

# SAFEGUARDS

## CONSUMER GOODS AND RETAIL

SOFTLINES

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## ECHA RELEASES DEFINITION OF "PROLONGED SKIN CONTACT" FOR NICKEL DIRECTIVE

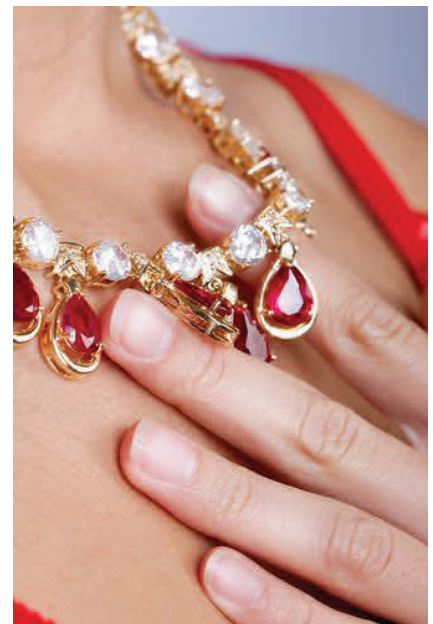
The Nickel Directive is the European Union directive regulating the use of nickel in jewellery and other products that come into contact with the skin, in order to reduce the incidence of nickel allergies and dermatitis and preventing non-compliant items from reaching the marketplace. This Directive is included under the REACH Regulation (EC) No 1907/2006, entry 27 of Annex XVII. Recently, the European Chemicals Agency (ECHA) provided a proposal for a definition for "prolonged contact with the skin" in relation to nickel restriction with justification based on available scientific evidence<sup>1</sup>.

Nickel (Ni) is commonly used in the composition of an alloy, including the surface finish, non-homogeneity and plating among other parts. However, it was found to be the most common cause of allergic contact dermatitis.

Sensitisation to nickel can result in severe allergic reactions. The contact allergy may be caused by exposure to nickel that when in contact with the skin triggers an inflammatory reaction. In order to protect the health of the consumer, the EU Nickel Directive restricts the release rate of nickel from articles intended to come into direct and prolonged contact with the skin and with post assemblies intended to be inserted into piercings in the body.

Under the EU Nickel Directive, the concentration of nickel in any post assembly, for use in piercings, should not release greater than 0.2 µg/cm<sup>2</sup>/week, and products that come into direct and prolonged contact with the skin should not release greater than 0.5 µg/cm<sup>2</sup>/week. The regulation also applies to articles that have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles which come into direct and prolonged contact with the skin does not exceed 0.5 µg/cm<sup>2</sup>/week for a period of at least two years of normal use. However, the restriction does not define the term "prolonged contact with the skin", therefore, the ECHA was requested to provide guidelines and to clarify how to understand this term in relation to the nickel entry.

The objective of the released proposal was to define the term "prolonged contact with the skin" in relation to nickel restriction. The definition has to have a justification based on available relevant scientific information and assign a minimum contact time. According to the document, the term "prolonged contact with the skin" is defined as



<sup>1</sup> [The official document published from ECHA –](#)

contact with the skin to articles containing nickel of potentially more than:

- 10 minutes on three or more occasions within two weeks, or
- 30 minutes on one or more occasions within two weeks.

Thirty (30) minutes of skin contact to an alloy releasing nickel product is the rate of the legal threshold that should adequately protect against skin reactions in most of the Ni-sensitised individuals.

EN 1811 is the internationally recognised test method to determine the rate of release of nickel from articles such as jewellery, spectacle frames and other items intended to come into direct and prolonged contact with the skin. Articles having a non-nickel coating should be subjected to EN 12472, which is the method for the simulation of wear and corrosion for the detection of nickel release from coated items followed by the migration test according to EN 1811.

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