SHE-SPE-LETTER01
Revision 0
Date of Issue: 29/08/2025

STAINLESS STEEL SAFETY INFORMATION SHEET

1. INTRODUCTORY INFORMATION

Stainless steel products are considered as articles under the REACH Regulation (1907/2006/EC), concerning the Registration, Evaluation, Authorization and Restriction of Chemicals, REACH (1), 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/articles for steel and steel products (http://www.eurofer.org/Issues%26Positions/REACH/REACH).

In accordance with REACH and the CLP Regulation (1272/2008/EC) (2), 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:

Columbus Stainless Steel products in massive product forms: semi-finished products, plate, sheet, coil & slab.

Stainless steel as defined in European Standard EN 10088:1 covering the composition of stainless steels and EN 10095 heat resisting steels and nickel alloys.

2.2. Article supplier details:

COLUMBUS STAINLESS (PTY) LTD
Hendrina Road,
Middelburg,
South Africa
Telephone: +27 (0)13 247 9111
Web: https://www.columbus.co.za

2.3. Article composition:

According to the definition of European EN 10020 standard, 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), Vinadium (V), 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.

Due to the natural origin of the material also some elements that have not been intentionally added may be present as impurities such as Cobalt (Co), Arsenic (As), Antimony (Sb). The concentration of these elements in some cases could accumulate up to 0.6%.

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.

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

STAINLESS STEEL SAFETY INFORMATION SHEET

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.

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. This oxide film (known as passive or boundary layer) is very thin (2-3 nanometres). [1 nanometre = 10-9 m]. 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 2.4) 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) (3), nickel is classified as a Carcinogen Category 2, Specific Target Organ Toxicity Repeated Exposure 1 (STOT RE1) and Skin Sensitizer 1.

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 (particularly when being produced out of scrap). 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.

In vivo studies (4) conducted with pure cobalt metal powder revealed a carcinogenic hazard in cobalt metal powder when inhaled by test animals. Based on these studies the Dutch authorities have prepared a proposal for the classification of cobalt metal as part of the 14th Adaptation to Progress (14th ATP) of the CLP regulation. This 14th ATP as adopted and published in the EU’s Official Journal on 18 February 2020. The 14th ATP applies from 1 October 2021.

This new CLP classification for cobalt metal includes:

- Carcinogenic category 1B (H350)
- Reprotoxic category 1B (H360F)
- Mutagenic category 2 (H341)

This classification is for all routes of exposure (dermal, oral and inhalation).

This classification is based on the T25 methodology. An international T25 Expert Group has been established to look into the suitability of the carcinogenic potency calculations for inorganics and inhalation carcinogens. During the deliberations of this Expert Group a Generic Concentration Level (GCL) of 0.1% is being used. In case the Expert Group considers the T25 methodology suitable the GCL may be turned into a Specific Concentration Limit (SCL) of 0.01%

It is established that 80% of all commercial stainless grades have cobalt content above this GCL of 0.1%. It is estimated that 99% of all commercial grades have content above the SCL of 0.01%.

Following the revision of the harmonised classification of the substance in Table 3 of Annex VI to CPL Regulation, all manufacturers, importers and users of the substance in the EU must classify the substance accordingly, enabling the ultimate users to be better informed about the substance, its potential effects and how best to make use of it safely. This however does not apply to articles and as was indicated in the introductory information in chapter 1, stainless steel products are considered articles (5).

Like it is the case for nickel; when the exposure route for the classification would be limited to inhalation it would not affect massive stainless steel as stainless steel in solid form cannot be inhaled. The cobalt classification proposal however is for all routes of exposure.

Because the individual metals such as cobalt and nickel are embedded in stainless steel, the metal ions are not readily released or bioavailable as would be the case with a simple mixture of the alloying elements. Hence, a refinement of the classification for alloys has been proposed which is based on the bio-availability of the ions. This bio-availability can only be proven by doing in vivo testing using test animals. There are tests described in literature for in Vivo testing of stainless powder (6, 7 & 8).

Another way to assess the toxicity of alloys is to test alloys themselves. As industry is encouraged to find alternative ways to testing the non-ferrous metals industry in Europe is developing a testing methodology based on Bio-elution (9). This methodology is an in vitro methodology thus preventing the necessity of in vivo testing. In Bio-elution body fluids like sweat, saliva, gastric and lung fluids are mimicked and the specific release of constituents (cobalt- and nickel ions) is tested. In these tests the bio-accessibility from the alloy relative to that from the pure metal is being established. In the bio-elution the relative Bio-accessible concentration (BC) is measured. This BC can be directly compared to the GCL of 0.1% (11).

