

Stainless Steel issues and impacts due to the classification of Nickel

Consequences of the hazardous classification of Nickel for stainless steel products

About Stainless Steel

Stainless steel is the term used to describe a remarkable and extremely versatile family of steel grades, which are known for their corrosion and heat resistant properties.

All stainless steels contain iron as the main element and a minimum of 10.5% chromium. At this level, chromium reacts with oxygen and moisture in the environment to form a protective, adherent and coherent, oxide film which envelopes its entire surface. This oxide film (known as passive or boundary layer) is very thin (2-3 nanometres). [1nanometre = 10⁻⁹ m]. The passive layer on stainless steels exhibits a truly remarkable property; when damaged (eg abraded), it self-repairs as chromium in the steel reacts rapidly with oxygen and moisture in the environment to reform the protective layer. Increasing the chromium content beyond the minimum of 10.5% confers still greater corrosion resistance.

Besides chromium, nickel is the main alloying constituents in many stainless steels. addition of 8% or more nickel modifies strongly the mechanical properties and improves corrosion resistance further as does the addition of molybdenum. The use of chromium and nickel as alloying constituents ensures corrosion resistance, longevity, durability and clean-ability. Due to their characteristics, stainless steel is widely applied in a wide range of products in the food industry, medical devices, kitchen utensils, cutlery, automotive- and aerospace industries, construction materials, toys and furniture.

The stainless steel family tree has several branches, which may be differentiated in a variety of ways; in terms of their areas of application, by the alloying elements used in their production, or, perhaps the most accurate way, by the metallurgical phases present in their microscopic structures:

Name	Typical grades "common names"	European designation	Typical Cr (%)	Cr for grades in EN10088	Typical Ni (%)	Ni for grades in EN10088	Typical Mo (%)	Mo for grades in EN10088	Typical C (%)	C for grades in EN10088
Ferritic	409, 430	1.4512, 1.4016	12.5 – 17.0	10,5-30,0		<2.5		<4.5		<0.08
Martensitic	410, 416, 420	1.4006, 1.4005, 1.4028	10.5 – 18.0	11,0 – 19.0		<11,3		<2.8	0.2 – 1.0	<1.20
Austenitic	304, 316	1.4301, 1.4401	16.0 – 26.0	14,0-28.0	6.0 – 25.0	0.5 – 28.0		<8.0		<0.15
Austenitic-Ferritic, Duplex	2205	1.4462	18.0 – 26.0	18.0 – 30.0	4.0 – 7.0	1.0-9.5	0.0 – 4.0	<8.0		<0.05

Nickel Classification on Stainless Steels as mixtures

In the last years, a Global harmonised System (GHS) for classification has been set up at OECD/UN level and has been adopted by most of industrial countries. In Europe, it has been implemented since 2009, January, 1st by the Regulation of Classification, Labelling and Packaging of products (CLP).

Nickel is one of the few metals which are classified:

- Carcinogenic category 2 (suspected for human)
- Skin Sensitizer
- STOT RE 1 (SPECIFIC TARGET ORGAN SYSTEMIC TOXICITY)

The case of nickel is very representative for the difficulty of the classification of metals: it is classified carcinogenic by inhalation, which is an impossible exposure route for the massive form unless the metal is in powder form. For the time being it has not been possible to discriminate the classification by forms. In the assessment also the totality of the Ni compounds is classified as carcinogenic. The EU makes little distinction between the metallic form and its chemical compounds.

Stainless steel is a metallic alloy. The issue of alloys is even more complex as they are considered as mixtures. In the EU classification system only concentration are considered not the metallurgical bondings and the effect of the chemical matrix. More than half of the production of stainless steel contains nickel; and even the Ni free grades might contain more than 1% of nickel, which is the cut off limit for the Category 2 carcinogenicity classification.

In the GHS, the classification of mixtures is normally based on rules depending of the concentration of the hazardous constituents. A direct assessment of the mixtures themselves is possible but not if the constituents are classified carcinogenic.

Although it was initially a system for information, the EU legislation is now used as a tool for regulation. In this respect, the simplified and conservative aspect of the system creates a lot of difficulties. As a general consequence, directly or indirectly regulation is based more on hazard than risk.

Metals and alloys in massive form which are classified as hazardous have a derogation for labelling. However, the classification has some practical consequences in other regulations (for example transportation information) and a Safety Data sheet has to be provided to downstream users of substances and mixtures. Since steel products in general are “articles”, and not “substances nor mixtures” (www.eurofer.org: Eurofer Position Paper 28/10/2008 determining the borderline between preparations/articles for steel and steel products) the stainless industry has chosen to provide relevant safety information in a Safety Information Sheet instead.

