



NORTH AMERICAN STAINLESS



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RE: REACH Conformity

On June 1, 2007, major new legislation entered into force in the European Union ("EU"), dramatically overhauling the system for regulating chemicals, including chemicals in mixtures and articles, that are manufactured or imported into Europe. Known as "REACH" – the Registration, Evaluation, and Authorization of Chemicals – the legislation imposes substantial requirements on companies to register and provide health risk information on chemicals manufactured in Europe or imported in excess of one metric ton per year. In essence, the regulatory system requires chemical manufacturers and importers to prove the safety of a substance before being allowed to place it on the market. The list of restricted substances is update periodically. The most recent amended list (amended January 13, 2021) as published on the European Chemicals Agency (ECHA) website was reviewed.

NAS has studied the products and substances contained in and can confirm that our product does not contain substances of the following categories:

- Carcinogenic, mutagenic or toxic to reproduction, category 1
- Persistent, bioaccumulative and toxic
- Very persistent and very bioaccumulative
- Substances of Very High Concern (SVHC) included in the ECHA (European Chemicals Agency) Candidate List in a concentration above 0.1% by weight

Stainless steel is currently classified as an article. NAS's stainless steel does contain SVHCs below the 0.1% by weight threshold, and these SVHCs are not intended to be released. As such, stainless steel does not currently have to be registered.

Nickel is listed on Annex XVII. Attached are the restriction that applies for nickel, and the Safety Information Sheet as used in EU by our parent company.

Information about the safe use of products is available to our customers. The Safety Data Sheet is available on our website. NAS continues to review material safety data sheets (and Safety Information Sheets) for materials used at NAS as means of REACH conformity.

Sincerely,

A handwritten signature in blue ink, appearing to read "Maria Eichelberger", is written over a light blue circular stamp.

Maria Eichelberger
Environmental Manager
North American Stainless



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1.- INTRODUCTORY INFORMATION

Stainless steel products are considered as articles under the REACH Regulation (1907/2006/EC), a position adopted by all European stainless steel producers as presented in the EUROFER position paper determining the borderline between preparation/articles for steel and steel products (1).

In accordance with REACH and the CLP Regulation (1272/2008/EC), only substances and preparations require a Safety Data Sheet (SDS). While articles under REACH do not require a classic SDS, REACH Article 32 requires articles to be accompanied by sufficient information to permit safe use and disposal. In order to comply with this requirement, EUROFER members have developed of this Safety Information Sheet (SIS) that provides information on the safe use of the stainless steel and its potential impacts on both human health and environment.

2.- ARTICLE DATA

2.1.- Article name and description:

Acerinox stainless steel products in massive product forms: semi-finished products, plate, sheet, strip, bar, tube, fittings, wire rod and wire.

Stainless steel as defined in European Standard EN 10088-1:2014 cover corrosion resisting, heat resisting, and creep resisting steels

2.2.- Article supplier details:

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Telephone : +34 91 3985100
E-mail: exportacion@acerinox.com
Web: www.acerinox.com

2.3.- Article composition:

Stainless steels are iron alloys that contain more than 10.5% chromium and less than 1.2% carbon. Composition below is given in weight percentages.

Chromium: 10.5% to 30%
Nickel: Up to 38%
Molybdenum: Up to 11%
Carbon: less than 1.2%
Iron: Balance

Other elements such as Manganese (Mn), Nitrogen (N), Niobium (Nb), Titanium (Ti), Copper (Cu) and Silicon (Si) may be present. For more information on the chemical composition of standard stainless steels: see EN 10088-1:2014.

Due to the natural origin of the material also some elements that have not been intentionally added may be present as impurities (Co, As, Sb). The concentration of these elements in some cases could accumulate up to more than 0.1%.

2.4.- Article physical and chemical properties:

- . Physical state: solid
- . Colour: silver-grey
- . Odour: odourless
- . Density: 7.7 – 8.3 g/cm³
- . Melting point: 1,325 to 1,530 °C
- . Water solubility: Insoluble

Stainless steels are stable and non-reactive under normal ambient atmospheric conditions, because in solid form all alloying elements are firmly bonded in the metallic matrix. Solid stainless steel does not contain Chromium VI compounds. Only when molten or during welding operations (i.e. heated to very high temperatures), fumes may be produced.

