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Research Article

STAINLESS STEEL IN COSMETIC PACKAGING: HOW TO ENSURE ITS SAFETY AND COMPLIANCE WITH EUROPEAN LEGISLATION ?

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ABSTRACT

Stainless steel is an important material for cosmetic packaging, due to its properties such as corrosion resistance and surface inertness. It has a long history of safe use in packaging applications. The European regulation on cosmetics contains no clear rules concerning the assessment of stainless steel for use in cosmetic packaging. The different European member states have a wide range of approaches, making navigating through the different legislation in Europe difficult. This article presents a proprietary risk management approach named Material Regulatory Risk Management (M2RM), a new decision-making process for verification or demonstration of stainless steel compliance with the cosmetics regulation. This document intends to be guidance for manufacturers or users of stainless steel as well as the cosmetics industry as a whole by simplifying the way of tackling the current complex legislative framework.

Keywords: stainless steel, cosmetic, packaging, compliance, legislation, safety, risk management

INTRODUCTION

The EU Regulation 1223/2009[1] is the core the legislation for cosmetic packaging in Europe. A fundamental requirement of this legislation is that the packaging should not release substances at levels that may endanger human health. To fulfill this requirement a risk assessment of the packaging is required. However, this is difficult to perform since the cosmetics regulation contains no clear provision on how to meet its safety requirement. To help in the compliance work, a decision[2] by the European Commission recommends that the framework regulation[3] on food contact materials may be a useful reference for cosmetic packaging. To apply the Commission recommendation, compliance with the legislation existing specifically for the different groups of food contact materials is needed as a minimum. This is easy to achieve for materials governed by specific regulatory measures (e.g. plastic materials). On the other hand, for materials with no dedicated legislation such as metals and alloys, the compliance work is difficult to perform.

After general information on stainless steel, this article collates the most relevant European legislation and presents a new regulatory risk management approach for deciding or demonstrating whether a stainless steel material is safe and suitable for use in cosmetic packaging.

Definition and designation of stainless steel

The European Standard EN 10020[4] defines stainless steels as iron based alloys containing at least 10.5% chromium and a maximum of 1.2% carbon. The properties of stainless steels can be adjusted with several alloying elements in addition to chromium and nickel. During a process named passivation, the chromium at the

surface of the metal reacts with oxygen in the air to produce chromium oxide, as illustrated hereafter (Figure 1). The invisible chromium oxide layer provides excellent corrosion resistance and renders further surface treatment unnecessary. Stainless steel also contains varying amounts of carbon, silicon and manganese. Other elements such as molybdenum may be added to impart other useful properties such as enhanced formability and increased corrosion resistance.

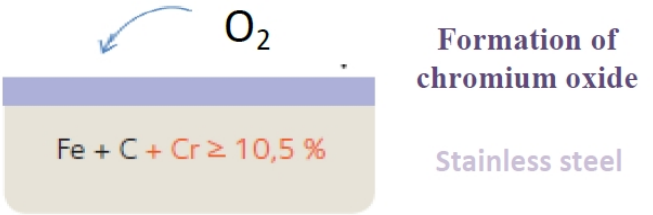

Figure 1 : Stainless steel passivation

The European standard EN 10088-1[5] is the main standard concerning "general purpose" stainless steels. This standard provides two designation systems: a symbolic and numerical.

The symbolic designation, according to the standard EN 10027-1[6], starts with the letter "X", representing steels containing at least one alloying element whose content is equal to or greater than 5%. This letter is followed by the carbon content x100, and then by the chemical symbols of the alloying elements, by decreasing order of their content. The average contents of these elements are then indicated, separated by dashes, in the same decreasing order (e.g. X12Cr13 – X2CrNiMo17-12-2).

The numerical designation definided by EN 10027-2[7] contains five digits (Figure 2). The first digit corresponds to the material main group number (1=steel), the second two digits correspond to a particular family of grades and take into account the chemical composition (40 = stainles steel with <2.5% Ni without Mo, Nb and Ti; 41=stainless steel with <2.5% with Mo without Nb), while the last two are assigned arbitrarily (e.g. 1.4003, 1.4404).

