

# SAFETY DATA SHEET

## SECTION 1. IDENTIFICATION



Great Lakes Orthodontics  
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Tonawanda, NY 14150

716-871-1161  
800-828-7626  
CHEMTREC: 800-424-9300

**Product Name:** Expansion Screws  
**Product Number:** 125-001, 125-002, 125-003, 125-004, 125-028, 125-035

Effective Date: 3/27/13

## SECTION 2. HAZARDOUS IDENTIFICATION

The products this safety data sheet refers to are in the form of massive metallic alloy and when used under usual conditions and in accordance with the intended use, they are generally not considered hazardous to man or environment. A different use of the product not conforming to the indications of use may alter the performances of the product and induce potential hazards to health and safety. In case the products undergo to any process that causes the change in the state of the raw material, the following health hazards shall be applied to the personnel involved in the raw material's processing and not to the final user.

Prolonged and repeated exposure to dust and fumes, generated from successive working processes of the products involving grinding, melting, brazing, thermal treatment, welding and pickling or any other process that causes a release of dust or fumes, could cause potential human health hazards.

### Potential Health Effects:

#### **Primary Routes of Entry**

- Inhalation
- Ingestion
- Skin Contact
- Eye Contact

### Human Effects and Symptoms of Overexposure:

The following is a list of potential health effects for hazardous elements that are possibly contained in stainless steel alloys and which may be inhaled, swallowed or get in contact with skin and eyes.

*Iron oxide:* it has caused irritation of the eyes, nose, and skin of test animals. It may have the same effect on humans.

*Chromium:* ferrochrome alloys have been associated with lung changes in workers exposed to these alloys. Chromium is classified by IARC<sup>3</sup> as a suspect carcinogenic agent.

*Manganese:* inhalation of manganese fume may cause “metal fume fever” with symptoms of chills, fever, nausea, cough, dry throat, weakness, muscle aches and a sweet or metallic taste in the mouth. Prolonged or repeated exposure may affect the nervous system, with difficulty in walking and balancing, weakness or cramps in the legs. Hoarseness of the voice, trouble with memory or judgment, unstable emotions or unusual irritability. The respiratory system may also be affected by pneumonia like illness with symptoms of coughing, fever, chills, body ache, chest pain and other common signs of pneumonia.

*Nickel:* fumes are respiratory irritants and may cause respiratory disease. Skin contact can also cause an allergic skin rash. Nickel and its compounds have been reported to cause cancer of the lungs and sinuses. Nickel is classified by IARC as a suspect carcinogenic agent.

Nickel is classified by EC Directive 67/548/EEC and further modifications as suspect carcinogen (category 3 – R40) and a skin sensitizer (R43). The classification rules of the European Directive 99/45/EC and further modifications state that all preparations containing 1% Nickel or more must be automatically classified as suspect carcinogen (R40)

<b>SECTION 3.                    COMPOSITION / INFORMATION ON INGREDIENTS</b>
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### **Hazardous Components**