In contact with strong acids, stainless steels may release gaseous acid decomposition products (e.g. hydrogen and oxides of nitrogen) and chromium may be released in the form of Chromium III.



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In contact with strong oxidizers at high pH (e.g. alkaline cleaners at pH 10-14), very small amounts of Chromium VI compounds may form at ambient temperatures.

None of these substances are intended to be released under normal or reasonably foreseeable conditions of use. Exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal is negligible.

3.- GENERAL INFORMATION ON THE SAFE USE OF STAINLESS STEEL PRODUCTS

All stainless steels contain a minimum of 10.5% chromium, which ensures the formation of a protective, adherent nanometric, oxide film covering the entire surface. Thus, the alloying elements in stainless steel are firmly bonded in its chemical matrix. Increasing the chromium content beyond the minimum of 10.5% confers still greater corrosion resistance. Corrosion resistance may be further improved, and a wide range of properties provided, by the addition of other chemical elements (e.g. nickel and molybdenum). Corrosion from stainless steel in aggressive media can be avoided by use of the proper grade in accordance with relevant European or international standards.

Stainless Steels are alloys. The alloying elements in stainless steel are firmly bonded in its chemical matrix. Due to this bonding and to the presence of a protective oxide film the release of any of the constituents is very low and negligible when the steel is used appropriately.

Stainless steels are generally considered non-hazardous to human health or the environment (see paragraph 3.2) and regularly applied where safety and hygiene is of utmost importance (e.g. equipment in contact with drinking water, food contact materials, medical devices, etc.).

This SIS presents relevant information for downstream users in order to secure a proper use of the stainless steel articles supplied.

4.- SAFETY INFORMATION

4.1.- Description of Hazards

4.1.1.-Classification and Bio-elution

All intentionally added alloying elements in Stainless Steel with the exception of nickel are not classified as hazardous. Nickel is the only substance of major importance with regard to the hazard classification of stainless steels in the solid form. In accordance with (EC) Regulations 1272/2008 (CLP) and 790/2009 (ATP 1), nickel is classified as a Carcinogen Category 2, Specific Target Organ Toxicity Repeated Exposure 1 (STOT RE1) and Skin Sensitizer 1.

The exposure route for the nickel carcinogenic Category 2 classification is inhalation. However Stainless Steel in solid form cannot be inhaled, only when it is in powder form. The risk of being exposed to nickel in stainless steel can therefore also only exist when the stainless steel is in powder form. Nevertheless the European Classification is based on Hazard rather than on Risk. Therefore it is the obligation of the steel industry to provide proof that stainless steel is safe.

Even when steel is in powder form the likelihood of being exposed to nickel is far less than the pure metal thanks to the alloying effect. In other words when nickel is in the form of stainless it doesn't necessarily become available to the organism which is inhaling the stainless powder. It is not bio-available.



This bio-availability can only be proven by doing *in vivo* testing using test animals. There are two tests described in literature for *In Vivo* testing of stainless powder (2, 3, 4).

As industry is encouraged to find alternative ways to animal testing the non-ferrous metals industry in Europe is developing a testing methodology based on Bio-elution. This methodology is an *in vitro* methodology thus preventing the necessity of *in vivo* testing. In Bio-elution body fluids like saliva, gastric, lung and intestinal fluids are mimicked and the specific release of constituents is tested. In these tests the bio-accessibility is being established.

The European Steel Industry together with the European Non-ferrous industry strongly believe that bio-accessibility *in vitro* tests will become a good and sustainable alternative to animal testing and we believe that bio-accessibility data are a good predictor of bioavailability and toxicity for use in hazard assessment.

4.1.2.-Sensitization

According to REACH (5), alloys that contain Ni and that could come in frequent contact with skin, may be tested according to European standard EN1811 to determine the release rate of Ni. Tests conducted in accordance with this standard determined that stainless steels release nickel at levels significantly below the criteria set for classification as a skin sensitizer. Thus, stainless steels in general are suitable for use as piercing posts (where the maximum nickel release limits is 0.2 µg/cm²/week) and for those applications involving close and prolonged contact with the skin (where the maximum nickel release limits is 0.5 µg/cm²/week).

