SAFETY INFORMATION SHEET FOR STAINLESS STEEL

1 INTRODUCTORY INFORMATION

Stainless steel products are considered as articles under the European Regulation (EC) 1907/2006, concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), a position adopted by all European stainless steel producers as presented in the EUROFER (European Confederation of Iron and Steel Industries) position paper determining the borderline between preparation and articles for steel and steel products (1).

In accordance with REACH and the European Regulation (EC) 1272/2008 on Classification, Labelling, and Packaging of substances and mixtures (CLP), only substances and preparations require a Safety Data Sheet (SDS). While articles under REACH do not require a formal SDS, REACH Article 32 requires articles to be accompanied by sufficient information to permit safe use and disposal (2). In order to comply with this requirement, EUROFER members have developed a 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

Stainless steel products in massive product forms, non-coated or coated. Hot and cold rolled steel products like plate, sheet, strip, bar, rebar, wire rod, and wire

Stainless steel as defined in European Standards EN10088-1:2014 covering the composition of stainless steels, EN10095:1999 heat resisting steels and alloys, and EN10302:2008 creep resisting steels and alloys.

2.2. Article supplier

Outokumpu

For regional contacts see our web page: www.outokumpu.com

E-mail: stainless.info@outokumpu.com

2.3. Article composition

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

- Chromium 10.5% to 30%
- Nickel max. 38%
- Molybdenum max. 11%
- Carbon max. 1.2% (most frequently below 0.5%)
- Iron balance (> 50%)

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 unintentionally added elements such as cobalt (Co), arsenic (As) or antimony (Sb) may be present as impurities. The concentration of these elements in some case 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 Cr (VI) compounds. When heated to very high temperatures (melting or during welding operations), 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.

In contact with strong oxidizers at high pH (e.g. alkaline cleaners at pH 10-14), very small amounts of Cr (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

Stainless steel is the term used to describe a versatile family of engineering materials, which are selected primarily for their corrosion and heat resistant properties. Corrosion resisting stainless steels contain a minimum of 10.5% chromium, which ensures the formation of a protective, adherent nanometric, oxide film covering the entire surface (The passive layer). When damaged (eg abraded), the passive layer self-repairs as chromium in the steel reacts rapidly with oxygen and moisture in the environment to reform the oxide layer.

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 alloying elements like 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 4.1) 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. In accordance with (EC) Regulations 1272/2008 (CLP) and 790/2009 (ATP 1), nickel is classified as a Carcinogen Category 2 (inhalation route), Specific Target Organ Toxicity Repeated Exposure 1 (STOT RE1) and Skin Sensitizer 1. (3,4)

Normally no cobalt is intentionally added. Due to the fact however that cobalt is present in raw materials stainless steel inevitably contains at least trace amounts of cobalt. Depending on the grade this can amount up to 0.6%. This has been the case for the past decades without any associated health risk.

Cobalt has a harmonised classification as Carcinogen Category 1B, Mutagenic Category 2, Skin Sensitizer 1, Respiratory Sensitizer 1, Reprotoixic 1B and Aquatic Chronic 4. (18)

The likelihood of being exposed to cobalt or nickel is far less compared to the pure metal thanks to the alloying effect in stainless steel. In other words when cobalt or nickel is embedded in stainless steel it doesn’t necessarily become available to the organisms contacting it. This bio-availability can be proven by doing in-vivo testing using test animals. There are tests described in literature for in-vivo testing of stainless powder (5,6). Lately, bio-elution has been proposed as an alternative to in-vivo testing, to avoid unnecessary animal testing. In Bio-elution body fluids like saliva, gastric, lung and intestinal fluids are mimicked and the specific release of constituents (forn example cobalt and nickel) is tested. In these tests the bio-accessibility is being established. Bio-accessibility is considered to overestimate the bio-availability of the constituents and therefore should be considered to be a safe indicator. Bio-accessibility data are a good enough predictor of bioavailability and toxicity (8,9).

4.1.2 Sensitization

According to REACH (2), for all alloys that contain Ni and that could come in frequent contact with skin, the determination of the release rate of Ni, should be tested according to European standard EN1811 (10). 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/cm^2/week) and for applications involving close and prolonged contact with the skin (where the maximum nickel release limits is 0.5 µg/cm^2/week).

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 (12).

