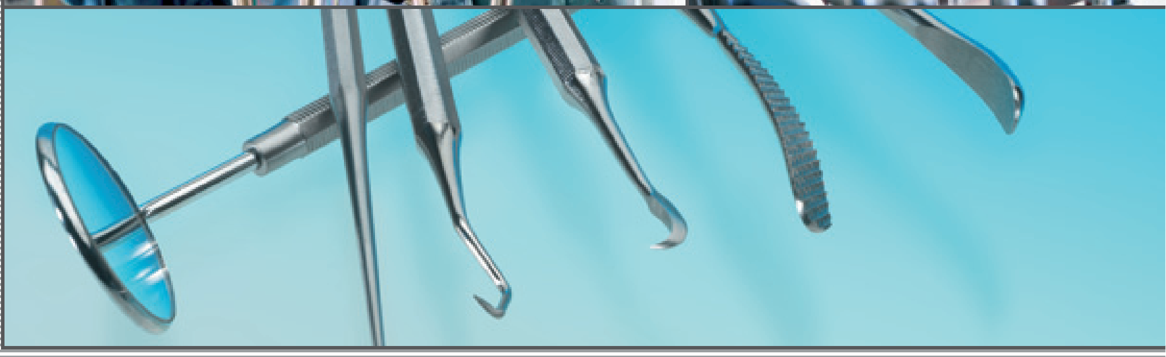
euro inox
The European Stainless Steel Development Association

Stainless Steel – When Health Comes First





Environment and Human Health Series, Volume 2

Euro Inox

Euro Inox is the European market development association for stainless steel. Members of Euro Inox include:

- European stainless steel producers
- national stainless steel development associations
- development associations of the alloying element industries

The prime objectives of Euro Inox are to create awareness of the unique properties of stainless steel and to further its use in existing applications and in new markets. To achieve these objectives, Euro Inox organizes conferences and seminars and issues guidance in printed and electronic form to enable architects, designers, specifiers, fabricators and end users to become more familiar with the material. Euro Inox also supports technical and market research.

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Editor
Euro Inox
Diamant Building, Bd. A. Reyers 80,
1030 Brussels, Belgium
Phone +32 2 706 82 67
Fax +32 2 706 82 69
E-mail: info@euro-inox.org

Author
Ulrich Heubner, Werdohl (D)

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Content

1 Introduction

Today stainless steels have a wide range of applications including those where human health may be involved. In these applications, stainless steels may come either in close direct contact with the human body as with jewellery, cutlery, medical devices and implants, or they may be used in kitchens, in the food, beverage and pharmaceutical industry and in plumbing systems where they are expected to perform without exerting any negative influence on food, drinking water and beverage or the pharmaceutical preparations they come in contact with and, in addition, they are expected to be easy to clean. The aim of this paper is to demonstrate that in all these applications stainless steels are safe and contribute to human health.

This paper considers stainless steel in its normal use by end-users. For manufacturing of stainless steels, e.g. by cutting, bending and welding, the relevant safety advices as described in the suppliers' Material Safety Data Sheets have to be considered in addition.

2 What are Stainless Steels?

2.1 Definition and principal characteristics

Stainless steels are defined as iron based alloys containing at least 10.5 % chromium and a maximum of 1.2 % carbon (1).

One of the most important characteristics of stainless steels is their resistance to corrosion in a multitude of different environments. Corrosion resistance is not an intrinsic property of a material, but the behaviour of that material that stems from the interaction with the surrounding medium and the material's surface. Indeed, corrosion resistance in stainless steels is provided by a passive surface film which acts as a barrier between the alloy and the surrounding medium (2). The passive film is a continuous and non-porous surface layer which, if broken, is self-healing under normal conditions.

Chromium plays an essential role in the formation and the stabilization of the passive film. A minimum of 10.5 % chromium is required for the formation of a protective layer of chromium oxide on the steel surface. The effectiveness of this protective (passive) layer increases with increasing chromium content. While other elements can influence the effectiveness of chromium in forming or maintaining the film, no other element can, by itself, create the characteristics of stainless steels.

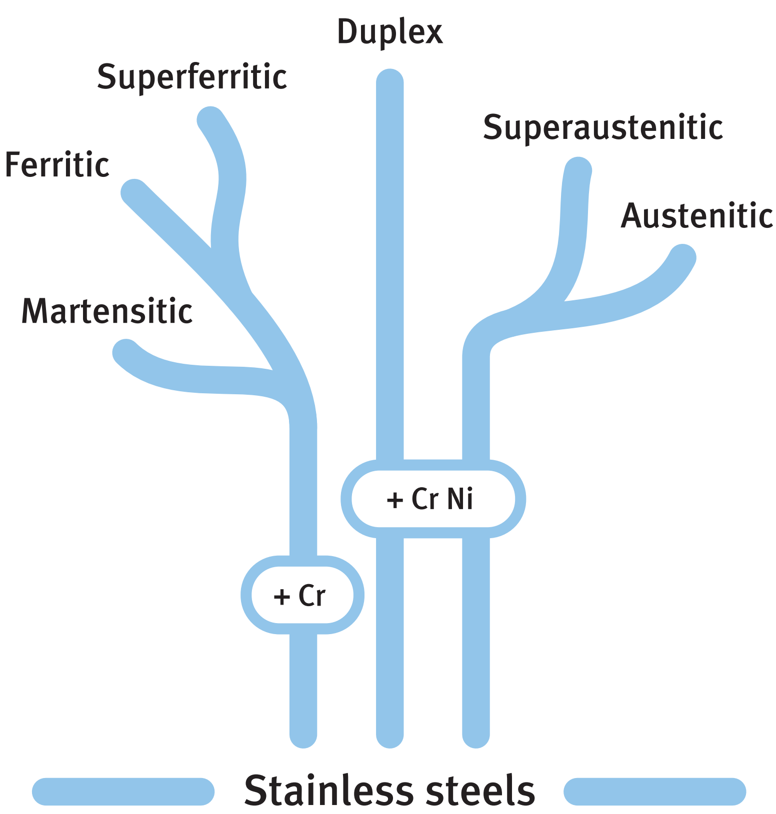
Increasing the chromium content from 10.5 % to 18 % (a level typical of the austenitic stainless steels) provides greater corrosion resistance (i.e. increased stability of the passive film). Corrosion resistance may be further improved, and a wide range of properties provided, by alloying the steel both with chromium and nickel. In particular, this will markedly facilitate passivation (2).

Molybdenum as an alloying element to stainless steels acts in a twofold way. Firstly, it facilitates the formation of the passive layer, even when added in comparatively small amounts (2). Secondly, in combination with chromium, it is very effective in stabilizing the passive film in the presence of halides (e.g. chlorides). In this way it considerably improves the resistance to pitting and crevice corrosion in neutral and acid chloride solutions (2).

2.2 Categories of stainless steels

The stainless steel family tree has several branches which may be differentiated in a variety of ways, but usually and most accurately by the metallurgical phases present in their microscopic structures. According to (1) there are four groups:

- Austenitic stainless steels,
- Austenitic-ferritic stainless steels,
- Ferritic stainless steels,
- Martensitic and precipitation hardening stainless steels.



Austenitic stainless steels consist primarily of iron, 16 - 28 % chromium (1) and up to 35 % nickel (1). In some cases Ni can be replaced by other austenite forming elements like Mn, N and Cu. Table 1 shows the principal alloying constituents of some selected austenitic stainless steel grades. Additional alloying elements such as molybdenum or nitrogen may be present in many grades to improve the corrosion resistance. Beyond the scope of Table 1 there are a number of very high alloyed austenitic grades, the so called superaustenitic stainless steels, e.g. 1.4529 with 19.0 - 21.0 % chromium, 6.0 - 7.0 % molybdenum and 0.15 - 0.25 % nitrogen (1). These superaustenitic grades are required for highly demanding corrosive applications. In contrast, in the low-nickel austenitic CrMn grades [1], alloying with 5.5 - 10.5 % manganese (1) helps to maintain the austenitic structure, but without favouring the re-passivation as nickel does (2). The overall corrosion resistance of CrMn grades tends to be lower than that of the classic CrNi grades. The entire austenitic group contains more grades, which are used in greater quantities, than any other category of stainless steel.

The austenitic grades offer excellent formability and are not subject to embrittlement at low temperatures. They are generally readily welded.

[1] typical representatives include 1.4372 and 1.4618

Austenitic-ferritic (duplex) stainless steels combine the features of both the ferritic and the austenitic category. Table 2 shows the principal alloying constituents of some selected austenitic-ferritic stainless steel grades.