However, tests conducted in accordance with EN 1811 (6) have shown that the resulphurised free-machining stainless steels (containing 0.15 – 0.30 % sulphur) release nickel at levels close to, or above, the maximum nickel release limit 0.5 µg/cm²/week. Resulphurised free-machining stainless steels are, therefore, not suitable for use as piercing posts or for applications involving prolonged contact with the skin (i.e. jewellery, watch backs and watch straps, etc.).

Clinical studies did not reveal any risk of allergy among individual already sensitised to nickel. Thus, frequent intermittent contact with stainless steels of all types should not pose a problem to downstream users or consumers (7).

4.1.3.-Specific Target Organ Toxicity

In accordance with the CLP Regulation, stainless steels are considered to be mixtures (8, 9). This means that stainless steels containing more than 10% nickel should be classified as Specific Target Organ Toxicity Repeated Exposure 1 (STOT RE1) and stainless steels containing 1 - 10% nickel should be classified as STOT RE 2. Stainless steels containing less than 1% nickel are not classified.

However, a 28-day repeated inhalation study on rats with stainless steel in the powder form (2) clearly indicates a lack of toxicity (i.e. no adverse effects were seen, even at the highest concentration of stainless steel, which was 1.0 mg/L in the study), whereas the lowest nickel dose (0.004 mg/L) resulted in clear signs of toxicity in a 28-day nickel inhalation study (3, 4). No classification of stainless steel for STOT is proposed.

4.1.4.- Carcinogenicity

In accordance with the CLP Regulation, stainless steels are considered to be mixtures. This means that stainless steels containing more than 1% nickel should be classified as Carcinogen Category 2 when it is classified as a simple mixture. However, no carcinogenic effects resulting from exposure to stainless steels have been reported, either in epidemiological studies or in tests with animals (7). Therefore, it can be concluded that the weight of evidence supports the non-carcinogenicity of stainless steel.

In addition, IARC (International Agency for Research on Cancer) has concluded that stainless steel implants are not classifiable as to their carcinogenicity to humans (10). Several stainless steel grades are specifically designed for use in human implant parts (see ISO 5832). Stainless steels containing less than 1% Ni are not classified.



4.1.5.-Summary classification

According to CLP an alloy can be classified either on its constituents classification (simple mixture) or on the hazard properties the mixture if they have been tested. Based on studies on the stainless steel alloy (7) the steel industry proposes the following classification for stainless steel:

No classification for most stainless steel grades.

For re-sulphurised grades (0.15 – 0.30 % sulphur)
Skin Sensitizer .

For a comparison between classification according to constituent and classification based on alloy testing, see Annex 1.

4.2.- Specific process and exposure controls

Dust and fume may be generated during processing e.g. in welding, cutting and grinding. If airborne concentrations of dust and fume are excessive, inhalation over long periods may affect workers' health, primarily of the lungs. Dust and fume quantity and composition depend on specific practice. Oxidized forms of the various alloying elements of stainless steel may be found in welding fumes.

Over long periods, inhalation of excessive airborne levels may have long term health effects, primarily affecting the lungs. Studies of workers exposed to nickel powder, and dust and fumes generated in the production of nickel alloys and stainless steels have not indicated a respiratory cancer hazard (7).

Chromium in stainless steel is in the metallic state (zero valence) and stainless steel does not contain hexavalent chromium. Welding and flame cutting fumes may contain hexavalent chromium compounds. Studies have shown that some hexavalent chromium compounds can cause cancer. However, epidemiological studies amongst welders indicate no extra increased risk of cancer when welding stainless steels, compared with the slightly increased risk when welding steels that do not contain chromium. IARC has defined the welding process and welding fumes as a risk, irrespectively of which metals that are involved (11).

The process of welding should only be performed by trained workers with the personal protective equipment in accordance with the laws of each Member State relating to safety. Guidance on the welding of metals and alloys is provided on the European Welding Association website (12). The guidance document will provide background information on health hazards posed by welding processes and appropriate Risk Management Measures.

There are no specific occupational exposure limits for stainless steel. However, specific occupational exposure limits have been established for some constituent elements and compounds. Users of this Safety Information Sheet are strongly advised to refer to the Occupational Exposure Limits set by their EU Member State for the substances in stainless steel and where relevant, welding fumes.