However, tests conducted in accordance with EN 1811 have shown that the re-sulphurised free-machining stainless steels (containing 0.15 – 0.30 % sulphur) release nickel at levels close to, or above, the maximum nickel release limits of 0.5 µg/cm2/week) (11). Re-sulphurised free-machining stainless steels are, therefore, not suitable for use as piercing posts or for applications involving prolonged and close with the skin (i.e. jewellery, watch backs and watch straps, etc).

The impurity levels of cobalt in stainless steel are below the generic concentration limit for Skin Sens 1. As further support, the 10 000-fold lower release of cobalt from stainless steels in artificial sweat in comparison with that from cobalt metal makes cobalt-related skin sensitization to stainless steel very unlikely.

The concentration of cobalt in stainless steels may exceed the generic concentration limit for Resp. Sens. 1 (≥0.1 wt.%), but the observed more than 100 000-fold lower release of cobalt from stainless steels in artificial lysosomal fluid in comparison with cobalt metal (relative bioaccessible concentration ≤0.001%) does not support classifying stainless steels for Resp. Sens. 1. (19)

4.1.3 Specific Target Organ Toxicity

If simple mixture rules in accordance with the CLP Regulation were applied, stainless steel 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% Ni would not be classified.

However, a 28-day repeated inhalation study on rats (5) with stainless steel in the powder form 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 (6,7). No classification of stainless steel for STOT is proposed.

4.1.4 Carcinogenicity

Applying the CLP simple mixture rule on stainless steel containing more than 1% of nickel or 0.1% cobalt would result in a classification as Carcinogen Category 2 or Category 1. However, no carcinogenic effects resulting from exposure to stainless steels have been reported, either in epidemiological studies or in tests with animals (5,12). 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 (13). Several stainless steel grades are specifically designed for use in human implant parts (see ISO5832).

4.1.5 Aquatic toxicity

The bulk concentration of cobalt in stainless steels is below the general concentration limit for constituents to be taken into consideration in the acute toxicity classification of mixtures. In combination with the relatively much lower release of cobalt from stainless steel, cobalt-related acute toxicity of stainless steels is not expected. Also the lack of adverse effects in the 28-day inhalation toxicity study showed together with long experience from the use of stainless steels do not support classification for acute oral or dermal toxicity.(5)

4.1.6 Germ cell mutagenicity

Of the constituents/impurities of stainless steel, cobalt has a harmonized CLP classification for Muta. 2. However, the concentration of cobalt in stainless steel, below the generic concentration limit of 1.0 wt.% for this hazard category, and the demonstrated more than 10 000-fold lower release of cobalt in physiological fluids than from cobalt metal, do not support classifying stainless steel as a germ cell mutagen.

4.1.7 Reproductive toxicity

Although the bulk concentration of cobalt in stainless steels may exceed the generic concentration limit of ≥0.3 wt.% for Repr. 1B, the observed more than 10 000-fold lower release of cobalt from stainless steels in physiological fluids relevant for oral, dermal or inhalation exposure than that from cobalt metal (relative bioaccessible concentration <0.01%) does not support classifying stainless steel as a reproductive toxicant.

In further support of the non-classification of stainless steels for reproductive toxicity, the 28-day inhalation study of stainless steel showed no significant effects on the weight or histopathology of reproductive organs (19)

4.1.8 Summary classification

According to CLP, articles such as the products described in this Safety Information Sheet, do not need to be classified as such. In addition available studies indicate that no classification would be needed for the alloy stainless steel (9,10, 19). However, as a precausion we advice not to use the re-sulphurised grades (0.15 – 0.30 % sulphur) in close and prolongued contact with the skin.

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 (containing cobalt levels up to 0.6% have not indicated a respiratory cancer hazard (12).

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, irrespective of which metals are involved (14).

The process of welding should only be performed by trained workers with the personal protective equipment in accordance with the state laws relating to safety. Guidance on the welding of metals and alloys is provided on the European Welding Association website (15). 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 national occupational exposure limits 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.

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 applications. 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, 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 (CoE) has published technical test to ensure the suitability and safety of finished articles of metals and alloys in food contact (16). 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

In many cases stainless steel is the only material which can be used for medical devices and/or implants. As is indicated in literature (12,13) the use of stainless in implants and in medical devices is safe.

4.5.3 Drinking Water

The “4MS Common Approach: Acceptance of metallic materials used for products in contacts with drinking water - Part A” which has been agreed between Germany, France, the Netherlands and the United Kingdom describes a procedure by which material is tested. 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 (17).

4.5.4 Toys

Safe stainless steel use 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. Both manufacturing and post-consumer stainless steel scrap 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.

6 REFERENCES

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