1.4XXX	Stainless and Heat Resisting steels	Number = 1.40XX Stainless steel with Ni < 2.5 % without Mo, Nb and Ti Number = 1.41XX Stainless steel with Ni < 2.5 % and Mo but without Nb and Ti Number = 1.42XX - Number = 1.43XX Stainless steel with Ni >= 2.5 % without Mo, Nb and Ti Number = 1.44XX Stainless steel with Ni > = 2.5 % with Mo but without Nb and Ti Number = 1.45XX Stainless steels with special additions Number = 1.46XX Chemical resistant and high temp Ni alloys Number = 1.47XX Heat resistant steels with Ni < 2.5 % Number = 1.48XX Heat resistant steels with Ni > = 2.5 % Number = 1.49XX Materials with elevated temperature properties

Figure 2: Stainless steel designation numbering system

In the USA, stainless steel used to be designated by a four digit AISI/SAE system (e.g. 304, 304L), identifying grades according to standard chemical compositions (Figure 3). Since the AISI no longer writes material specifications, the relationship between AISI and grade designations has been discontinued. The Unified Numbering System (UNS) which is now in charge of

designations uses an alphanumeric system consisting of a letter followed by 5 numbers (e.g. S30400, S30403.). For the most part, systems such as AISI designations were incorporated into the UNS so that some familiarity was given to the system where possible.

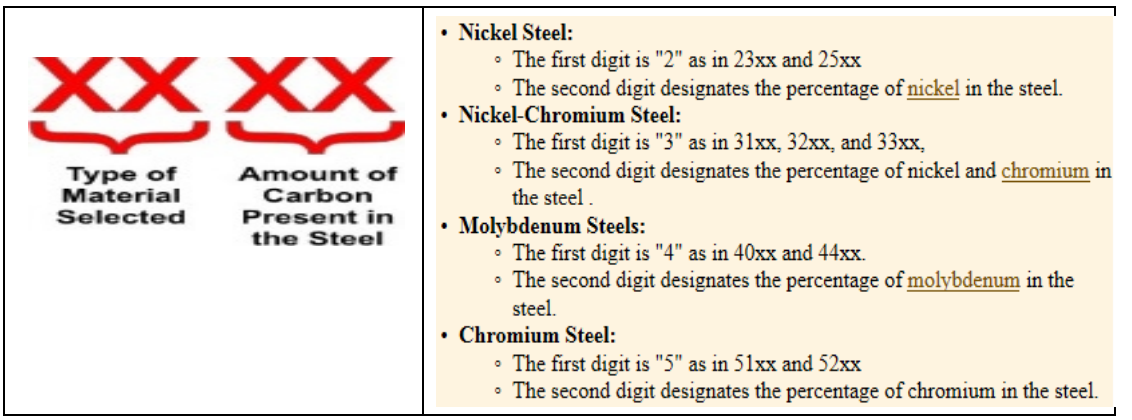

Figure 3: AISI/SAE designation system for stainless steel

Uses of stainless steel in cosmetic packaging

Stainless steel has come into widespread use due to its corrosion resistance to a wide range of chemicals and solutions. Compared to other materials, the corrosion resistance of stainless steel is significantly higher and can be used for a broader range of applications (e.g. household and personal care products, perfumery).Stainless steel also provides excellent mechanical properties. It is an outstanding choice for applications that requires high strength, elasticity and hardness. The main applications of stainless steel in the cosmetic packaging are in balls, springs and actuators for complex engineering systems such as dispenser pumps and valves, as illustrated below (Figure 4).

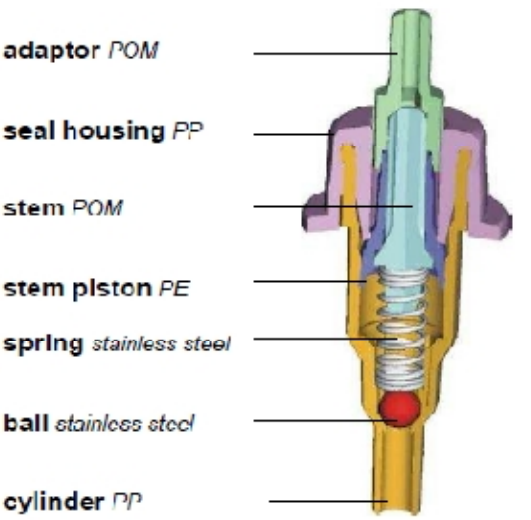

Figure 4: Pump dispenser cross-section

How safe is stainless steel ?