As Table 2 shows, the principal alloying constituents of the austenitic-ferritic stainless steel grades are selected in a manner that results in a microstructure of about 50 % austenite and 50 % ferrite. Due to their mixed austenitic-ferritic microstructure these types of stainless steels are also called duplex stainless steels. Duplex stainless steels are weldable but care must be exercised to maintain the correct balance of austenite and ferrite. The superduplex grades may be considered for very demanding corrosive environments.

Table 1: Principal alloying constituents of some selected austenitic stainless steel grades

<table>
<tr><th rowspan="2">Group</th><th rowspan="2">Steel designation according to EN 10088 (AISI)</th><th rowspan="2">EN Number</th><th colspan="5">Composition (in mass %)</th></tr>
<tr><th>Cr</th><th>Ni</th><th>Mo</th><th>C max.</th><th>Others</th></tr>
<tr><td rowspan="4">Austenitic (CrNi)</td><td>X5CrNi18-10 (304)</td><td>1.4301</td><td rowspan="2">17.5-19.5</td><td rowspan="2">8.0-10.5</td><td rowspan="4"></td><td>0.07</td><td rowspan="3">max. 0.11 N</td></tr>
<tr><td>X2CrNi18-9 (304L)</td><td>1.4307</td><td rowspan="2">0.03</td></tr>
<tr><td>X2CrNi19-11 (304L)</td><td>1.4306</td><td>18.0-20.0</td><td>10.0-12.0</td></tr>
<tr><td>X6CrNiTi18-10 (321)</td><td>1.4541</td><td>17.0-19.0</td><td>9.0-12.0</td><td>0.08</td><td>5xC-0.7 Ti</td></tr>
<tr><td rowspan="3">Austenitic (CrNiMo)</td><td>X5CrNiMo17-12-2 (316)</td><td>1.4401</td><td rowspan="3">16.5-18.5</td><td rowspan="2">10.0-13.0</td><td rowspan="3">2.0-2.5</td><td>0.07</td><td rowspan="2">max. 0.11 N</td></tr>
<tr><td>X2CrNiMo17-12-2 (316L)</td><td>1.4404</td><td>0.03</td></tr>
<tr><td>X6CrNiMoTi17-12-2 (316Ti)</td><td>1.4571</td><td>10.5-13.5</td><td>0.08</td><td>5xC-0.7 Ti</td></tr>
<tr><td rowspan="2">Austenitic (CrMn)</td><td>X12CrMnNiN17-7-5 (201)</td><td>1.4372</td><td>16.0-18.0</td><td>3.5-5.5</td><td rowspan="2"></td><td>0.15</td><td>5.5-7.5 Mn / 0.05-0.25 N</td></tr>
<tr><td>X9CrMnNiCu17-8-5-2 a) (201Cu)</td><td>1.4618 a)</td><td>16.5-18.5</td><td>4.5-5.5</td><td>0.10</td><td>5.5-9.5 Mn/1.0-2.0 Cu max. 0.15 N</td></tr>
</table>

a) the grade has not been yet included in the EN 10088
EN / AISI comparison is approximate (nearest AISI equivalent)

Table 2: Principal alloying constituents of some selected austenitic-ferritic stainless steel grades

<table>
<tr><th rowspan="2">Group</th><th rowspan="2">Steel designation according to EN 10088</th><th rowspan="2">EN Number</th><th colspan="5">Composition (in mass %)</th></tr>
<tr><th>Cr</th><th>Ni</th><th>Mo</th><th>C max.</th><th>Others</th></tr>
<tr><td rowspan="2">Duplex</td><td>X2CrNiN23-4*</td><td>1.4362</td><td>22.0-24.0</td><td>3.5-5.5</td><td>0.1-0.6</td><td rowspan="3">0.03</td><td>0.10-0.60 Cu 0.05-0.20 N</td></tr>
<tr><td>X2CrNiMoN22-5-3**</td><td>1.4462</td><td>21.0-23.0</td><td>4.5-6.5</td><td>2.5-3.5</td><td>0.10-0.22 N</td></tr>
<tr><td>Super-duplex</td><td>X2CrNiMoN25-7-4***</td><td>1.4410</td><td>24.0-26.0</td><td>6.0-8.0</td><td>3.0-4.5</td><td>0.24-0.35 N</td></tr>
</table>

* often referred to as 2304 ** often referred to as 2205 *** often referred to as 2507

Table 3: Principal alloying constituents of some selected ferritic stainless steel grades

Group	Steel designation according to EN 10088 (AISI)	EN Number	Composition (in mass %)			
			Cr	Mo	C max.	Others
Ferritic	X6Cr17 (430)	1.4016	16.0-18.0		0.08	
	X2CrTiNb18 (441)	1.4509	17.5-18.5		0.03	[3xC+0.30] to 1.0 Nb / 0.1-0.6 Ti
	X3CrTi17 (439)	1.4510	16.0-18.0		0.05	[4x(C+N)+0.15] to 0.80 Ti*
	X2CrMoTi18-2 (444)	1.4521	17.0-20.0	1.80-2.50	0.025	[4x(C+N)+0.15] up to 0.80 Ti*

* Alternatively stabilization can be made by addition of Nb or Zr (1)

Ferritic stainless steels consist primarily of iron and chromium. The chromium content is typically around 12.5 % or 17.5 % (1). Table 3 shows the principal alloying constituents of some selected ferritic stainless steel grades.

As illustrated in Table 3, ferritic stainless steels are essentially nickel-free and are consequently less resistant to corrosion in reducing environments than those grades being alloyed with nickel. However, their resistance to corrosion is adequate in many applications and may be improved by the addition of molybdenum. Although they undergo a ductile-brittle transition at low temperatures, they possess adequate formability. Ferritic stainless steels are readily welded in thin sections, especially when stabilized by addition of elements like titanium, niobium or zirconium, but suffer grain growth with consequential loss of properties when welded in thicker sections.

Martensitic stainless steels consist essentially of iron, chromium and carbon (1). Table 4 shows the principal alloying constituents of some selected martensitic stainless steel grades.

Due to their carbon content the martensitic stainless grades are hardenable by heat treatment. They are used where, in addition to corrosion resistance, wear resistance is a requirement though their corrosion resistance may be described as moderate. Their weldability is very much limited.

Table 4: Principal alloying constituents of some selected martensitic steel grades

Group	Steel designation according to EN 10088 (AISI)	EN Number	Composition (in mass %)			
			Cr	Mo	C	Others
Martensitic	X20Cr13 (420)	1.4021	12.0-14.0		0.16-0.25	
	X17CrNi16-2 (431)	1.4057	15.0-17.0		0.12-0.22	1.5-2.5 Ni
	X39CrMo17-1	1.4122	15.5-17.5	0.8-1.3	0.33-0.45	≤ 1.0 Ni

EN / AISI comparison is approximate (nearest AISI equivalent)

3 The main alloying constituents of stainless steels as essential elements

3.1 General considerations

Metals are naturally occurring components of the environment albeit often in small quantities. For example, as shown above, chromium and nickel are the main alloying constituents of stainless steels. Correspondingly, the life of plants, animals and humans is naturally adapted to the exposure to most of these metals. Indeed, some of them have become essential for the biological and metabolic activities.

However, anything entering the body in excess, whether it be in the form of nutrition, special foodstuffs, drugs, metallic elements or even vitamins, can have a negative influence (3). For many of the metals the dose-response relationship in Figure 1 illustrates the concept of deficiency-sufficiency-toxicity.

The dose-response curve in Figure 1 when applied to essential elements demonstrates a positive influence on man and the environment when the exposure is in the sufficiency range, or they may exert a negative influence on health and the environment when the exposure is insufficient or in the toxicity range.

Even if such elements are present in large quantities or concentrations, exposure is often low and within the sufficiency range. In natural environments, elements are often adsorbed to minerals and therefore their bioavailability is low. In metallic alloys, they are contained in a chemical matrix that prevents the constituent elements being released easily.