4.3.- First Aid Measures

There are no specific First Aid Measures developed for the stainless steel. Medical attention should be provided in case of an excessive inhalation of dust or a physical injury to the skin or to the eyes.

In case of eye injury note that austenitic stainless steel particles are non-magnetic or only slightly magnetic and may not respond to a magnet placed over the eye. In such cases seek hospital treatment.

4.4.- Handling and Storage

There are no special measures for handling stainless steels. Normal precautions should be taken to avoid physical injuries produced mainly by sharp edges. Personal protective equipment must be used e.g. special gloves and eye protection.

Stainless steels should be stored in manner that prevents iron contamination. Avoid placing or storing stainless steel in uncoated iron or steel racks and protect from iron emissions from cutting/grinding operations.



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Care should be taken to avoid exposing fine process dust (e.g. from grinding and blasting operations) to high temperatures as it may present a potential fire hazard.

4.5.- Uses

Stainless steels are present in a wide variety of activities. Main use areas include industrial processes, architectural and building, house appliances and kitchenware, catering and transportation.

4.5.1.-Food Contact

Stainless steel has been in use for contact with food for many years and is present in various articles (kitchenware, bowls, and industrial kitchen appliances). Depending on the application (knives, blades, forks, spoons, bowls), different grades are selected and have been recognized as safe. The Council of Europe has published new technical test guideline to ensure the suitability and safety of finished articles of metals and alloys in food contact (13). The release of specific constituents has to be below certain specific release limits (SRL). Some national laws also give detailed information on the choice of grades that should be allowed for food contact.

4.5.2.- Medical devices and implants

In many cases stainless steel is the only material which can be used for medical devices and/or implants. Presently the Directive 90/385/EEC on Active Implantable Medical Devices and Directive 93/42/EEC on Medical Devices are being revised.

4.5.3.-Drinking water

The four Member States Common Approach (agreed between Germany, France, the Netherlands and the United Kingdom) describes a procedure by which a material is approved. The list of "Metallic materials suitable for drinking water under hygienic aspects" includes those metallic materials, for which the hygienic suitability for drinking water has been demonstrated. This includes stainless steel.

4.5.4.-Toys

Safe use of stainless steel in toys is recognized in European Directive 2009/48/EC.

5.- ENVIRONMENTAL INFORMATION

There are no hazards to the environment from stainless steel in the forms supplied.

Stainless steel is part of an integrated life cycle and it is a material that is 100% recyclable. Thus, surplus and scrap (waste) stainless steel is valuable and in demand for the production of prime new stainless steel. Recycling routes are well-established, and recycling is therefore the preferred disposal route. While disposal to landfill is not harmful to the environment, it is a waste of resources and therefore to be avoided for the benefit of recycling.



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6.- REFERENCES

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9. Regulation (EC) No 790/2009 1st Adaptation to Technical Progress (ATP) to the CLP Regulation
10. IARC (1999). Surgical implants and other foreign bodies. Geneva, World Health Organization, IARC.
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13. Metals and Alloys used in food contact materials and articles, EDQM, CoE, 2013, 1st Edition, ISBN 978-92-871-7703-2, Specific chapter on Stainless Steels pp165, www.edqm.eu.

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ANNEX 1

Table 1 gives classification proposal based on testing performed on stainless steel, and Table 2 gives the classification according to constituents (in this case nickel).

Table 1- Classification proposal based on testing performed on stainless steel.

	Skin Sensitizing	Specific Target Organ Toxicity STOT	Carcinogenicity
Stainless steel	No Classification For re-sulphurised grades only: Skin Sensitizer 1 H317	No Classification	No Classification*

* As this proposal is based on weight of evidence on alloy testing it is not the CMR classification according to mixture rules in CLP. According to CLP, the carcinogenicity classification outlined in Table 2 should apply.

Table 2- Classification based on constituents.

	Skin Sensitizing	Specific Target Organ Toxicity STOT	Carcinogenicity
Stainless steel <1% Ni	No Classification	No Classification	No Classification
Stainless steel 1 – 10 % Ni	Skin Sensitizer 1 H317	STOT RE2 H373 (Inhalation)	Carcinogen Category 2 H351 (Inhalation)
Stainless Steel >10% Ni	Skin Sensitizer 1 H317	STOT RE1 H372 (Inhalation)	Carcinogen Category 2 H351 (Inhalation)