	7440-57-5	N/A	70-82
Nickel, Ni	7440-02-0	231-111-4	18-30

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

Inhalation: If signs and symptoms of toxicity are observed, remove subject from area, administer oxygen and seek medical attention. Keep the subject warm and at rest. Perform artificial respiration if breathing has stopped.

Skin Contact: Remove contaminated clothing. Wash affected area with large quantities of water for at least five minutes. Seek medical attention if necessary. Launder or dry-clean clothing before use.

Eye Contact: Flush affected areas with water for at least fifteen minutes. Seek medical assistance if necessary.

Ingestion/Swallowing: If subject is conscious, induce vomiting. If unconscious or convulsive, seek immediate medical assistance. Do not give anything by mouth to an unconscious or convulsive person.

Notes to the Doctor:

None of the components are acutely toxic by ingestion, nor are they absorbed through the skin. Skin exposure may cause contact or allergic dermatitis.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Use dry chemical. Do not use water.

5.2 Special Exposure Hazards from Substance/Mixture

These products are non-flammable and non-explosive. If present in a fire or explosion, they may emit fumes of the constituent metals or their oxides.

5.3 Advice for Firefighters

If fighting a fire in which these products are present, wear a self-contained breathing apparatus with full face piece operated in pressure-demand or other positive pressure mode.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

Avoid contact with skin, eyes and mucous membranes

6.2 Environmental Precautions

Prevent spills from entering sewers or contaminating soils

6.3 Methods & Material for Containment & Cleaning Up

If a finely-divided form of product is spilled, clean up spillage so as to minimize dispersion of dust. Either wet sweeping or vacuuming using HEPA filtration is recommended.

6.4 Reference to other sections (as applicable)

None

7 HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures: No special handling precautions are required.

General Occupational Hygiene: To prevent ingestion following use of the product, wash hands and face before eating, drinking, applying cosmetics, or using tobacco. Remove contaminated clothing or protective equipment before entering eating/drinking areas.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Do not store in proximity to incompatible materials (see Section 10)

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Gold, Au	No OSHA PELs	NO ACGIH TLVs
Nickel, Ni	1 mg/ m ³ TWA	1.5mg/ m ³ TWA

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

Use dilution or local exhaust ventilation adequate to maintain concentrations of all components and their by-products to within their applicable standards.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

Wear eye protection adequate to prevent eye contact with the product and injury if the products are used with a flame. Plastic-frame spectacles with side-shields and filter lenses (shade* 3/#4) are recommended.

8.2.2 Skin Protection

Wear protective gloves and clothing to prevent skin injuries if the products are used with a flame. Avoid flammable fabrics.

8.2.2.3 Respiratory Protection

If an exposure level to a component(s) exceeds an applicable standard, use a NIOSH-approved respirator having a configuration (face-piece, filter medical assigned protection factor, etc.) effective for the concentration of the component(s) generated. For guidance on selection and use of respirators, consult American National Standard Z88.2 (ANSI, New York, NY 10036, USA)

8.2.2.4 Thermal Hazards

None

Reference Section 5 for specific personal protective equipment advice

8.2.3 Environmental Exposure Controls

None

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	gold-gray metals, various forms
Odor:	Odorless
Odor Threshold:	N/A
pH:	N/A
Melting Point:	>1981°F / 1083°C
Relative Densit (H2)y:	approx.. 16.0
Solubility(ies):	Insoluble in H2O

9.2 Other Information

None

10 STABILITY AND REACTIVITY

10.1 Reactivity

None reasonably foreseeable

10.2 Chemical Stability

Stable

10.3 Conditions of Instability

None

10.4 Possibility of Hazardous Reactions

None reasonably foreseeable

10.5 Conditions to Avoid

None reasonably foreseeable

10.6 Incompatible Materials

Ammonia, aqua regia, peroxides, ammonium nitrate, halogens, hydrazine, hydrazoic acid, performic acid, sulfur, phosphorous, selenium, tellurium, dioxane, titanium plus potassium chlorate

10.7 Hazardous Decomposition Products

Heating to elevated temperatures may liberate metal/metal oxide fumes

10.8 Hazardous Polymerization

Will not occur

11 TOXICOLOGICAL INFORMATION

This product has not been subject to toxicological testing by the supplier/manufacturer.

