DENTSPLY

MATERIAL SAFETY SHEET

In accordance with European Commission Directive 91/155/EEC, recognised by Ministerial Decree 28.01.1993 (Official Gazette 29.02.92, general series n. 50) and explanatory circular 15, 01.04.92 (Official Gazette 22.04.92, general series n. 94) of European Commission Directive 93/112/EEC.

SECTION 1 – IDENTIFICATION OF THE PRODUCT AND COMPANY

Name of alloy: MEAlloy
Description: Non-precious dental alloy for ceramic use
Supplier: DENTSPLY LIMITED
UK EXPORT DIVISION
HAMM MOOR LANE
WEYBRIDGE
SURREY KT15 2SE,
UNITED KINGDOM.
Tel. +44 1932 853422; Fax. +44 1932 840168

SECTION 2 – COMPOSITION BY ELEMENT AND WEIGHT

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>NOMINAL COMPOSITION %</th>
<th>CONCENTRATION RANGE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cr</td>
<td>25</td>
<td>23.0 – 26.0</td>
</tr>
<tr>
<td>Mo</td>
<td>9,5</td>
<td>8.5 – 10.0</td>
</tr>
<tr>
<td>Si</td>
<td>3,3</td>
<td>2.5 – 3.5</td>
</tr>
<tr>
<td>Ni</td>
<td>62</td>
<td>Up to 100%</td>
</tr>
</tbody>
</table>

Other elements such as Fe, Cu, Mn, Al, C, Ce, etc. may be present. The concentration by weight of these other elements is within the limits given in the supplement to Official Gazette 29.02.1992, general series n. 50. They are not classified as health hazards or are not subject to recognised exposure limits.

DANGEROUS ELEMENT CAS no. Conc. % Danger symbol
Nickel 7440-02-01 Up to 66% Xn R40/R43

SECTION 3 – HAZARDS

The main component of the alloy is nickel, classified by Directive 67/548/EEC as a suspect carcinogen (category 3) and as a skin irritant after prolonged contact. The classification regulations of European Directive 67/548 state that any material containing 1% or more nickel must automatically be classified as a suspect carcinogen (R40).
However, the elements contained in the alloy lose their individual characteristics and the alloy assumes its own distinctive properties. In the case of a highly passive alloy (therefore highly resistant to corrosion), as in the case of the alloy in question, Cr and Mo, kinetically active elements, form a “passive film” several atomic layers thick which is able to isolate the alloy from the external environment, however aggressive. The amount of nickel released from contact with artificial saliva is below the irritation limit (<0.5 µg/cm² week). Therefore, the alloy cannot affect the skin in the case of prolonged contact. Given that the mucous membrane in the mouth is much less sensitive than the skin, the risk of local problems during use is considered to be negligible, even in the case of persons who are sensitive to nickel.

**Description of the risks**

The alloy as supplied is not dangerous to persons and/or the environment. However, during working (for example, the fusion, welding, cutting and moulding procedures), dust and fumes may be formed. The dust and fumes caused by working have the same composition as the alloy. Should the concentration of dust in the air become excessive, inhalation over a long time period may affect the health of the worker, especially causing damage to the respiratory organs. Current exposure limits are listed in section 15 “information on regulations”.

**SECTION 4 – FIRST AID MEASURES**

In the case of irritation to the skin or eyes, consult a doctor.

**SECTION 5 – FIRE PREVENTION MEASURES**

The product is not combustible. There are no specific hazards or precautions to be taken should it be placed near a flame.

**SECTION 6 – MEASURES IN CASE OF ACCIDENTAL SEEPAGE**

Not applicable.

**SECTION 7 – HANDLING AND STORAGE**

There are no specific technical measures to be taken in handling these materials and for their storage. The alloy is stable and non-reactive under all atmospheric conditions.