Consequences of Nickel Classification

The real regulatory problem, especially in Europe, is not in classification as such but as a consequence of a potential ban on hazardous substances contained in materials like stainless steel in other regulation, for example in:

- The Toys Directive 2009/48/EC; CMR substances, are no longer allowed in accessible parts of toys. For certain substances like nickel tolerable limit values have been introduced. Nickel in stainless steel is derogated.
- Eco labelling / GPP regulation; 2010/66/EC; Article 6 (6) and 6 (7) ban the use of hazardous. So a product containing stainless steel could not be eco labelled. Derogations are needed for every application, and have so far been granted.
- The End of Life Directive for vehicles (ELV) 2000/73/EC; Vehicle manufacturers, in liaison with material and equipment manufacturers, to limit the use of hazardous substances in vehicles and to reduce them as far as possible from the conception of the vehicle.
- The Eco design Directive 2009/125/EC, preventing the use of hazardous substances, no specific stainless issues for taps and showers.
- Potential amendments in the Medical Devices directive 2001/83/EC Due to the existing hazard classification of nickel metal the new regulation could impact the nickel-containing stainless steel products. It could restrict the use of nickel containing stainless steel in medical devices and push for a phasing out 8 years after adoption of the Regulation with potential severe hygiene impacts in hospitals and other medical environments.
- Metals and Alloys used in food contact materials and articles; a practical guide for manufacturers and regulators 2013/09/15
- Waste prevention, the classification put the Nickel containing wastes as hazardous wastes to be regulated.
- Water regulation, the classification put the Nickel and then stainless steel in priority substances to be regulated.

What has been done?

The metal (stainless steel) Industry has been very active on this issue for at least 20 years. There are two different issues: environment classification and human health classification. For Environment under the leadership of ICMM and Eurometaux, guidance has been developed to assess alloys for the environmental endpoints using appropriate methodologies like the OECD "Transformation/Dissolution protocol". The final version of the guidance will be published this autumn.

For human health, guidance based on existing knowledge and experience is under development since 2009. The main drivers are the needs to avoid animal testing and to consider the specific properties of alloys, in part A possible solution is to find a protocol to estimate the bioavailability of the constituents of the alloys, by measuring the metals release from the alloy in biological fluids (e.g. sweat). This is the "bioelution". Unfortunately, to date, there are no internationally protocols for all relevant endpoints, even if such protocols are already used by regulatory bodies and/or embedded in regulatory work (e.g. EN 1811, ASTM). The lead has been taken by Eurometaux; a roadmap is under consultation at least to propose something at European level and to standardise the bio-elution protocol via the OECD/UN route. This is essential for the classification of mixtures in the EU – deadline June 2015. For stainless the challenge is find a methodology for "grouping" the alloys in order to test a few families instead of thousands of different grades.

The way forward for stainless steel.

Eurofer Stainless will work together with Eurometaux to continue the works on bioelution and subsequent actions.

A more political approach for Europe could be the development of a different parallel way using the weight of evidence that stainless steel is safe. This could include the following actions, many of which are already investigated:

- Leaching tests in different biological fluids (bio elution)
- In vitro and partial in vivo study
- A good independent review of health and Stainless Steel (FIOH)
- Tests for food contact ongoing with KTH
- Epidemiologic studies for workers.
- Benchmarking of the regulatory situation with other countries (e.g. USA)

Ideally this should lead to the reconsideration of the classification for stainless steel.

Conclusions

Classification of nickel could lead to unwanted and scientifically unjustified bans on the use of stainless in many product applications due to the alleged hazardous qualities of nickel in stainless.

Many data show that this classification is not scientifically justified for stainless steel where nickel is an inextricably part of the alloy. The behaviour of stainless steel is not the same as nickel metal: due to the self-repairing layer of chromium oxide, the releases are extremely low in any fluids.

Therefore unnecessary additional efforts are needed to ask for derogations for stainless steel. The use of nickel-containing stainless steels in surgical instruments, medical devices, implants, food, manufacturing industry and construction is safe and beneficial for human health. It is based on many decades of practical experience and is subject to international ISO and ASTM standards.

This should be acknowledged in a more scientifically justified classification of alloys as mixtures containing hazardous substances. This is however complicated due to the complexity of the technical and political aspects. Complicating factor is that the issue on metallic alloys is close to many other similar issues in classification regulation and hence could create precedents.