In 2016/2017 KTH in Stockholm have tested 5 different stainless grades for bio-elution both in massive from and in powder (10). The results in gastric fluid being the most aggressive bio-elution fluid showed that the relative BC of cobalt in all cases was significantly below 0.1%. This clearly demonstrates the effective alloying effect in stainless preventing the release of constituents.

On top of that, no carcinogenic effects resulting from exposure to stainless steels have been reported, either in epidemiological studies or in tests with animals (6, 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 classified as to their carcinogenicity to humans (13). Several stainless steel grades and high cobalt containing super-alloys are specifically designed for use in human implant parts (see ISO 5832).

According to CLP an alloy can be classified either on its constituent's classification (mixture) or on the hazard properties of the mixture if they have been tested. Based on studies on the stainless steel alloy (12) and bio-elution testing on cobalt (11), the steel industry proposes the following interpretation of the classification for stainless steel:

Classification of Co and Ni in Stainless Steel

Co in stainless steel	Carcinogenicity	Mutagenicity	Repro-toxicity
Co BC < 0.1%<0.3%	No Classification	No Classification	No Classification
Co BC > 0.1% < 0.3%	Carcinogenic category 1B (H351) for inhalation only	No Classification	No Classification
Co BC > 0.3%	Carcinogenic category 1B (H351) for inhalation only	No Classification	Reprotoxic category 2 (H361F)
Ni in stainless steel	Skin Sensitizing (based on EN1911)	Specific Target Organ Toxicity STOT (based on SS specific data)	Carcinogenicity
Ni BC < 1%	No Classification	No Classification	No Classification
Ni BC > 1%	No Classification	No Classification	Carcinogenicity Category 2 H351 for inhalation*).
Ni in resulphurised grades	Skin Sensitizer 1 H317	No Classification	

4.1.2.Sensitization

According to REACH (1), alloys that contain Ni and that could come in frequent contact with skin, may be tested according to European standard EN1811 (14) 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 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 of for the applications involving prolonged and close contact with the skin (i.e. jewelry, watch backs and watch straps, etc.).

Clinic studies did not reveal any risk of allergy among individuals already sensitized to nickel. Thus, frequent intermittent contact with stainless steels of all types should not pose a problem to downstream users or consumers (12)

4.1.3. Specific Target Organ Toxicity

In accordance with the CLP Regulation, stainless steels are considered to be mixtures (2). 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 (6) 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 (7 & 8). 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 classified as to their carcinogenicity to humans (13). 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.

4.2. 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 (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, irrespectively of which metals that are involved.

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: www.european-welding.org. 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 the OHS Act and HCS Regulations 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.

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 (CoE) has published new technical test guideline to ensure the suitability and safety of finished articles of metals and alloys in food contact (15). The release of specific constituents has to be below certain specific release limits (SRL). South Africa aligns its food safety regulations with international standards, using SANS guidelines based on the Codex Alimentarius and enforcing hygiene and material requirements for food contact surfaces under the Foodstuffs, Cosmetics and Disinfectants Act (FDCA)Act 54 of 1972 (17 & 18).

The Swedish laboratory KTH has tested certain stainless steels according to the guidelines and used citric acid as food stimulant (16). The use of citric acid in the new test guideline is relevant as it is commonly present in both acidic and alkaline food. Those studies show that:

- None of the constituent alloying elements in stainless steel are released in amounts exceeding their corresponding release limits (SRLs), stipulated in the CoE protocol.
- Metal release rates decrease with time due to a gradually improved passivation of the stainless steel surface.
- Amounts of released metals diminish upon repeated use.

4.5.2. Medical devices and implants

Stainless steel is widely used in surgical instruments and implants in South Africa. Its use is regulated under the Medicines and Related Substances Act through SAHPRA, supported by the 2016 Medical Devices Regulations, which cover classification, labeling, and performance. Compliance with ISO 13485 is also required, ensuring safety and quality in stainless steel medical components. (19, 20 & 21).

As indicated in literature (13) the use of stainless in implants and in medical devices is absolutely safe.

4.5.3. Drinking water

SANS 241 – Drinking Water Quality outlines permissible limits for metals such as chromium, nickel, and iron, which are key elements in stainless steel (22). As such, stainless steel is deemed safe for use in water supply systems—including pipes, tanks, and fittings—and is recognized as an approved material under SANS 10252-1 – Water Supply Installations for Buildings (23). The National Water Act (Act 36) regulates water quality and infrastructure, including the materials used in distribution networks (24).