Steel Type	Elements									
	C	Si	Mn	P	S	Cr	Mo	Ni	Others	Fe
AISI 301	≤ 0.15	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	16.0-18.0	-	6.00-8.00	-	rest
AISI 302	≤ 0.15	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	17.0-19.0	-	8.00-10.00	-	rest
AISI 303	≤ 0.15	≤ 1.00	≤ 2.00	≤ 0.200	≥ 0.150	17.0-19.0	-	8.00-10.00	Zr o Mo ≤ 0.60	rest
AISI 304	≤ 0.08	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	18.0-20.0	-	8.00-10.50	-	rest
AISI 304L	≤ 0.03	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	18.0-20.0	-	8.00-12.00	-	rest
AOSO 305L	≤ 0.08	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	17.0-19.0	-	10.50-13.00	-	rest
AISI 316L	≤ 0.03	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	16.0-18.0	2.00-3.00	10.00-14.00	-	rest
AISI 316L+S	≤ 0.03	≤ 1.00	≤ 2.00	≤ 0.045	0.01-0.03	17.0-19.0	2.00-3.00	-	-	rest
AISI 316L (ISO 5832-1)	≤ 0.03	≤ 1.00	≤ 2.00	≤ 0.025	≤ 0.010	17.0-19.0	2.25-3.00	13.00-15.00	N ≤ 0.10; Cu ≤ 0.50	rest
AISI 410	≤ 0.15	≤ 1.00	≤ 1.00	≤ 0.040	≤ 0.030	11.5-13.5	-	-	-	rest
AISI 420	≤ 0.15	≤ 1.00	≤ 1.00	≤ 0.040	≤ 0.030	12.0-14.0	-	-	-	rest
AISI 420F	≤ 0.15	≤ 1.00	≤ 1.25	≤ 0.060	≥ 0.015	12.0-14.0	≤ 0.6	-	-	rest
AISI 420F PLUS	0.20-0.26	≤ 1.00	≤ 2.00	≤ 0.040	0.15-0.27	12.5-14.0	1.00-1.50	.075-1.50	-	rest
AISI 440A	0.60-0.75	≤ 1.00	≤ 1.00	≤ 0.040	≤ 0.030	16.0-18.0	≤ 0.75	-	-	rest
AISI 630	≤ 0.07	≤ 0.70	≤ 1.50	≤ 0.040	≤ 0.015	15.0-17.0	≤ 0.6	3.0-5.0	5xC≤Nb≤ 0.45; Cu 3-5	rest
Leowire®	≤ 0.15	≤ 1.00	≤ 2.00	≤ 0.045	≤ 0.030	16.0-18.0	≤ 0.80	6.00-9.00	-	rest
AISI 630MOD	≤ 0.03	≤ 0.50	≤ 0.50	≤ 0.015	≤ 0.015	11.0-12.5	≤ 0.50	7.50-9.50	Cu 1.50-2.50; Nb + Ta 0.10-0.50; Ti 0.90-1.40	rest
AISI 420MOD	0.35-0.50	≤ 1.00	≤ 1.00	≤ 0.040	≤ 0.015	14.0-16.0	1.00-2.50	-	N 0.1-0.3; V ≤ 1.50	rest
AISI 440B	0.85-0.95	≤ 1.00	≤ 1.00	≤ 0.040	≤ 0.015	17.0-19.0	0.90-1.30	-	V 0.07-0.12	rest
CAS Number of the elements	1333-86-4	7440-21-3	7439-96-5	7723-14-0	7704-34-9	7440-47-3	7439-98-7	7440-02-0	Cu 7440-50-8; Nb 7440-25-7 N 7727-37-9; Zr 7440-67-7 Ta 7440-25-7; Ti 7440-32-6	7439-89-6

## SECTION 4. FIRST AID MEASURES

- Not applicable to be finished products this safety data sheet refers to.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material.

### Eye Contact

Flush thoroughly with water, consult a physician.

### Skin Contact

Wash with water and mild detergent.

### Inhalation

Move person to fresh air until recovered. Consult a physician.

### Ingestion

While ingestion of large enough quantities to cause health effects is unlikely, consult a physician if it occurs.

## **SECTION 5. FIRE FIGHTING MEASURES**

- The finished products this safety data sheet refers to are not flammable.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material.

### **Suitable Extinguishing Media**

Use fire-fighting measures suitable to the environment.

### **Special Fire Fighting Procedures**

Put on breathing apparatus. Collect contaminated firefighting water separately. It must not enter the sewage.

### **Unusual Fire / Explosion Hazards**

Its combustion's products or flue gases: fume or metal oxide. Metal dust dispersed in the air may cause fire or explosion hazards. Molten metal may ignite combustibles.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

- The finished products this safety data sheet refers to, if dispersed, may be picked up with mechanical means.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material.

### **Spill and Leak Procedures**

Collect dust and waste material. Dispose of according to Section 13. Do not allow product to reach sewage system or water bodies. Personal precautions: avoid breathing in fumes and dust and use protection as described at section 8.

## **SECTION 7. HANDLING & STORAGE**

- The finished products this safety data sheet refers to have to be restricted to skilled and licensed professionals, in accordance with the intended use.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material.

### **Handling**

Prevent formation of dust. If dust/fume is developed, avoid breathing dust/fume. Avoid skin and eye contact. Make sure that all applicable workplace limits are observed.

### **Storage Precautions**

Specific storage measures are not necessary.

## SECTION 8.

## EXPOSURE CONTROLS / PERSONAL PROTECTION

The following control measures should be taken in case the product undergoes the processes listed in section 2.