**SECTION 8 – EXPOSURE CONTROL/ENVIRONMENTAL PROTECTION**

*Exposure limits*

There are no exposure limits for nickel-based alloys. Exposure limits are applied to the base elements and some of their compounds. Such limits are regulated, in the work place, by appropriate union contracts. In general, the
limits refer to the recommendations of the Association of American Health Experts (ACGIH). During work, exposure to the metallic materials and fumes and dust they produce must be kept within the limits provided by the law. In any case, protective devices and tools must be used. During the fusion, welding, cutting and moulding procedures, dust and fumes may generate material particles containing elements which are subject to exposure limits. To ensure that these limits are not exceeded, all rooms must be sufficiently aired and/or have fume exhaust devices.

**Individual protection**

*Respiratory protection*

In the case of insufficient ventilation during work, workers must wear protective devices for breathing, such as masks and appropriate filters, to avoid inhalation.

*Hand protection*

During work, hand protection must be worn when there is a risk of irritation to the skin, flying particles, burns or radiation from soldering devices.

*Eye protection*

During work, safety goggles must be worn when there is a risk of flying particles or radiation from soldering devices.

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Solid, metallic grey colour</td>
</tr>
<tr>
<td>Smell</td>
<td>Odourless</td>
</tr>
<tr>
<td>pH</td>
<td>N/A</td>
</tr>
<tr>
<td>Boiling point</td>
<td>1,320-1,230 °C</td>
</tr>
<tr>
<td>Fusion point</td>
<td>1,150-1,280 °C</td>
</tr>
<tr>
<td>Casting temperature</td>
<td>1,460 °C</td>
</tr>
<tr>
<td>Thermal expansion coefficient (20-500 °C)</td>
<td>14.1 (10^-6 °C)</td>
</tr>
<tr>
<td>Thermal expansion coefficient (20-600 °C)</td>
<td>14.2 (10^-6 °C)</td>
</tr>
<tr>
<td>Metal-ceramic adhesion</td>
<td>&gt; 70 MPa</td>
</tr>
<tr>
<td>Inflammability</td>
<td>N/A</td>
</tr>
<tr>
<td>Self-inflammability</td>
<td>N/A</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>N/A</td>
</tr>
<tr>
<td>Combustant properties</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>N/A</td>
</tr>
<tr>
<td>Density</td>
<td>8.1 g/cm³</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>N/A</td>
</tr>
<tr>
<td>Lipo-solubility</td>
<td>N/A</td>
</tr>
<tr>
<td>Octanol/water ratio</td>
<td>N/A</td>
</tr>
<tr>
<td>Ultimate tensile strength UTS</td>
<td>500 MPa</td>
</tr>
<tr>
<td>Yield point Rp 0.2%</td>
<td>350 MPa</td>
</tr>
<tr>
<td>Elasticity coefficient</td>
<td>200,000 MPa</td>
</tr>
<tr>
<td>Extension percentage</td>
<td>8 %</td>
</tr>
<tr>
<td>Vickers HV 30 hardness</td>
<td>220</td>
</tr>
</tbody>
</table>
SECTION 10 – STABILITY AND REACTIVITY

The alloy is stable and non-reactive under normal atmospheric conditions. It is reactive if it comes into prolonged contact with strong acids, developing gaseous decomposition products from the acids.

SECTION 11 - TOXICOLOGICAL INFORMATION

The alloy contains nickel, which has been classified by Directive 67/548/EEC as a suspected Category 3 carcinogenic substance (e.g. it may affect human health, but available information is lacking for sufficient evaluation of the hazards).

Toxicity may only occur through inhalation of the substance.

The dispositions of Directive 88/379/EEC concerning compounds are such that mixtures, solutions and alloys containing more than 1% nickel must by default be classified in the same way.

This product, supplied in a solid state, cannot be inhaled or swallowed, and therefore does not present toxic risks.

During machining, fusion, flame cutting or soldering, dust and fumes may be created. These can cause long-term illnesses, mainly to the lungs, only if inhaled over a long period of time.

In any case, epidemiological studies conducted on workers exposed to nickel dust and/or dust or fumes generated in the production of nickel alloys do not indicate cancer risks to the respiratory organs.

