

Information Note

Tattoo Inks – Restriction under REACH

Tattooing and permanent make-up (PMU) are usually applied by injecting the inks into the dermis of the skin. As such they are intended to be permanent, and will result in prolonged / lifelong exposure to the chemicals contained within the inks. Printing inks manufactured and placed on the market by EuPIA members are **not intended** for use in tattooing and PMU, and such uses are **neither recommended nor supported by EuPIA**.

In December 2015 the European Commission asked the European Chemicals Agency (ECHA) to assess the risks of chemicals classified as CMR (carcinogenic, mutagenic or toxic to reproduction) or as skin sensitisers which are contained in tattoo inks, by preparing an Annex XV dossier for a restriction under REACH. A dossier proposing a restriction of CMRs, skin sensitisers and certain other substances in tattoo inks and PMU was submitted in October 2017. After assessment and completion of the appropriate regulatory procedures the European Commission published a comprehensive restriction on the use of hazardous chemical substances in tattoo inks and permanent make-up, <u>Commission Regulation (EU) 2020/2081</u> on 14th December 2020.

This restriction came into effect (so-called 'entry into application') on 5th January 2022 (apart from two pigments, Pigment Blue 15:3 and Pigment Green 7, with entry into application of 5 January 2023).

The official scope of the restriction is as follows:

Use of a mixture 'for tattooing purposes': injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on the body

• Substances with harmonised classification under the Classification, Labelling and Packaging (CLP) Regulation

• For carcinogenicity, mutagenicity or toxicity to reproduction, skin sensitisation, skin corrosion or irritation, serious eye damage or irritation

• Substances prohibited by the EU Cosmetic Products Regulation

• Impurities including heavy metals and PAHs, methanol and azo dyes not classified for carcinogenicity or mutagenicity but that may undergo decomposition or contain residual aromatic amines classified as carcinogenic or mutagenic

Specific concentration limits have been set for each of the above substance categories / types – details may be found in the regulation and in a <u>presentation</u> accompanying an ECHA webinar on the topic.

Further information and details may be found on the ECHA Webpage Tattoo Inks

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