### **Ventilation Measures**

Should the processes generate dust or fumes, use local ventilation and suction system, to maintain the concentrations of dust and fumes transported by the air below the limit values outlined by the local authorities.

### **Respiratory Protection**

Should the processes generate dust or fumes higher than the maximum exposure limit, special approved breathing apparatus against dust and fumes transported by the air should be worn.

### **Hand Protection**

Gloves and protective barrier creams may be necessary to prevent skin sensitization.

### **Eye Protection**

Protective or safety glasses should be worn.

### **Skin and Body Protection**

No special skin protection requirements during normal handling and use.

- Exposure limits for finished products related to this safety data sheet are not known. Exposure limits, if applicable, apply to dust and fume of some constituent elements and certain of their compounds as generated from the working processes listed in section 2. Exposure limits are stated by local laws consult your Occupational Safety and Health Authorities.

Herewith the limits outlined by ACGIH in the USA:

Carbon (C), occupational exposure limit (TWA): 50ppm (monoxide)

Silicon (Si), occupational exposure limit (TWA): 10 mg/m<sup>3</sup>

Manganese (Mn), occupational exposure limit (TWA): 5.0 mg/m<sup>3</sup>

Chromium (Cr), occupational exposure limit (TWA): 0.5 mg/m<sup>3</sup>

Molybdenum (Mo), occupational exposure limit (TWA): 10 mg/m<sup>3</sup>

Copper (Cu), occupational exposure limit (TWA): 1.0 mg/m<sup>3</sup> (powder), 0.2 mg/m<sup>3</sup> (fumes)

Iron (Fe), occupational exposure limit (TWA): 5.0 mg/m<sup>3</sup> (oxide)

Nitrogen (N), occupational exposure limit (TWA): 3ppm (dioxide)

Nickel (Ni), occupational exposure limit (TWA): 1.0 mg/m<sup>3</sup>; 0.5 mg/m<sup>3</sup> in Germany; 1.0 mg/m<sup>3</sup> in Italy.

## SECTION 9.

## PHYSICAL & CHEMICAL PROPERTIES

- **Appearance** – Massive form
- **Color** – Metal - silver gray
- **Odor** – Odorless
- **Boiling Point** – not determined
- **Melting Point** – not determined
- **Solubility in Water** – Insoluble
- **Density @ 20 °C** - > 3 g/cm<sup>3</sup>

**Not applicable:** PH, Flash Point, Auto Ignition Temperature, and Lower Explosion Limit.

## **SECTION 10. STABILITY & REACTIVITY**

**Hazardous Reactions** – Hazardous polymerization will not occur.

**Stability** – Stable

**Materials to Avoid** – None

**Conditions to Avoid** – None

**Hazardous Decomposition Products** – Metal oxide fumes.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

Toxicity Data:

**Acute oral toxicity**

- See hazards outlined in section 2.

**Chronic toxicity**

- See hazards outlined in section 2.

**Skin Irritation**

- Sensitization possible by skin contact.
  
- Do not dispose of in the environment; slightly hazardous for water.

## **SECTION 12. ECOLOGICAL INFORMATION (non-mandatory)**

- Do not dispose of in the environment; slightly hazardous for water.

## **SECTION 13. DISPOSAL CONSIDERATIONS (non-mandatory)**

**Waste Disposal Method**

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 “Regulations on environment subject”, application of European Directive on environmental protection, and subsequent modifications and integrations. Do not dispose of together with household garbage, do not allow product to reach sewage and water bodies. Recycling possibility must be verified in accordance with local and national regulations.

## **SECTION 14. TRANSPORT INFORMATION (non-mandatory)**

The product is not hazardous within the meaning of transport regulations.

## **SECTION 15. REGULATORY INFORMATION (non-mandatory)**

Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances: There is no obligation to label the product.

Information related to further dispositions: The products which wear the CE marking on the label are in accordance with the essential requirements of 93/42EEC Directive, Annex I, on medical devices.

<b>SECTION 16. OTHER INFORMATION (non-mandatory)</b>
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The safety data sheet has been written according to relevant European provisions on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3, related to nickel:

Hazard symbols:	Xn	Harmful
Risk phrases:	R40	Limited evidence of a carcinogenic effect
	R43	May cause sensitization by skin contact

Further advice on the preparation:

Safety phrases:	S22	Do not breathe dust
	S36/37	Wear suitable protective clothing and gloves are not shown on the product label.