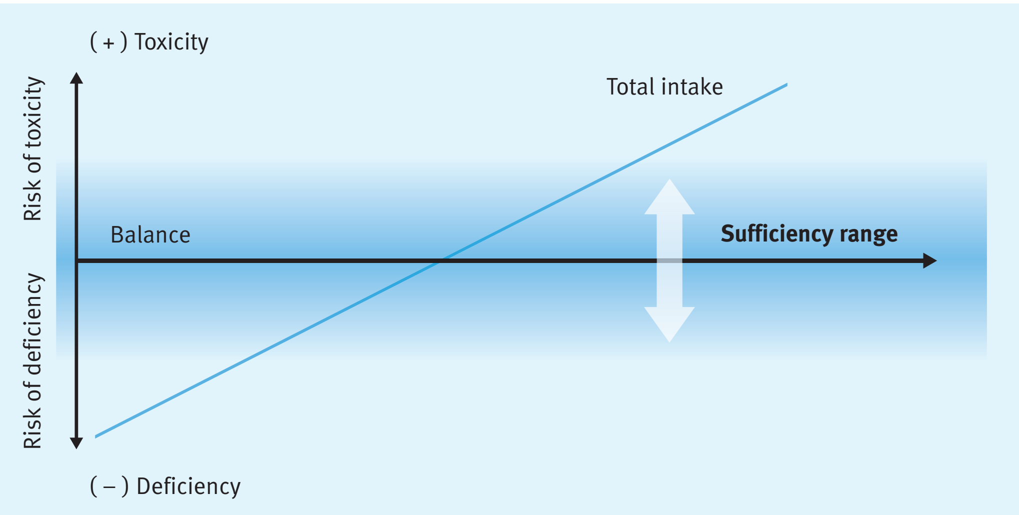
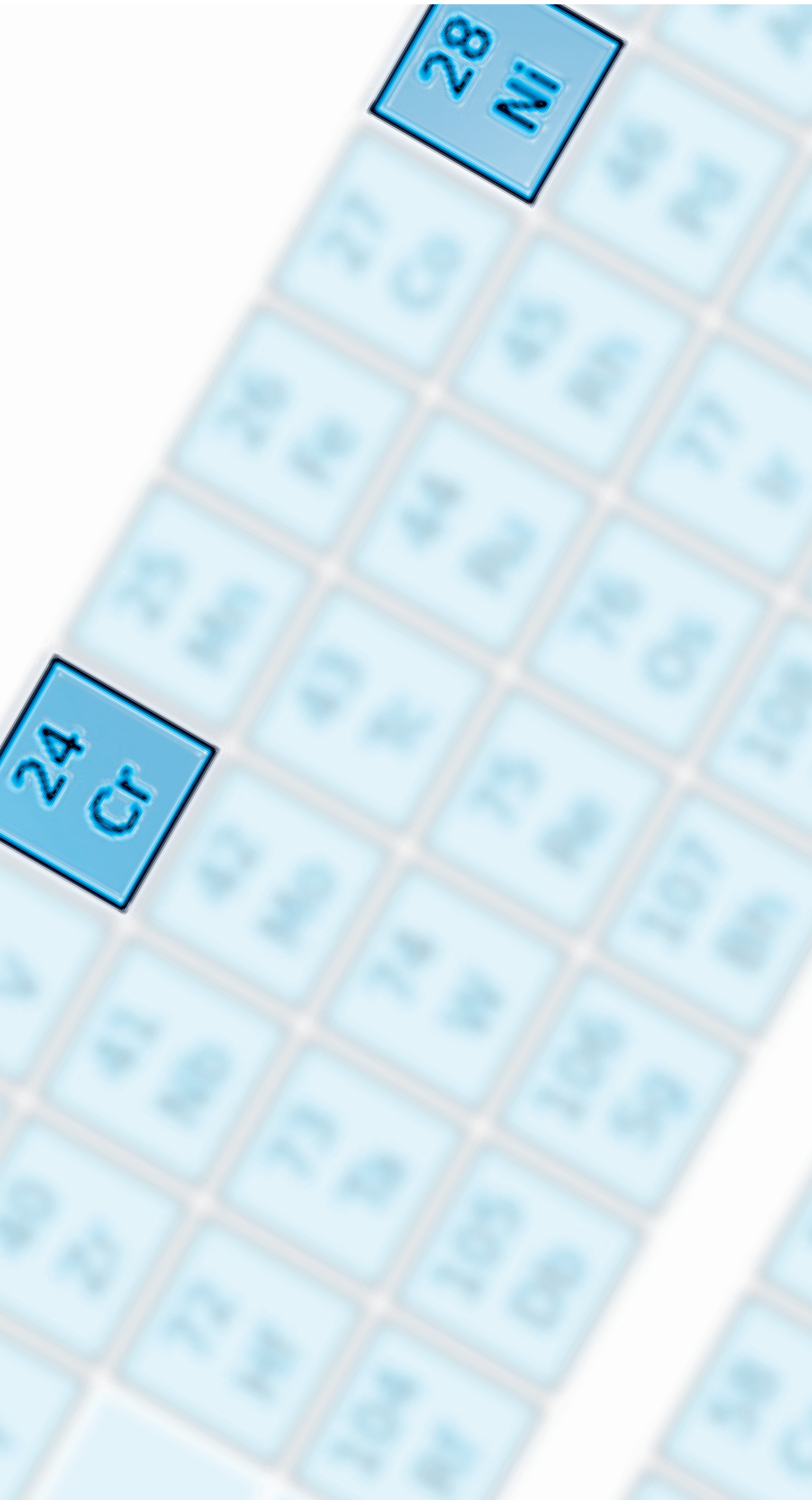


Figure 1: Typical dose-response curve for an essential element



3.2 The essential character of chromium

Elemental chromium (Cr) is biologically inert; it is not absorbed and has no nutritional value. Divalent chromium (Cr II) is not present in biological systems. Almost all naturally found chromium is trivalent (Cr III), whereas hexavalent chromium (Cr VI) is mostly of industrial origin (4).

Chromium toxicity is associated mainly with hexavalent chromium, whereas trivalent chromium is considered to be a highly safe mineral (4).

Stainless steel does not contain hexavalent chromium. Instead, the chromium in stainless steel is in the metallic form (i.e. the zero valency state). Hexavalent chromium is not an issue with stainless steel in its normal use.

Trivalent chromium is the most stable oxidation state in which chromium is found in living organisms. The main path for trivalent chromium to enter the organism is through the digestive system. It is essential to normal carbohydrate, lipid and protein metabolism. With chromium acting as a cofactor of insulin, chromium activity in the organism is parallel to insulin functions.

In human nutrition, chromium is used as a nutritional supplement recommended in impaired carbohydrate metabolism characterised by reduced glucose tolerance and impaired insulin action, for weight reduction and last but not least as a prevention for the formation of atherosclerotic plaques in blood vessels (4).

3.3 The essential character of nickel

Although nickel may occur in the valency states -1, 0, +1, +2, +3 and +4, the most common valency of nickel is +2.

The main path for divalent nickel (Ni II) to enter the organism is through the digestive system. Indeed, many kinds of food contain appreciable amounts of nickel. Diets high in chocolate, nuts, dried beans, peas, and grains could supply more than 900 µg/day, while conventional diets usually provide around 150 µg/day. The other routine source of nickel in the diet is found in drinking water. Generally, the levels found in drinking water from sources around the world vary from 5-20 µg/l (5).

Some foodstuffs have appreciable natural nickel content, among them grains, nuts and dark chocolate.

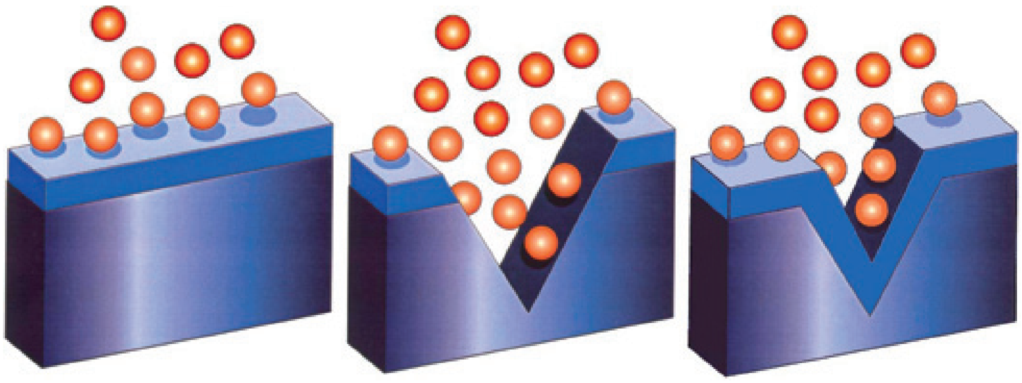
In 1975, a monograph on nickel was published in which numerous enzyme systems were studied. The conclusion was that divalent nickel (Ni II) under various conditions could either activate or inhibit several enzymatic reactions which are considered to be of crucial importance in humans and other animals, and that interference with these reactions could have severe deleterious effects (6).