Nickel and chromium are the two substances of major importance with regard to the hazard classification of stainless steel in the solid form. Many stainless steels contain nickel and chromium as a deliberate alloying addition. The most commonly used stainless steels contain about 10% of nickel. However, the range covers 0 – 38% nickel, and even many of the so-called nickel-free stainless steels contain up to 1% nickel as an impurity. Chromium represents 6 – 30% of the stainless steel composition.

In accordance with the CLP regulation[8], nickel metal is classified as a Carcinogen 2 and Skin Sensitizer 1. Since metal alloys are considered as special mixtures under the REACH[9] and CLP[8] regulations, mixtures containing 1% or more of nickel should therefore be classified with the same hazards. However, the guidance on the application of the CLP criteria (CLP guidance, 2015)[10] emphasizes that metal alloys, are not simple mixtures of metals, since the alloy clearly has distinctive properties compared to a classic mixture. In the same sense, annex I to CLP regulation[8] indicates that metals in the massive form, as well as alloys, do not require a label if they do not present a hazard to human health by inhalation, ingestion or contact with skin in the form in which they are placed on the market, despite being classified as hazardous. The EU directive 2009/48/EC[11] on the safety of toys - appendix A of annex II - states that "nickel in stainless steel has proven to be safe, and consequently it is appropriate that it can be used in toys".

Hexavalent chromium, the only toxic form that is currently known for chromium, is subject to authorization under REACH regulation[9]. Passivation of stainless steel is a natural process that leads to the constituting chromium at the surface reacting with oxygen in the air to produce chromium (III) oxide. The passivationlayerconsistsof metallic chromium, and there is no co-deposition Cr(VI). Chromium (III) oxide on the passive layer of stainless steel is in metallic form, which is not hazardous according to the CLP Regulation.[8]

As for stainless as a whole, the European regulation N°10/2011[12], in annex I, authorizes its use in the form of powders, flakes and fibres in plastic for food contact materials.

In the light of the above elements, stainless steel may be considered as a safe material for use in cosmetics packaging.

General regulatory framework applicable to cosmetic packaging in Europe

European regulation 1223/2009[1] is the core legislation regarding the safety of cosmetic products, including the packaging. However this regulation contains no clear provision on how to ensure compliance with its safety requirements with regard to the packaging. Therefore the European Commission has highlighted in a Guideline document[2]that the Framework regulation on food contact materials (EU regulation 1935/2004)[3] shall be considered as a useful reference to ensure the safety of cosmetic packaging.

Like the cosmetic regulation[1], the framework regulation[3] on food contact materials requires that food packaging must be sufficiently inert to prevent substances from being released in quantities that may endanger human health or bring about an unacceptable change in the composition. The framework regulation[3] emphasizes that implementing measures should be adopted in order to help achieve its safety requirement. However compliance with this requirement is easy to perform only for materials which are comprehensively regulated (e.g. plastics for food contact), and very difficult to realize for materials with no detailed legislation as is the case for metals, including stainless steel. In the absence of harmonized EU legislation, the framework regulation stipulates that national legislation within the EU, when existing, may be useful reference to help achieve the compliance. However, there is currently no clear picture when it comes to the regulation of metal packaging for food contact materials. The different Member States within the European Union have a wide range of approaches. At present, only France and Italy have clear legislative requirements in this area.

In addition to national legislation, it is commonly agreed that non-legally binding documents such as Council of Europe resolutions, standards, and some Member States guidelines may be useful references in demonstrating compliance. General regulations such as REACH[9] and the European directive 94/62/EC on packaging and packaging waste[13] are also admitted

as relevant references to complete the demonstration of the safety of packaging materials.

