



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 1223/2009¹ 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 decision² by the European Commission recommends that the framework regulation³ 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 10020⁴ 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

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