As summarized in (5), early research done in chicks and rats indicated both macroscopic and microscopic changes in the liver of these animals when placed on nickel deficient diets. Many of the changes which were most consistently observed are considered to be indicative of an essential role for nickel in protein synthesis in animals.

According to the recent summary (5) of past research work, in later studies, goats were selected as representative of ruminant animals that may ingest nickel through dietary uptake of plants. These animals, when kept on a six-year diet in which the animals received 100 µg Ni/kg of food compared to the control animals which received 4000 µg Ni/kg, demonstrated a significant increase in mortality of offspring born to the nickel-deficient goats. Interestingly, this study produced evidence of decreased amounts of calcium and zinc in the nickel-deficient goats. This may suggest a role for nickel in the normal utilization of zinc. According to (5), studies in lambs produced results that were consistent with those found in other species. Nickel has also been shown to play an interactive role with other materials important to the proper biological functioning of various metabolic systems (5).

Chromium and nickel in small amounts are part of a normal diet. According to today's knowledge they are to be considered beneficial for the health of living beings.

4 Stainless steel as a safe containment of its alloying constituents



Stainless steels have a self-repairing passive layer that forms a barrier between the bulk steel and its environment.

The corrosion resistance of stainless steel is due to a so-called passive, chromium-rich complex, oxide film that forms naturally on the surface of the steel. This is the normal condition for stainless steel surfaces in their daily use and is known as the passive state or passive condition. Stainless steels will naturally self-passivate whenever a clean surface is exposed to an environment that can provide enough oxygen to form the chromium-rich oxide surface layer. This passive layer of about 1 to 2 nm thickness constitutes an effective barrier which in many cases reduces metal release from stainless steel to negligible values and, hence, migration of the alloying constituents into the surrounding media is markedly restricted.

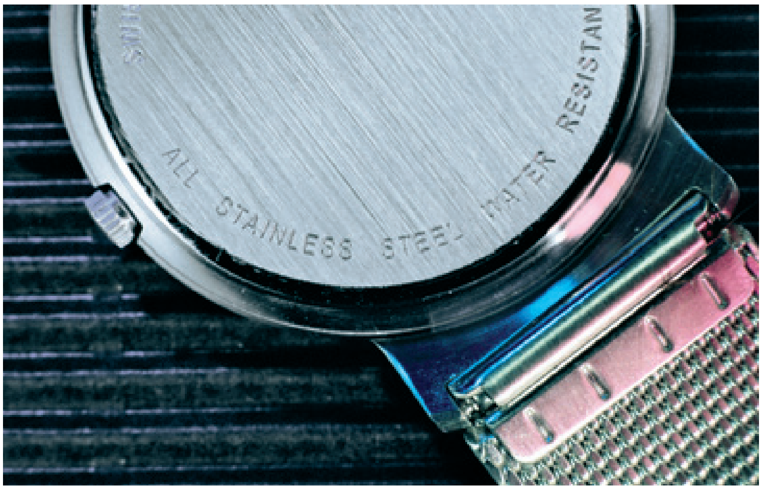
The amount of migration that may be observed will depend on the type of the stainless steel and the surrounding medium. However, today's knowledge of metal release allows migration to be kept within the sufficiency range of Figure 1. This is true even in critical applications.

The fact that it contains alloying constituents does not necessarily mean that it releases them in significant amount. Stainless steel in its normal passive state is a safe containment of its alloying constituents. It is important to select high enough an alloying content, among others of chromium and nickel, to make stainless steel a safe choice.

5 Applications of stainless steels with relation to human health

5.1 Stainless steels in contact with human skin

There are a great number of applications of stainless steels where they come into contact with the human skin (7). This contact may be transient skin contact as frequently experienced with handrails or in daily handling e.g. of bottle openers, cutlery and kitchen equipment. Typical stainless steel grades involved include the austenitic grades 1.4301 and 1.4307, the ferritic grades 1.4016 and 1.4510, and the martensitic grades 1.4021 and 1.4122. As proven by long decades of daily experience this type of contact is safe for human health.



However, nickel allergy can be found in some individuals. In case of direct and prolonged contact of metallic articles with the human skin as may be experienced with jewellery, watch backs, watch buckles, and watch straps, it may result in metal release through contact with the human sweat. If metallic nickel or nickel-containing metallic alloys are used, this will result in the release of bioavailable divalent nickel ions (8) that migrate to the human skin and may elicit an allergic reaction in already nickel-sensitized individuals.

However, this first allergic reaction is preceded by sensitization (i.e. nickel allergic contact dermatitis or nickel ACD). The development of nickel ACD requires that an individual become immunologically sensitized to nickel. This is termed the induction phase or sensitization phase and takes from 1 to 3 weeks of intimate skin contact with a form of nickel that can provide sufficient amount of soluble nickel ions to the skin primarily via sweat. The quantity of nickel ions that is sufficient to induce sensitivity varies with the individual. If the skin is already damaged, sensitization will be induced more quickly and by lower amounts of the solubilized nickel. Temperature, the presence of other allergic conditions, race, sex and age may also be determining factors on the susceptibility for and the speed of sensitization to nickel. Induction of ACD is more common if exposure is combined with skin irritants and/or moist skin.

Table 5: Chemical composition (in mass %) of the stainless steel grades and the unalloyed metallic nickel plating used in the nickel allergy studies according to (14,15,16)

Alloying element	Steel designation number (AISI)				
	1.4016 (430)	**1.4301 (304)**	**1.4404 (316L)**	**1.4305 (303)**	**Nickel plating**
Ni	0.11	8.65	11.29	8.45	99.8
Cr	16.59	18.18	17.87	17.25	
Mo	0.11	0.26	2.15	0.26	
C	0.037	0.036	0.021	0.064	
S	0.0010	0.0069	0.0018	0.2753	0.0021
Mn	0.43	0.81	1.67	1.79	
Si	0.33	0.49	0.61	0.54	

Once sensitization has occurred (this is termed the elicitation phase), the quantity of soluble nickel required to elicit an allergic dermatitis in a sensitized person is very much reduced. Elicitation can occur in skin remote from the site of contact with nickel. Hence it is important to know the threshold of exposure of the human skin to bioavailable nickel above of which the elicitation of dermatitis in a sensitized person is likely to occur. Establishing such a threshold had been the subject of dermatological research work (9).

Today it is generally acknowledged and has been verified (10) that in many uses the likelihood of dermatitis elicitation in sensitized persons is sufficiently minimised if a nickel migration limit of 0.5 µg/cm^2· week is not exceeded. This migration limit had been introduced into the Danish legislation already in 1989 (11) and has become part of the European Directive 94/27/EC (12) since 1994 for products that come into direct and prolonged contact with the human skin such as earrings, necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners, rivet buttons, and zippers.

In cases where close direct and prolonged contact with the human skin involves post assemblies which are inserted into pierced ears and other parts of the human body, a lower limit of 0.2 µg nickel/cm^2· week has become mandatory with the European Directive 2004/96/EC (13).

Therefore, there was a need to investigate the likelihood of nickel contact dermatitis that may result from a direct and prolonged contact of stainless steels with the human skin. In a series of studies (14,15,16), four different stainless steels were selected: the ferritic stainless steel grade 1.4016, the austenitic steel grades 1.4301, 1.4404 and the free-machining austenitic stainless steel grade 1.4305 with high sulphur for comparison with unalloyed metallic nickel in form of nickel-plated steel. Table 5 shows the chemical composition of the different materials used in these studies.

In approximation to EN 1811 (17), developed for implementation of Directive 94/27/EC (12), testing was carried out in artificial sweat solution consisting of 0.5 % NaCl, 0.1 % urea, 0.1 % lactic acid, and 1 % NH_3 to adjust the pH to 6.6 at ambient temperature. However, with regard to the broad scatter of the pH of human sweat (16), the leaching experiments were performed mainly in a more aggressive acidified artificial sweat solution at pH 4.5. The composition of the acidified artificial sweat solution was 0.3 % NaCl, 0.1 % Na_2SO_4, 0.2 % urea and 0.2 % lactic acid. The samples were tested in the as-received condition and immersed for one week in 100 ml of the naturally aerated solution.

In addition, clinical patch tests (8) were performed in accordance with the recommendations of the International Contact Dermatitis Research Group (14) on 50 already nickel-sensitized persons, with circular samples of the four stainless steel grades and of the nickel plating in the as received conditions.