In summary, the safety of cosmetic packaging, notably metallic products, may be ensured through compliance with legislation in the following order of priority:

1. EU Legislation (Regulations, Directives and Decisions)
2. Where EU legislation is incomplete or does not exist, relevant national legislation of EU member states.
3. In the absence of specific EU product requirements, national requirements or voluntary standards transposing EU standards or legislation, compliance is determined according to guidelines and standards.

Overview of the EU legislation applicable to metallic materials in the cosmetic packaging

The term legislation covers different regulatory instruments including legally binding texts such as EU regulations and directives, and the non-binding documents also known as "soft-legislation" such as resolutions, guidelines and standards. Soft-laws are generally established by consensus between authorities, industry, experts and other interested parties, based on consolidated results of science, technology and experience. Below are outlined the regulatory instruments that have been identified as the most relevant for the compliance work on metallic packaging materials.

EU regulation 1223/2009[1] on cosmetic products

The EU regulation on cosmetic products applies to both the cosmetic formula and its packaging. A key requirement in this regulation is that the packaging shall not release prohibited substances into the cosmetic formula in quantities that may present a risk for consumer health.

Commission Implementing Decision 2013/674/EU[2]

The aim of these guidelines on Annex I to the cosmetics regulation[1] is to assist in meeting the obligations of the cosmetics regulation. It makes it clear that reference to Regulation (EC) No 1935/2004 could be useful in compliance work.

EU Regulation 1935/2004[3]

Also known as the framework regulation[3], this text is the regulation which applies to all food contact materials. Article 3 of the regulation establishes a key rule that "under normal and foreseeable conditions, food contact materials should not endanger human health or change the composition of the product it contains". The influence of this regulation extends far beyond food contact materials. For instance it is commonly used as a reference in the cosmetic and pharmaceutical packaging industry.

REACH Regulation[9]/ CLP Regulation[8]

REACH Regulation (Regulation (EC) No 1907/2006) and CLP Regulation (Regulation (EC) No 1272/2008) are two key pieces of EU legislation governing chemical products in Europe. CLP classifies chemicals based on their toxicological profile, and is the starting point for the management of chemicals according to REACH.

Regulation (EU) N°10/2011[12]

The regulation establishes specific rules for plastic materials and articles destined to come into contact with food. It contains a positive list otherwise known as the Union List of monomers, additives and others starting substances that can be used in the production of food contact plastics. The Union list includes metallic materials (e.g. stainless steel powders, flakes and fibres, and tin). Its influence extends to areas such as cosmetic and pharmaceutical packaging.

Directive 94/62/EC[13]

This EU Directive covers all commercial and industrial packaging waste in the European Union market. It aims to provide a high level of environmental protection from hazardous substances and materials, restricting the presence of certain heavy metals (Hg, Pb, Cr6+, Cd) in packaging and packaging waste.

CoE Resolution on metals and alloys used in food contact materials and articles[14]

This resolution has been published with the aim of overcoming the lack of specific regulations on metals and alloys used as food contact materials in the EU. With specific relation to health risks arising from consumer exposure to certain metal ions, the Resolution recommends the adoption of legislative actions and other measures to the Member States. The Resolution defines quality requirements for materials for which no specific EU regulations exist. The text recommends the implementation of Specific Release Limits (SRL) in Council of Europe member states for metal ions that are released from materials in contact with foodstuffs

Technical guide on metals and alloys used as food contact materials[15]

Published in 2013 by the Council of Europe, this document covers a wide range of metals and alloys that are used in contact with foodstuffs or that may occur as impurities of food contact materials. The document specifies release limits for 21 metal ions from articles, as shown in the table below. The provisions apply to the unintentional release of metal ions from materials and articles at the end-use level, whether coated or uncoated, partly or fully made of metals and alloys. Even if not legally binding, it serves as a reference for the implementation of the framework Regulation.