4.5.4. Toys

Stainless steel is permitted in toy components such as fasteners and structural parts. Its use is regulated by safety standards like R1090, which limits metal bioavailability (e.g., chromium, nickel, lead) (25), and the SANS 50071 series, which covers mechanical safety, flammability, and elemental migration.

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.

6. REFERENCES

1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging (CLP) of substances and mixtures
3. Regulation (EC) No 790/2009 1st Adaptation to Technical Progress (ATP) to the CLP Regulation
4. NTP Technical Report on the Toxicology Studies of Cobalt Metal (CAS NO. 7440-48-4) (Inhalation) National Toxicology Program (NTP) TR 581, December 2014, National Institutes of Health, Public Health Service, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
5. EUROFER position paper 1 determining the borderline between preparations/articles for steel and steel products
6. Inhalation carcinogenic study with nickel metal powder in Wistar rats. A.R. Olier et al., Toxicology and Applied Pharmacology 233 (2008) 262-275
7. SafePharm Laboratories (2008). Stainless steel powder (Grade 316L): Twenty-eight day Repeated dose exposure inhalation (nose only) toxicity study in the rat, SafePharm Laboratories: 1 - 249.
8. WIL Research Laboratories, I. (2002). A 4-week range-finding inhalation toxicity study of nickel metal in albino rats, WIL Research Laboratories, Inc.: 1-319.
9. Stockmann-Juvala, H., Hedberg, Y., Dhinsa, N.K., Griffiths, D.R., Brooks, P.N., Zitting, A., Wallinder, I.O., Santonen, T., 2013. Inhalation toxicity of 316L stainless steel powder in relation to bioaccessibility. Hum. Exp. Toxicol. 32 (11), 1137–1154.
10. Henderson RG, Verougstraete V, Anderson K, Arbildua JJ, Thomas O Brock, Brouwers T, Cappellini D, Delbeke K, Herting G, Hixon G, Odnevall Wallinder I, Rodriquez PH, Van Assche F, Wilrich P, Oller AR, 2014. Inter-laboratory Validation of Bioaccessibility Testing for Metals. Regul Toxicol and Pharmacol. 70(1): 170-181.
11. Wang, X., Wallinder, I.O., Hedberg, Y., Nickel and cobalt release testing from several stainless steel grades in several synthetic body fluids (bio elution testing) August, 2018 KTH Royal Institute of Technology, Division of Surface and Corrosion Science, Sweden.
12. Review on toxicity of stainless steel, Finnish Institute of Occupational Health (FIOH), 2010 http://www.ttl.fi/en/publications/Electronic_publications/Pages/default.aspx
13. IARC (1999). Surgical implants and other foreign bodies. Geneva, World Health Organization, IARC
14. EN 1811:2011+A1:2015 Standard: Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin (test for measuring Ni release in artificial sweat)
15. 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
16. Surface changes and metal release in the presence of citric acid for food applications Stainless steel grades 201, 304, 204, 2101, 316L, 430, and EN1.4003, December, 2014 KTH Royal Institute of Technology, Division of Surface and Corrosion Science, Sweden
17. Codex Alimentarius International Food Standards (www.fao.org › fao-who-codexalimentarius › sh-proxy)
18. Republic of South Africa Department of Health. Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (https://www.health.gov.za/food-control-acts/)
19. South African Health Product Regulatory Authority (SAPHRA) Medicines and Related Substances Act, 1965 (Act No 101 of 1965) As Amended (https://www.sahpra.org.za/document/medicines-and-related-substances-act-1965-act-no-101-of-1965-as-amended/)
20. South African Health Product Regulatory Authority (SAPHRA) Regulations relating to Medical Devices and IVDs, published in the Government Gazette No. 40480, on 09 December 2016 (https://www.sahpra.org.za/document/regulations-relating-to-medical-devices-and-in-vitro-diagnostic-medical-devices-ivds/)
21. International Standards ISO13485:2016 Medical Devices – Quality management system – Requirements for regulatory purposes.
22. SANS 241 – Drinking water quality
23. SANS 10252-1 – Water Supply Installations for Buildings. The National Water Act (Act 36 of 1998)
24. National Water Act 36 of 1998 (https://www.gov.za/documents/national-water-act)
25. Republic of South Africa Department of Health. Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972. Regulations Relating to Objects Packed in Foodstuffs Intended for Children (https://www.gov.za/documents/notices/foodstuffs-cosmetics-and-disinfectants-act-regulations-objects-packed-foodstuffs)

STAINLESS STEEL SAFETY INFORMATION SHEET

Suggestions for or descriptions of the end use or application of products or methods of working are for information only and Columbus and its affiliated companies accept no liability in respect thereof. Customers are responsible for ensuring the suitability of any products supplied or manufactured by the company before use.