Table 6 illustrates that the leaching experiments in the acidified artificial sweat solution resulted in a very low nickel release of less than 0.03 $\mu g/cm^2 \cdot$ week for the ferritic stainless steel grade 1.4016. Indeed, this stainless steel grade is not alloyed with nickel (cf. Table 3) and therefore, as may be verified by reference to Table 5, it contains a very small amount of nickel as an unintentional added element. However, Table 6 shows that nickel release from the nickel-containing austenitic stainless steel grades 1.4301 and 1.4404 is extremely low, too. This latter result demonstrates that the passive surface layer constitutes a safe containment of the alloying elements when these

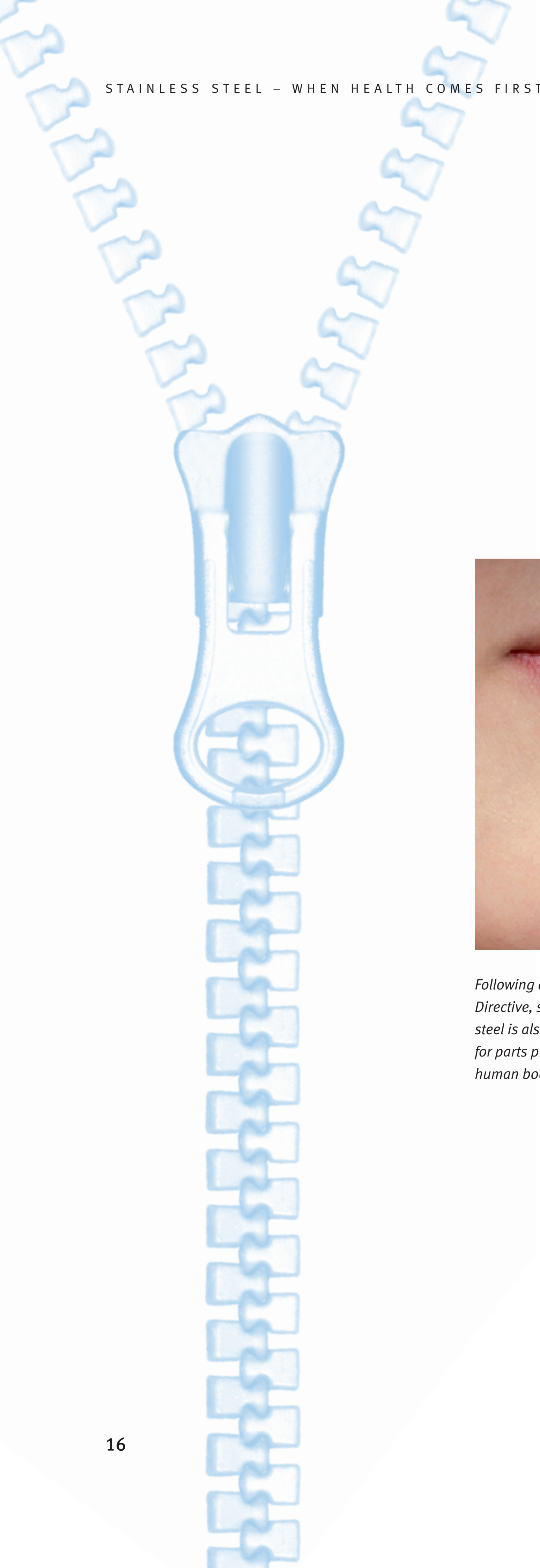
Table 6: Results of stainless steel in direct and prolonged contact with human skin in comparison with nickel release in artificial sweat

EN Number (AISI)	Ni release in acidified artificial sweat at pH 4.5, $\mu g/cm^2 \cdot$ week	Allergic reaction in clinical test, % of persons tested	Conclusion
1.4016 (430)	‹ 0.03	0	Safe for human health when used in direct and prolonged contact with human skin
1.4301 (304)			
1.4404 (316L)			
1.4305 (303)	about 1.5	14	Must not be used in direct and prolonged contact with human skin
Nickel plating	about 100	96	

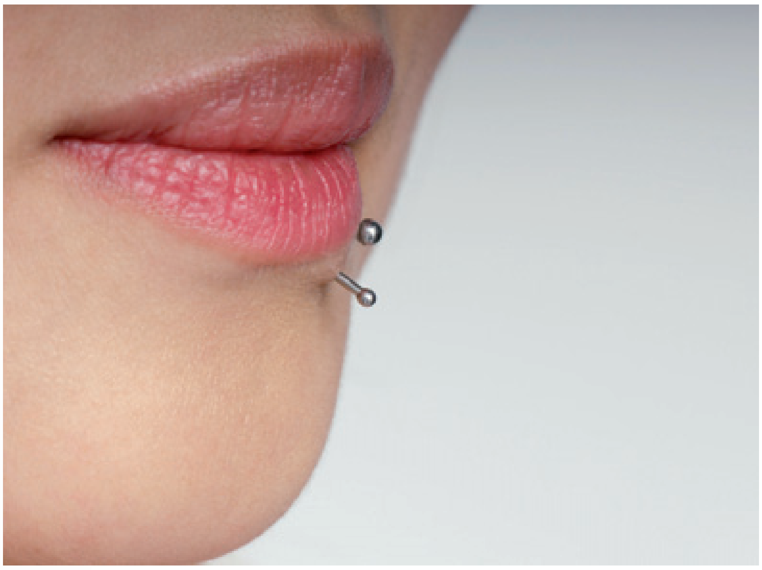
stainless steel grades are exposed to human sweat. Consequently, as shown in Table 6, allergic reactions in the clinical patch tests were zero and the austenitic stainless steel grades 1.4301 and 1.4404 as well as the ferritic grade 1.4016 are safe for human health in applications where direct and prolonged contact to the human skin occurs. However, due to the protective effect of the passive layer, the level of safety can be enhanced further by utilizing stainless steels with even higher corrosion resistance like 1.4435 and 1.4439. These grades are commonly used in the watch industry for components that are in direct contact with the human skin.

In contrast, in the acidified artificial sweat solution of pH 4.5 the intentionally resulphurised austenitic stainless steel for increased machinablility grade 1.4305 shows a nickel release of about 1.5 $\mu g/cm^2 \cdot$week (i.e. well above the limit of 0.5 $\mu g/cm^2 \cdot$ week as defined by the European Directive 94/27/EC (12) for products intended to come into direct and prolonged contact with the human skin, and above the limit of 0.2 µg nickel/$cm^2 \cdot$ week as defined in the European Directive 2004/96/EC (13) for all post assemblies which are inserted into pierced ears and other pierced parts of the human body). Furthermore, in the less aggressive pH 6.6 artificial sweat solution [similar to the test solution of EN 1811 (17)], the nickel release was approximately 0.3 $\mu g/cm^2 \cdot$ week, i.e. close to the 0.5 $\mu g/cm^2 \cdot$ week limit as defined by the European Directive 94/27/EC (12) for products intended to come into direct and prolonged contact with the human skin and above the limit of 0.2 µg nickel/$cm^2 \cdot$ week as defined in the European Directive 2004/96/EC (13) for all post assemblies which are inserted into pierced ears and other pierced parts of the human body.

With the exception of free-machining grades, stainless steels are safe for human health when used in direct and prolonged contact with the human skin as with earrings, necklaces, bracelets and chains, finger rings, wrist-watch cases, watch straps, rivet buttons, and zippers. Free-machining stainless steel grades are unsuitable for these applications.



As shown by Table 6, in clinical patch tests, grade 1.4305 elicited allergic reactions in 14 % of the subjects. Therefore, it is concluded that this and other types of resulphurised free-machining stainless steel grade is unsuitable for products that come into direct and prolonged contact with the human skin [2].



Following a European Directive, stainless steel is also admitted for parts piercing the human body.

[2] In case of watch-cases and accessories made from stainless steel with vapour deposited coatings on their surface, the requirements of the ISO standard 16253 (18) have to be observed. Where the base (substrate) material of the coated part is likely to release nickel (i.e.particularly when a free-machining stainless steel grade is used as base material), the coated items must be submitted to the tests specified in the European standard EN 12472 (19) for the simulation of two years' wear and corrosion, followed by the measurement of nickel release. A test suitable for the supervision of current production of coated items is referred to in addition (18).

5.2 Stainless steels in contact with the human tissue – medical devices and implants

It is important to distinguish between stainless steel grades used for implant applications and the commercial grade stainless steels as e.g. 1.4305, 1.4301, 1.4401 and 1.4404 used for other medical devices (7). In the EU, the Council Directive 93/42/EEC (20) defines implants as medical devices that are exposed to human tissue for more than 30 days. Subsequent medical device guidance has, however, provided further clarification by the introduction of following three definitions based on the duration that the medical device is in contact with human tissue. Transient (normally intended for continuous for less than 60 minutes); Short term (normally intended for continuous for not more than 30 days); Long term (normally intended for continuous for more than 30 days).

