

INFORMATION FOR TATTOOISTS AND SEMI-PERMANENT MAKE-UP ARTISTS REGARDING THE EU- WIDE BAN ON PIGMENT BLUE 15:3 AND PIGMENT GREEN 7

1. BASIC GENERAL INFORMATION

Substances in tattoo ink and permanent make-up

Chemicals in tattoo ink are of concern for public health causing allergies and possible long-term adverse effects such as cancer. This restriction aims to achieve a harmonised high level of protection of human health and free movement of goods within the EU and to ensure that EU citizens are equally protected, independently of the country where the tattoo was performed and the origin of the ink. This REACH Restriction covers all substances banned by the EU Cosmetic Products Regulation, substances with harmonised classification as CMRs or as skin sensitizer, skin irritant or corrosive, eye damaging and irritant substances, as well as a list of impurities, aromatic amines and colorants.

The REACH restriction was prepared by the European Chemicals Agency (ECHA) in collaboration with the Norwegian Environment Agency, the Italian Istituto Superiore della Sanità, the Danish Environmental Protection Agency and with the contribution of the German Federal Institute for Risk Assessment (BfR) and Federal Institute for Occupational Health and Safety (BAuA) following a request from the European Commission in 2015. The restriction includes practical concentration limits established either for groups of substances or for individual substances such as certain azodyes and carcinogenic aromatic amines, polycyclic aromatic hydrocarbons (PAHs), metals and methanol as well as harmonised labelling requirements to safeguarding consumers whilst carrying out proper investigations in the event of adverse health effects. In addition, tattooists are provided with additional information about the implementation of the restriction and help prevent fragmentation of the internal market.

The Risk Assessment Committee (RAC) concluded that the risk of cancer as well as the non-carcinogenic hazards could not be ruled out, primarily due to the lack of adequate information in general and the stakeholders' failure to submit additional data on their safety. As tattoo inks are injected into the skin and is considered as a potential risk to human health, the Commission proposed a transitional period of 24 months for Pigment Blue 15:3 and Pigment Green, 12 months shorter than initially proposed by SEAC. The Commission considers that this is enough time to allow ink formulators to find safer alternatives whilst ensuring the availability of the inks on the market in the meantime.

2. THE EU LEGISLATION

Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up.

The Commission states that it is the responsibility of Member States to enforce the REACH legislation. This includes the establishment of controls to prevent the placing on the market and use of hazardous tattoo inks that do not comply with the harmonised provisions of the restriction under REACH. Moreover, the Member States are also in charge of the possible national safety rules beyond REACH. MALTA will ensure that such controls are carried out through inspection procedures.

Please find the full versions of the above legislation in English and in Maltese:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2081&from=EN>

<https://eur-lex.europa.eu/legal-content/MT/TXT/PDF/?uri=CELEX:32020R2081&from=EN>

3. CONCLUSION

The Commission has carefully considered the concerns on the alternatives to Pigment Blue 15:3 and Pigment Green 7 during the whole preparation of the restriction. This was also subject to extensive discussions with the Member States in the REACH committee. The European Parliament made no comments to the draft Regulation that was notified in accordance with Article 5a (3) of Decision 1999/468/EC5 for its scrutiny until 18 October 2020. The Commission considers that the protection of human health from potentially hazardous substances, where safety for injection into the human body has not been sufficiently proven, needs to prevail. ***The transitional period for the two pigments until 4 January 2023 provides for enough time to find safer alternatives.*** Finally, the Commission recalls that it is the responsibility of Member States including Malta to enforce EU legislation.

References:

1. REACH restriction: [Restrictions \(europa.eu\)](#)
2. EU Legislation: <https://eur-lex.europa.eu/eli/reg/2020/2081/oj>
3. EU-wide ban on Pigment Blue 15:3 and Pigment Green 7 - https://www.europarl.europa.eu/doceo/document/PETI-CM-689748_EN.pdf
4. Sequence of events: [Registry of restriction intentions until outcome - ECHA \(europa.eu\)](#)

RECOMMENDATIONS

1. Caution should be exercised for media articles which are not based on the proper interpretation of the EU legislation as they spread misinformation.
2. The ban on these pigments officially starts on the 4th January 2023 and therefore it is recommended that whilst purchasing ink supplies, such pigments are avoided.
3. After the 4th January 2023, any left-over batches of Pigment Blue 15:3 and Pigment Green 7 must be discarded. Health Care Standards inspectorates will retrieve any found pigments during the inspections.
4. The Health Care Standards Directorate will continue to notify the licensees are per EU instructions.
5. Website: <https://deputyprimeminister.gov.mt/en/hcs/Pages/health-care-standards.aspx>.