11.1 Information on Toxicological Information

Routes of entry: Ingestion; inhalation

Serious Eye Damage/Irritation: Eye contact with these products in finely-divided forms may cause irritation or conjunctivitis

Skin Sensitization: Skin contact with these products, particularly in finely-divided forms, may cause irritation and contact or allergic dermatitis

Ingestion: Ingestion of these products in finely-divided forms may cause nausea, vomiting and gastrointestinal irritation

Carcinogenicity: Nickel is classified as a potential human carcinogen by IARC (“2b”, possibly carcinogenic to humans) and NTP (“K”, known to be a human carcinogen). Exposure to some compounds of nickel has been shown to increase the risk of various cancers, although these effects have not been demonstrated among individuals occupationally exposed only to nickel metal. ACGIH classifies nickel metal as “A5” (not suspected as a human carcinogen).

Reproductive Toxicity: The product contains no chemicals determined to be damaging to fertility of the unborn child

Germ Cell Mutagenicity: The product contains no chemicals determined to be germ cell mutagens.

Aspiration Hazard: Inhalation of toxicologically-significant quantities of the components is unlikely when the product is used in accordance with instructions and specified protective measures (see Section 8)

Signs & Symptoms of Exposure: Chronic over-exposure by inhalation may aggravate pre-existing disease of the respiratory system

Medical Conditions Generally Aggravated by Exposure: Pre-existing pulmonary diseases (e.g. bronchitis, asthma) may be aggravated by inhalation overexposure, particularly as fume.

11.1.1 Acute Toxicity

Toxicological Data:

Gold

LD50: No data available

LC50: No data available

Nickel

LD50: 5 000 mg/kg (oral/rat)

LC50: No data available

Acute Toxicity Estimates

LD50 (oral): >5 000 mg/kg

LD50 (dermal): no data available

LC50: no data available

12 ECOLOGICAL INFORMATION

No ecological data is available for the product. Available ecological data for the components is as follows:

Gold:

No data available for Aquatic Toxicity to Fish and Invertebrates, Aquatic Toxicity to Plants and Microorganisms, Toxicity to Terrestrial Organisms, Persistence and Degradability, Bioaccumulation Potential, Mobility in Soil.

Nickel:

Aquatic Toxicity: LC50 >100 mg/L for 4 d. (Freshwater Fish)

Aquatic Toxicity: EC50 >100 mg/L for 48 hrs. (Daphnia)

Aquatic Toxicity: EC50 = 0.18mg/L for 3d. (Algae)

No data available for Terrestrial Organisms, Persistence and Degradability, Bioaccumulation Potential, Mobility in Soil.

Ozone Depletion Potential: This product contains no ingredients listed in the Annexes to the Montreal Protocol on substances that Deplete the Ozone Layer.

13 DISPOSAL CONSIDERATIONS

Do not discharge waste product into sanitary or storm sewers or allow it to contaminate the soil.
Consult applicable Federal, State/Provincial and local regulations.

14 TRANSPORTATION INFORMATION

Transport is not regulated by USDOT, TDG (Canada), IATA or IMO

15 REGULATORY INFORMATION**15.2 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU Regulations**

None

Canadian Regulations:

All components of these products are listed on either the Domestic Substances List (DSL) or the Nondomestic Substances List (NDSL)

WHMIS Class(es) and Division(s): D2A, D2B

Components on Ingredients Disclosure List: Nickel, elemental (CASRN 7440-02-0)

This product has been classified according to the hazard criteria of the CPR and this SDS contains all of the information required by the CPR.

National Regulations (USA):

All components of this product are listed on the EPA's TSCA inventory.

SARA Hazard Classes: Chronic Health Hazard

SARA Section 313 Notification: These products contain these components subject to the requirements of Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and 40CFR, Part 372: Nickel (CASRN 7440-02-0)

Nickel: California Proposition 65 listed chemical

15.3 Chemical Safety Assessment:

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

16 ADDITIONAL INFORMATION**16.2 Indication of changes/revision to SDS:**

1. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 04/22/2015

16.3 Abbreviations and acronyms:

None

16.4 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

16.5 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.**