This definition means that commercial grade stainless steels could be used in contact with human tissue in transient medical devices and for up to 30 days in short term medical devices. For example, pins made from the stainless steel grade 1.4401 could be used in conjunction with fixation devices to aid repair of fractured bones. As these pins (or rods) pass through the skin (and underlying tissue) and are fixed into bone on either side of the fracture, they are classified as short term and surgically invasive devices. Although these pins are machined, the stainless steel grades 1.4305 or 1.4301 are not used for this application. A stainless steel of the type 1.4401 is generally considered the minimum requirement and in many cases implant grade material (see below) would be used.

Stainless steel is a standard material for fixation devices to aid repair of fractured bones.

Martensitic stainless steels are common for dental and surgical instruments.

ISO 7153-1 (21) specifies stainless steels for surgical and dental instruments. It should be stressed that the grades in ISO 7153-1 are generic. This standard also provides an indication of typical applications for each grade. The steel grades given in the standard represent typical commercial steel compositions, which should be readily available. Therefore, they are not special steels and certainly not specifically prepared for surgical applications. They are, however, used worldwide by all dental and surgical instrument manufacturers for their non-implant products.

The free-machining stainless steel grade 1.4305 is used in medical devices, where its free-machining properties enhance the ease of manufacture as for instance medical devices with screw threads, with drilled and/or tapped holes. Handles of multi-part dental instruments are often manufactured in stainless steel grade1.4305, too. In this application, the lower corrosion resistance of the free-machining grade is not a disadvantage. The handle rarely comes into contact with the patient and, if it does, contact is transient. The austenitic stainless steel grade 1.4301 has applications in medical devices, where reasonable corrosion resistance and moderate strength are required (e.g. dental impression trays, hollowware, retractors, guide pins, etc.).

Martensitic stainless steels as e.g. the grades 1.4006, 1.4021, 1.4028 and 1.4125 are used extensively for dental and surgical instruments. These stainless steels can be hardened and tempered by heat treatment. Thus, they are capable of developing a wide range of mechanical properties (i.e. high hardness for cutting instruments and lower hardness with increased toughness for load-bearing applications). Martensitic stainless steels used in medical devices usually contain up to 1 % nickel to improve their metallurgical properties.

ISO standards 5832-1 (22) and 5832-9

(23) specify wrought stainless steels and high-nitrogen stainless steels, respectively, for surgical implants. These materials were originally developed from the stainless steel grade 1.4401, but their chemical composition is now enhanced (i.e. higher chromium, nickel and molybdenum contents). In addition, implant grade stainless steels have specific requirements for resistance to pitting corrosion and for very low level of non-metallic inclusion content specified that do not apply to commercial stainless steels. Hence, special production routes (i.e. vacuum induction melting or electroslag remelting) are used to produce “clean” implant steels.

Implants have very specific surface finish requirements (7). In many cases, the surfaces are highly polished and/or electro-polished. Polished surfaces offer enhanced corrosion resistance and, in the case of an electro-polished finish, a chemically clean surface with improved surface roughness. Furthermore implants are subject to stringent cleaning regimes designed to remove microbiological contamination, which again assists corrosion resistance, and are used in the sterile condition. Non-implant medical devices also have smooth and often highly polished surfaces. Electro-polishing is widely used for dental and surgical instruments. The non-glare surface finishes also follow the standard polishing route, but are finished with a Scotchbrite mop instead of a polishing mop. Once again, these devices are cleaned and sterilized prior to use.

The use of stainless steels in surgical instruments, medical devices and implants is safe for human health. It is based on many decades of practical experience and is subject of international standards.

Stainless steel resists the acidic conditions typically found in wine tanks.

5.3 Stainless steels in contact with food and beverages

Stainless steels are important food contact materials in the food and beverage industries where they are, for instance, used for transportation, e.g. in milk trucks; for processing equipment, e.g. in the dairy and chocolate industry, in processing of fruit such as apples, grapes, oranges and tomatoes; for containers such as wine tanks; for brew kettles and beer kegs; for processing of dry food such as cereals, flour and sugar; for utensils such as blenders and bread dough mixers; in slaughter-houses; in processing of fish; for nearly all of the equipment and many of the fittings in big kitchens, such as in restaurants, hospitals, schools etc (24). Stainless steels are also important in domestic food contact applications e.g. for electric kettles, cookware and kitchen fittings such as sinks, counters and drains; for bowls, knives, spoons and forks [3].

As shown in short below there are a great number of different stainless steels in use as food contact materials. However, the majority of stainless steels used in food contact applications contain around 18 % chromium as has been found to be the optimum concentration for corrosion resistance in a wide range of food and beverage media (25).

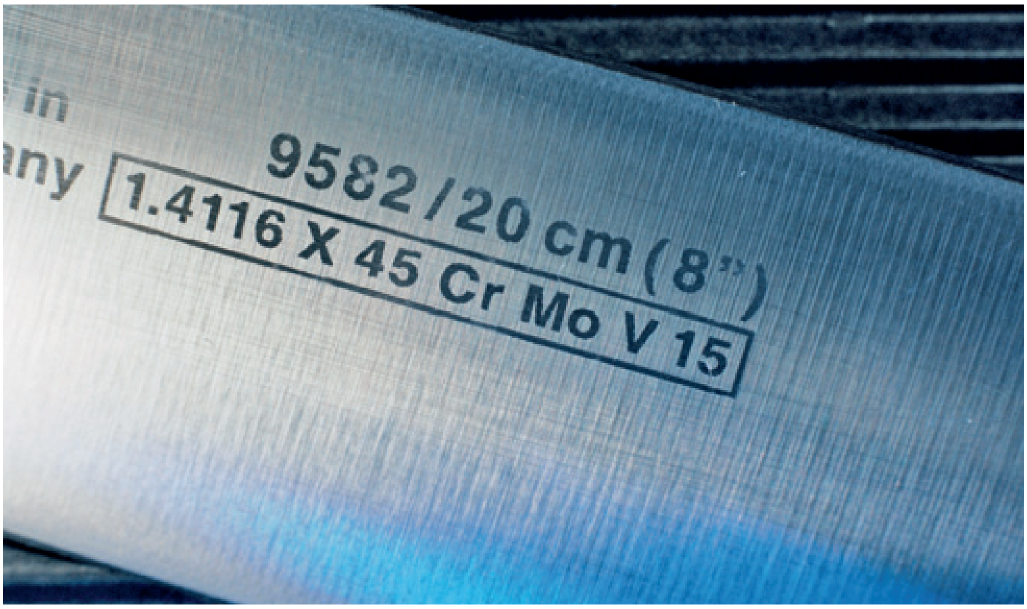
[3] An overview of applications of stainless steel in domestic appliances and hollowware can be found in the CD-ROM "At Home with Stainless Steel", Luxembourg: Euro Inox 2004. The animation can also be viewed on the Internet: www.euro-inox.org/fla_24_EN.html

Various types (1) of stainless steels are used in food contact application:

- Martensitic stainless steels for both cutlery and professional knives,
- Ferritic stainless steels for cutlery, hollow-ware, table surfaces, panels and worktops,
- Austenitic stainless steels grades in a very wide range of food contact applications, both domestic (cutlery, hollow-ware and kitchen utensils) and industrial (food processing, storage and transport equipment, pipe-work etc.),
- Austenitic-ferritic steels in contact with aggressive foodstuffs since the higher alloyed grades have a very high resistance to corrosion caused by, for example, saline solutions like in the meat industry.

Although there are no universal composition limits for stainless steels to be used in food contact applications, there are legislative requirements in France and Italy.

The extremely wide usage of stainless steels as food contact materials reflects the fact that stainless steels resist corrosion by foods and beverages. In addition they are readily cleaned, thereby providing hygiene in food preparation and handling. No flavours or discoloration are imparted to foods and beverages in contact with stainless steels (24).



The martensitic crystalline structure is instrumental in ensuring sharp edges.

Meat processing creates a corrosive environment to which suitable stainless steels are resistant.