There is no direct evidence that nickel based alloys have carcinogenic effects on humans or any indirect evidence from testing inhalation and swallowing on animals. In other studies, using unusual animal testing systems, alloys with more than 40% nickel content have not indicated an increased carcinogenic risk.

Nickel is classified as a skin irritant in the case of prolonged contact with the skin on some individuals (for example persons wearing jewellery). Numerous laboratory experiments and contact with stainless steel, such as 18 Cr10Ni and 25 Cr20Ni (patch test) which are less passive than the alloy in question have shown that they do not irritate the skin. This property should therefore be the same in the alloy in question.

SECTION 12 – ECOLOGICAL INFORMATION

The alloy is stable under normal temperature and pressure conditions. It is not soluble in water, has no known damaging effects and no specific precautions are required.

SECTION 13 – DISPOSAL CONSIDERATIONS

The alloy is recyclable for the production of new alloys.

SECTION 14 – TRANSPORT INFORMATION
No specific precautions are required.

SECTION 15 – INFORMATION ON REGULATIONS

Products containing 1% or more nickel are automatically classified according to Directive 88/379/EEC, but labelling is not required as they are in a non-dangerous form which prevents them from being inhaled or swallowed.

There are no exposure limits for nickel based alloys. The applicable limits concern some of the elements contained in them and their compounds. These elements may be contained in dust and fumes produced during the working processes. 1998 ACGIH limits for exposure to nickel and its compounds in work places are as follows:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metal nickel</td>
<td>1.5 mg Ni/m³</td>
<td>Cat 5 not suspected as carcinogenic to humans</td>
</tr>
<tr>
<td>Soluble nickel compounds</td>
<td>0.1 mg Ni/m³</td>
<td>Cat A4 not classifiable as carcinogenic</td>
</tr>
<tr>
<td>Insoluble nickel compounds</td>
<td>0.2 mg Ni/m³</td>
<td>Cat A1 carcinogenic</td>
</tr>
</tbody>
</table>

Dispositions

Nickel index No. 028-002-00-7
Cat. 3 cancer classification R40 possible risk of long-term irreversible effects
R43 may cause irritation due to skin contact
Xn danger symbol R40-R43
Safety warnings S22 do not inhale dust
S36 wear appropriate protective clothing

SECTION 16 – OTHER INFORMATION

Bibliography of main information:
1) H. Mulhe, B. Bellmann, W. Koch, R. Fust, S. Tanaka
Examination of potential carcinogenicity of nickel containing stainless steel dusts and pentlandite
Fraunhofer Institute for Toxicology and Aerosol Research, Hannover 1998
2) S. Ivankovich, W. J. Zeller, D. Komitowski, L. Edier, E. Lehmann, N. Frolich
Carcinogenesis of nickel alloys in hamster after intertracheal applications
3) F. Pott, R. M. Roller, M. Caisacky, M. Rosenbuch
Carcinogenicity of nickel compounds and nickel alloys in rats by interperitoneal injection
In nickel and human health, Current perspectives, 1992
4) H. J. Ralthel
Examination of the effects on 837 persons professionally exposed to nickel
5) S. Fairhurst and H. P. A. Illing
The toxicity of nickel and its organic compounds
Health and Safety Executive 3, London, 1987
Environ. Health 1990, 16, 1-82
7) International Agency in Research on cancer, chromium, nickel and welding IARC
Monograph Caricog. Risks Hum, Lyon, IARC 1990
8) A. Tamba
Biocompatibilità dei materiali in lega non ferosa utilizzati in protesi

DECLARATION

The safety information in this document is based on the actual known level from our
knowledge and experience at the time of publication.
The document describes the product from the viewpoint of safety requirements and is a
guide for the correct handling, use, working, moving, storage, transport and disposal of
the alloy.
The information provided is not intended as confirmation of the properties of the product
and does not constitute a legal contractual relationship, and the information should not be
used as a basis for ordering the product.

Revised: 25 October 2007