Table 1: Specific release limits

Metal	Council of Europe SRL (mg/kg)
Aluminium	5
Antimony	0.04
Arsenic	0.002
Barium	1.2
Beryllium	0.01
Cadmium	0.005
Chromium	0.250
Cobalt	0.02
Copper	4
Iron	40
Lead	0.010
Lithium	0.048
Magnesium	-*
Manganese	1.8
Mercury	0.003
Molybdenum	0.12
Nickel	0.14
Silver	0.08
Thallium	0.0001
Tin	100
Titanium	-*
Vanadium	0.01
Zinc	5

European Standards

Standards are approved and published by dedicated organizations. Available to the public, they are used voluntarily. Standards represent agreement to satisfying a recognized and approved level of quality and safety. Some standards support national or European legislation by citing them as reference documents. European standards are established by CEN (standards organization of European Union) or by standard bodies in the EU Member States. After publication of a European Standard by CEN, each of the national standards bodies is obliged to adopt the EN as an identical national standard and has to withdraw any pre-existing national standards, which are in conflict with the new EN. Standards on metallic materials are used as reference to help implement the provision in article of 3 of the EU Regulation (EC) No. 1935/2004[3].

Legislation specific to stainless steel

France and Italy are the only European member states known to have detailed legislation on stainless steel. The legislation in these two countries addresses stainless steel intended for food contact. A few soft-laws also exist at both European level and in some Members States to compensate for the lack of harmonized European legislation on the topic. The different texts that have been identified as relevant for stainless steel products are presented below.

France

- *Order of 13th January 1976 relating to materials and objects in stainless steel in contact with foodstuffs*[16]. The text lists elements that may be incorporated into the steel, with maximum concentration limits.
- *Order of 15th November 1945 listing the materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments*[17].This French order sets out the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments. The provisions of this law are extended to food contact materials by circular-letter of 28 October 1980.[18]
- *NF A 36 711 ": Non packaging steel – Stainless steel intended for use in contact with foodstuffs, products and beverages for human and animal consumption."*[19]. This French standard lists the different grades of stainless steel that are considered as suitable for use in contact with foodstuffs. It also specifies the maximum limits of the different alloying elements authorized.
- DM/4B/COM/001: *Methodology paper - Rules for metals and alloys intended to come into contact with foodstuffs*[20]. Applicable since January 2016, this document supersedes the procedures in DGCCRF Information Notice No. 2004-64[21] on the verification of the suitability regarding metals and alloys. It is the result of an agreement between French control authorities, testing laboratories, food industry, retailers, suppliers of raw material and producers of food contact articles. The document aims at specifying the methodology for verification of the suitability for food contact. It covers a wide range of metallic materials, including stainless steel.

Italy

Decree n. 140 of 11 November 2013 for food contact stainless steels[22]amended by the *Decree 195 of 6 August 2015*[23].The rules in these documents are based on the concepts of (1) positive lists of material grades, (2) migration limits and (3) standardized migration tests. The positive list of admitted stainless steels in Annex II indicates the type of stainless steel individuated by international denominations according to AISI, the Unification Italian Committee (UNI) and other international codes.

European Union

EN 10088-1 "Stainless steels - Part 1: List of stainless steels"[5]. This standard defines the chemical composition of stainless steels, which are subdivided, in accordance with their main properties, into corrosion resisting steels, heat resisting steels and creep resisting steels. It contains chemical analysis and physical property data for 160 stainless steels plus 18 nickel and cobalt alloys. Annexes to this standard give guidance data on some physical properties, information on the classification of stainless steel grades and empirical formulae for steel grade classification by microstructure.

How to select safe and compliant stainless steel? The M2RM approach

The review of the legislation existing at both European and national levels has highlighted some fundamental points that have to be considered in the compliance work for stainless steel. These points have been assembled in a structured set of requirements, identified as LICORT concept. The five components of this concept are explained below. Table 2 identifies the components of LICORT concept, and presents the legal texts in which they are derived.

LI - Material grades in authorized **LIsts** – The legal instruments existing in Europe for metals are generally based on the concept of positive lists of material grades. Indeed material grades that are listed in the legislation are viewed by control authorities in Europe as safe and suitable for use in packaging. Therefore this is as key point of our verification process.

CO – Officially recognized chemical **Composition** – The chemical composition is another common feature of the different legal instruments existing in Europe for metals. The legislation is

characterized by different compositional ranges associated to the lists of material grades. Therefore compliance in term of chemical composition is generally regarded as an indicator of safety and suitability for use in packaging. Chemical composition includes both the authorized alloying elements and the level of permitted impurities.