In France (26, 27), stainless steels for food contact products must contain at least 13 % of chromium and can contain nickel and manganese. Maximum limits are imposed for certain other alloying elements (4 % for Mo, Ti, Al and Cu; 1 % for Ta, Nb and Zr). These limitations have become part of the French standard NF A36-711 published by AFNOR in April 2002 (28), listing a great number of stainless steels suitable for use in contact with foodstuffs. For each application, however, the grades have to be selected for suitability with the envisaged food contact application and foreseeable cleaning regimes.

In Italy (29), there is a "positive list" of stainless steel grades for food contact, too. These grades must pass tests for corrosion in various media under specified conditions. New grades can be added to the list following appropriate testing.

In the UK, there are numerous specifications for a wide range of food contact applications for stainless steels (30).

Other countries as e.g. Germany also have a large number of similar regulations which are listed in (31). In addition, there are European standards for certain types of food contact application of stainless steels (24). The NSF International Standard / American National Standard for Food Equipment - Food equipment materials, adopted on April 3, 2007 (32) requires stainless steel used in food equipment to be of the type AISI 200, 300 or 400 series alloys. According to this standard, stainless steel when used in the food zone must have a minimum chromium content of 16 %. However, this standard does permit the use of stainless steel with a chromium content of less than 16 % for cutlery, blades and similar applications requiring a sharp edge.

Though, as a rule, stainless steels are selected to meet adequately the different requirements of corrosion resistance in the various foodstuffs, small amounts of the metallic elements in the stainless steel may migrate into foodstuffs from food preparation and cooking equipment leading to human ingestion. There is a need, therefore, to address the question whether such release can cause adverse health effects.

A wide range of stainless steels are highly resistant to corrosion in acetic acid (concentration range 1 – 20 %) at temperatures up to its boiling point (33). Similar corrosion resistance is seen in beer, citric acid (to 5 %), coffee, fruit juices, wines, lactic acid, milk and various detergents, while molybdenum-containing stainless steels are used in contact with foods or fluids which contain chloride ions. In Italy, stainless steels must meet certain migration criteria in a variety of media before they can be approved for food contact applications. The list of approved stainless steels includes the standard austenitic grades 1.4301 and 1.4404. In addition, some European standards specify the finish quality of the products and their ability to meet test criteria which minimise the likelihood of pitting or crevice corrosion occurring during the normal lifetime of the product.

The migration from stainless steel is generally assumed to be a time-dependent measure of metal transition. However, tests have shown that the migration of nickel from stainless steel decreases time-dependently to a minimum value, which is below 0.1 mg/m^2 (usually below 0.1 mg/kg foodstuff) for all the brand-new pots examined (34, 35).

Lactic acid is quite aggressive and requires corrosion-resistant materials like stainless steel.

Fruit and vegetables often have high acidity, which would be a challenge for metallic materials other than stainless steel.

Preparation of foodstuffs such as rhubarb, sauerkraut and red wine sauce in brand new stainless steel cooking pots may cause chemical changes in the stainless steel surface that modifies the protective layer and further reduces nickel migration (34, 35). The release of nickel ions from stainless steel pots is generally less than 0.1 mg/kg (36). The amount of nickel derived from the utensils in standard portions of various "aggressive" foodstuffs is 0-0.008 mg/kg.

The highest rates of chromium and nickel release from saucepans have been seen from new saucepans on first use (37). The nickel and chromium release was tested in rhubarb, apricots, lemon marmalade, tomato chutney and boiled potatoes. The release of nickel was approx. 0.2 mg/kg for apricots and rhubarb after the first cooking operation. After the first two cooking operations, the highest nickel release for apricots and rhubarb were reduced to approx. 0.07 mg/kg and 0.01 mg/kg, respectively. Correspondingly, the release of chromium was 0.05 mg/kg and 0.01 mg/kg, respectively.

There has been no formal evaluation of stainless steel products used in food contact applications in relation to their potential to give rise to concern for health so far. But numerous studies of corrosion in various media and of uptake of metals by foods cooked in stainless steel pans give no cause for concern for health with respect to excessive intakes of nickel or chromium. Furthermore, no significant difference in migration has been noted between these steels and glass (25, 38).

Studies of the migration of chromium and nickel from cooking utensils made of ferritic and austenitic stainless steel have shown that its contribution to an average daily diet is negligible compared with the natural contents of these elements in foodstuffs (25).

The selection of the appropriate grade of stainless steel for handling of specific foodstuffs is, in most cases, based on many years of practical experience. Where relevant experience is lacking, testing is required. Laboratory testing under simulated service conditions is only a first step, which has subsequently to be confirmed by testing under real service conditions.

The chloride content of drinking water is the reason why molybdenum-containing stainless steels are used for plumbing.

5.4 Stainless steels in contact with drinking water

As the requirements for drinking water are specified by the European Directive 98/83/EC (39), it will be treated separately in this section. Amongst the 48 chemical and microbiological parameters, set by the directive, drinking water is allowed to have chloride content up to 250 mg/l. However, European standard EN 12502-4 (40) indicates a high likelihood of pitting corrosion in molybdenum-free ferritic and austenitic stainless steels if the chloride content is above about 6 mmol/l (212 mg/l) in cold water and above about 1.5 mmol/l (53 mg/l) in heated water.

Stainless steel pipes intended to carry drinking water of various compositions in plumbing systems exposed to high chloride content are usually constructed with molybdenum-bearing stainless steels such as the austenitic grade 1.4401 or the ferritic grade 1.4521. This is in accordance with current German and Swiss approvals (41, 42) for plumbing systems that are based on many years of practical experience.

In using an appropriate grade of stainless steel for plumbing systems no intolerable migration of the alloying constituents from the stainless steel into the drinking water is to be expected. Using these kinds of stainless steels for plumbing systems is safe for human health.

5.5 Stainless steels for the preparation of pharmaceutical products

Pharmaceutical applications (7), in common with food and beverage, demand that the materials of construction are corrosion resistant and do not release significant quantities of contaminants into the product. Stainless steels are widely used in the pharmaceuticals industry where they are fulfilling these conditions: they are resistant to corrosion, inert and easily cleaned.

Although the austenitic stainless steel grade 1.4401 and its derivatives are the most widely used stainless steels in pharmaceutical plant and are considered by many as the industry standard, materials for each application are selected on the basis of their resistance to corrosion in a specific service environment. The selection of a suitable grade of stainless steel must also include consideration of the cleaning regime and cleaning agents used in the plant. Furthermore, the operation of the plant (whether continuous with a cleaning-in-place (CIP) system or batch operation with shutdowns to clean the plant) may also influence the choice of material.

In view of the remarks made above, it is difficult to provide a list of stainless steel grades used for specific applications. However, the following examples may serve to indicate the considerations made in selecting a suitable grade of stainless steel for pharmaceutical applications. The austenitic

In the pharmaceutical industry stainless steel is specified because its surface conditions ensure a maximum of corrosion resistance and cleanability.

stainless steel grade 1.4301 and its derivatives are used in mild environments where the chloride content is less than 200 mg/l, while grade 1.4401 and its derivatives may be used with chloride contents up to 500 mg/l. At higher chloride contents and especially if combined with increased operating temperatures, the duplex stainless steels grades 1.4462 and 1.4362 are used for their resistance to stress-corrosion-cracking. For more aggressive service environments, the superaustenitic grades as 1.4529 or superduplex grades as 1.4410 may be required.

Surface finish has a significant impact on the performance of pharmaceutical plant and equipment. For this reason, specifications for pharmaceutical plant and equipment usually have very specific surface finish requirements. In many cases, the surfaces are highly polished and/or electro-polished. Polished and electro-polished surfaces offer enhanced corrosion resistance and reduced micro-roughness.

Design, workmanship, installation and commissioning have a significant effect on the performance of both the plant and its materials of construction.

Many years of experience have proved that stainless steel is suitable material for the pharmaceutical industry.

5.6 Hygienic characteristics of the surface of stainless steel – cleaning and disinfection

The material most widely used for handling and processing of food is stainless steel. In their daily use, domestic sinks, pots and pans, dishes, cutlery and cooking utensils made from stainless steel are easily cleaned in using water assisted by detergents and, where necessary, further assisted by means of brushes. The same is true for any other stainless steel equipment in our daily life (e.g. handrails and door knobs) at home and anywhere else (e.g. in hospitals) where commercially available disinfectants might be used in addition.

Stainless steel is a preferred choice in domestic applications.