R – Specific **Release** limits - The Technical guide on metals and alloys by the Council of Europe[15], which is a key piece of European legislation on metallic materials for food contact, defines specific release limits for a certain number of metals in the packaging. These release limits concern only those metals and impurities likely to be present in significant amounts. By extension, these release limits are regarded as relevant for the determination of the safety of metallic materials for cosmetic packaging.

T - Surface **Treatment** -The surface characteristic of a metallic packaging is critically important in achieving high corrosion resistance, a surface appearance, a desired product finishing… Surface treatments such as anodization and galvanization are currently used for stainless steel. Although there is currently no legislation specifically addressing the safety of surface treatment, all treated surfaces must satisfy the requirements of Article 3 of EC Regulation 1935/2004 i.e. the packaging must be sufficiently inert to prevent substances from being released in quantities that may endanger human health or bring about an unacceptable change in the composition. While all metals used in surface treatment can have adverse effects, depending on their specification, four metals are of most concern for their environmental/health effects (cadmium, lead, nickel and chromium VI) and should not be used.

Table 2: Components of LICORT concept

Control point	Specific requirement	Supporting legislation
LI	Material grades used are listed in the legislation	- EN 10088-1 - NF A 36 711 - Italian Decree N° 140 of 11/11/2013
CO	Chemical composition meets the requirements	- EN 10088-1 - French Order of13th January 1976 - Italian Decree N° 140 of 11/11/2013
	Total heavy metals (Hg, Pb, Cr6+, Cd)<100 ppm	- Dir. 94/62/EC
R	SRL for the relevant metal ions are met	- Technical guide - Metals and alloys: Council of Europe (2013)
T	Surface treatment excludes cadmium, lead, nickel and chromium VI.	- REACH Regulation

In order to propose a simplified decision-making approach to the complex regulatory framework applicable to stainless steel, an alignment of the five components of the LICORT concept has been made to support our proprietary risk management approach called Material Regulatory Risk Management – M2RM. The approach refers to a set of key controls by which the regulatory risk on stainless steel is managed. It consists of a checklist of key points that should be completed in order to achieve compliance with the EU cosmetics Regulation and thus provide reasonable assurance of the material safety (see table 3). Within the M2RM, the five key requirements are of equal importance and mandatory. A free-choice option is given at some controls points, in relation with the European "mutual recognition" principle[24] which stipulates the possibility of using the compliance report of one member state in another European country. The verification of specific release limit is necessary only for chemicals thatare part of the alloying elements or for those used in the surface treatment. The requirement related to the surface treatment is only mandatory for materials that have been the subject of such a treatment.

Table 3: Check list of key requirements for achieving the regulatory compliance

➢ Material grade	- EN 10088-1 - Italian Decree N°140 - French NF A 36 711	☐ ☐ ☐ } At least one
➢ Material composition	- EN 10088-1 - Italian Decree N°140 - French Order of 13th January 1976	☐ ☐ ☐ } At least one
➢ Impurities of heavy metals	- EU Directive 94/62/EC	☐
➢ Release of relevant metal ions according to the Technical guide on metals and alloys		☐
➢ Surface treatment excludes cadmium, lead, nickel and chromium VI		☐

CONCLUSION

The compliance work on stainless steel is a difficult task that requires a good knowledge and understanding of the complex legislation framework. This document presents a simplified approach to managing the regulatory risk. The M2RM approach intends to be a useful tool for delivering compliance with the cosmetics regulation, and thus provide a reasonable assurance of safety. It is applicable not only to stainless steel, but also to other metallic materials such as aluminium, steel, tin plate and ZAMAK. The M2RM approach may also be applied to related areas such as food packaging, food containers and utensils as well as pharmaceutical packaging.

Abbreviations

AISI: American Iron and Steel Institute

CEN: European Committee for Standardization (Comité Européen de Normalisation)

CLP: Classification, Labelling and Packaging

M2RM: Material Regulatory Risk Management

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

SAE: Society of Automotive Engineers

SRL : Specific Release Limit

UNS: Unified numbering system

ZAMAK : a family of alloys with a base metal of zinc and alloying elements of aluminium, magnesium, and copper

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