In commercial food processing, however, the duration of contact of stainless steel surfaces with the food may be much longer than in domestic uses. Furthermore, stainless steel parts may not be easily accessible or removed for cleaning in the food processing industry and, hence, a cleaning-in-place (CIP) is often a requirement. Therefore, there is a great number of publications that deal with cleaning and cleanability of stainless steel surfaces in the food processing industry. An appropriate surface topography is the key to optimum cleanability of stainless steel in the food industry as well as in other applications. Generally, the surface has to be smooth and free from imperfections such as pits, folds and crevices. EN 1672-2 (43) and EHEDG Guideline Document 8 (44) define smooth as a surface finish of 0.8 µm Ra or better, although cleanability is strongly dependent on the applied surface finishing technology as this affects the surface topography (44). Cold rolled stainless steel has a roughness of 0.2 to 0.5 µm Ra and, provided the product contact surfaces are free from pits, folds and crevices when in the final fabricated form, it does not usually need to be polished in order to meet smoothness requirements for cleanability. However, as well as the selection of the appropriate stainless steel grade and its surface quality in the final fabricated form, equipment for processing of food has to obey hygienic design criteria in order to be safe for human health (24, 44).

As long exposure of food contact surfaces may lead to adherence and growth of microbes, the removal of microbiological contamination by disinfection may have to be considered. Microorganisms generally adhere quickly to surfaces with which they come into contact and thereby derive a number of advantages from adhesion, e.g. more abundant supply of nutritive molecules and a protective barrier formed by the extra cellular polymer matrix that they produce.

Research on the growth of biofilms on stainless steel has confirmed results obtained with other materials with regard to the process by which the biofilms are formed and in particular, the role of the extra cellular matrix and resistance to disinfectants. It is important to mention that there are numerous factors governing the adhesion of microorganisms to solid surfaces and, hence, the cleanability of such surfaces. On solid surfaces, physical-chemistry and, as mentioned above, surface roughness and topography are two important factors. Furthermore, the surface characteristics of the microorganisms may differ according to species or strain concerned. The physiological status and type of culture of the microorganisms and the contact time also play an important role (45).

Stainless steel has a surface structure that makes it easy to clean.

It long has been known that stainless steel surfaces are easier to clean than other materials such as aluminium or polymers (46). In tests, a standard commercial dishwasher using detergents eliminated 97 % of microorganisms adhering to stainless steel surfaces, whereas 16 – 31 % of the microbiological soil had still been detected on polymers after the same cleaning protocol. In the same study, it has also been shown that the cleanability of stainless steel is not only better than that of certain polymers and aluminium, but is comparable to that of glass and porcelain.

The cleanability of stainless steel has also been compared to that of glass, aluminium and nickel- or copper-based alloys in other studies. While the cleanability of stainless steel, nickel- and copper-based alloys has been found to be similar, the efficiency of cleaners on stainless steel is three to four times greater than on polymers or aluminium (47, 48). More recent studies have confirmed these findings (49). Microbiological residues on stainless steel are only about 1/5 of those on aluminium and much less than on certain fluoropolymers, whereas equivalent numbers of residual microorganisms were found on stainless steel surfaces and on enameled steel surfaces.

Furthermore, it has been shown that the number of microorganisms remaining on abraded stainless steel after a simple cleaning process with standard spray treatment was only 1/10 the number remaining on mineral-resin polymers (50). Other studies (51) suggest that polycarbonate, mineral resins and enameled steel sink surfaces are more readily damaged by abrasion such that they would require a more stringent cleaning programme. Even with extended cleaning, however, they may still not achieve a degree of surface hygiene comparable to abrasion-resistant materials such as stainless steel.

In addition to cleaning, research has also been conducted into the effect of disinfectants on surfaces contaminated with adherent microorganisms. These studies sought to define the minimum concentration of disinfectant that would reduce the number of adherent microorganisms by several orders of magnitude. The efficacy of a disinfectant depends on the type of surface material used. It has been shown (52), for example, that to disinfect stainless steel surfaces, the concentrations of quaternary ammonium chloride, sodium hypochlorite or iodophor required less than 1/10 the concentrations required to disinfect plastic or aluminium surfaces.

The efficiency of four commercial sanitizing agents was evaluated (53, 54) in an effort to control the potential hazard of dairy product contamination due to contact with various processing surfaces. The results indicate that all sanitizers tested were more efficient against Listeria monocytogenes attached to nonporous surfaces than to porous surfaces. After 10 minutes of contact time, the limit concentration of disinfectants was at least 5 to 10 times higher for sanitizing rubber than stainless steel or glass surfaces.

In an evaluation of the effect of cleaners and sanitizers on Listeria monocytogenes attached to typical materials used in food processing plant, it was found that the resistance of Listeria monocytogenes is related to the surface where the organism is attached. Stainless steel was much more easily cleaned and sanitized than the conveyor belt materials polyester or polyester/polyurethane (55).

Due to the findings mentioned above, gasket materials that are made e. g. from rubber and are used in stainless steel food processing equipment deserve special attention when disinfection is a matter of concern (56).

With regard to water supply systems, the efficacy of chloramine on biofilms of Pseudomonas aeruginosa on three materials, stainless steel, copper and carbon steel had been tested (57). Disinfection of the biofilm was more efficient on stainless steel than on the two other materials, while in addition carbon steel exhibited corrosion.

The type of surface also affects the composition of the biofilm, the ratio of viable to total bacteria, and the quantity of exopolysaccharides synthesised. In all studies, the nature of the surface is shown to affect the concentration required to disinfect the surface. In comparison to other materials, stainless steel requires lower concentrations of disinfectant in order to achieve the level of hygiene required by law and this helps to protect the environment by limiting the release of effluent (58).

Disinfection procedures are particularly efficient on stainless steel.

The antibacterial effect of copper when intended for use as a hygienic surface in hospitals requires an appreciable amount of copper ions to be released into the immediate surrounding environment (59), with an appropriate reactivity of the copper surface as a prerequisite. This latter requirement may cause problems with cleaning. An investigation involving soiling with Staphylococcus aureus suspended in a protein-based organic soil and a soiling / cleaning by wiping procedure over several days revealed that all materials were easily cleaned after the first soiling episode. A build-up of cells and soil was observed on the copper surfaces after several cleaning / wiping cycles, whereas stainless steel remained highly cleanable (60).

In comparison with other materials, stainless steel surfaces have greater cleanability and require lower concentrations of disinfectant to achieve the level of hygiene required by law, and also help to protect the environment by limiting the release of effluent. The cleanability of stainless steel is comparable to glass and significantly better than that of polymers and other metals.

6 Summary

- Stainless steels are iron based alloys. A high resistance to corrosion is the principal characteristic of stainless steels, which is provided by chromium as the main alloying constituent. Enhanced corrosion resistance may be imparted by additional alloying constituents, primarily by nickel and molybdenum.
- Their high resistance to corrosion and their restricted release into the surrounding environment when in the passive state constitute a safe containment of the alloying constituents in stainless steel.
- Stainless steel does not contain hexavalent chromium, and hexavalent chromium is not generated with stainless steel in its normal use by end-users.
- With the exception of resulphurized, free-machining grades, stainless steels are safe for human health when used in direct and prolonged contact with the human skin as with earrings, necklaces, bracelets and chains, finger rings, wristwatch cases, watch straps, rivet buttons, and zippers.
- The use of stainless steels in surgical instruments, medical devices and surgical implants is safe for human health. It is based on many decades of practical experience and it is subject of international standards.
- The extremely wide usage of stainless steels as food contact materials reflects the fact that they resist corrosion by foods and beverages and additionally they are readily cleaned, thereby providing hygiene in food preparation and handling. No flavours or discoloration are imparted to foods and beverages in contact with stainless steels.
- Studies on the migration of chromium and nickel using cooking utensils made of ferritic and austenitic stainless steel have shown that the migration of nickel and chromium from stainless steel cooking utensils represents a negligible contribution to an average daily diet compared with the natural contents of these elements in foodstuffs.
- Stainless steels in contact with drinking water meet the chemical parameters and water quality characteristics specified by European Directive 98/83/EC (Drinking Water Directive). This means that stainless steel in contact with drinking water is safe for human health (i.e. there is no intolerable migration of the alloying constituents).
- With proper selection of the steel grades to be used and appropriate design and manufacturing of the equipment stainless steels are safe for human health in pharmaceutical applications.
- In comparison with other materials, stainless steel surfaces have greater cleanability and require lower concentrations of disinfectant to achieve a satisfactory level of hygiene. The cleanability of stainless steel is comparable to glass and significantly better than that of polymers and other usual metallic materials.

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Diamant Building · Bd. A. Reyers 80 · 1030 Brussels · Belgium · Phone +32 2 706 82-67 · Fax -69 · e-mail info@euro-inox.org · www.euro-inox.org