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## Tattoo inks: risk assessment for Pigment Blue 15:3 and Pigment Green 7

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To date, there is no binding regulation governing the components used in tattoo inks at the European level. The EU Commission and member states are currently consulting on a proposal from the European Chemicals Agency (ECHA) for a uniform set of legislation within all member states. This proposal foresees a restriction under the European Chemicals Regulation (REACH), by means of which dangerous substances in consumer products can be banned or their use can be restricted. Pigment Blue 15:3 and Pigment Green 7 are also affected by this proposal. Because of these pigments in particular, the ECHA proposal is currently the subject of public debate.

As a consequence, the German Federal Institute for Risk Assessment (BfR) has reviewed the potential health hazards and risks posed by the pigments Blue 15:3 and Green 7.

The BfR concludes that the currently available data for both pigments indicate only a comparatively low level of toxicity. However, since the available data on harmful properties of both pigments are incomplete, the BfR is currently unable to provide a reliable health risk assessment of these pigments when used in tattoo inks. In particular, no assessment can be provided for the potential health risks involved in injecting these substances into deeper layers of the skin (intra-dermal application). The BfR recommends supplementing the available data sets for both pigments. As currently available data indicate only a comparatively low level of toxicity, however, the BfR does not see an acute need for further action at this time. In the view of the BfR, further work in this area should take into account that the pigments Blue 15:3 and Green 7 might be substituted by less well-investigated substances.

### 1 Background

In 2009, the Tattoo Inks Ordinance came into force in Germany<sup>1</sup>, listing substances banned from being used in tattoo inks. A small number of other EU member states have also passed similar legislation regulating the constituents of tattoo inks. Accordingly, the EU Commission asked the European Chemicals Agency (ECHA) to prepare a proposal for a uniform regulation governing prohibited substances in tattoo inks at a European level. This proposal initiated the 'restriction' procedure under the European Chemicals Regulation<sup>2</sup> (REACH), by means of which dangerous substances in consumer products can be prohibited, or restrictions placed on their use or manufacture.

In 2017, the ECHA submitted a restriction proposal to the EU Commission (ECHA 2019): this proposal sets out future prohibitions to protect consumers from certain dangerous substances in tattoo inks and permanent make-up (the term 'tattoo inks' is used subsequently as an umbrella term for both types of product). This proposal generally prohibits substances proven to be carcinogens, mutagens, developmental toxicants, or toxic to the human reproductive system. The proposal also covers substances that are eye or skin irritants, as well as allergens. Lastly, the proposal also bans substances in tattoo inks whose use in cosmetic

<sup>1</sup> 'Ordinance on inks used in tattoos including certain comparable substances and mixtures made up of individual substances' (German Tattoo Inks Ordinance)

<sup>2</sup> Article 67 ff. of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

products is either prohibited or restricted by certain annexes included in the current European Cosmetics Regulation<sup>3</sup>. This ban is justified by the argument that substances prohibited from use on the skin should also be prohibited from use under the skin. Altogether the restriction proposal covers about 4,200 substances whose use will be prohibited outright or allowed only in trace quantities in the future.

Currently, there is considerable public interest concerning the two pigments Blue 15:3 (PB15; CI 74160; CAS no. 147-14-8) and Green 7 (PG7; CI 74260; CAS no. 1328-53-6). Both pigments are commonly used in tattoo inks. These pigments may be used as colourants in cosmetics because they have been listed in the Cosmetics Regulation positive list (annex IV) following an assessment by the European Commission's Scientific Committee on Cosmetology (SCC)<sup>4</sup>.

Due to concerns that certain hair dyes could cause (bladder) cancer, the EU Commission also launched a programme in which all hair dyes were to be assessed by the European Commission's Scientific Committee on Consumer Safety<sup>5</sup>. As a result of this activity, the two pigments Blue 15:3 and Green 7 were added to the list of prohibited substances in annex II of the Cosmetics Regulation, and thus banned from use in hair dyes. However, this listing of both pigments is not based on a negative health risk assessment but instead on the fact that no dossiers have been submitted to the SCCS by the pigment manufacturers. Manufacturers could apply to have the substances removed from annex II of the EU Cosmetics Regulation, which would enable their use in hair dyes: this would require the submission of appropriate data to clarify any suspicions about the substances' hazardous properties. In this case, the SCCS would have to assess these substances.

According to annex IV of the Cosmetics Regulation, Pigment Green 7 is also banned from use in eye products. As a result, this also prohibits the use of the pigment in tattoo inks in Germany (section 1(2), no. 1 b) of the German Tattoo Inks Ordinance).

As a result of their listing in annex II, both pigments could be prohibited in the future due to the new restriction proposal for the use of substances in tattoo inks in EU member states.

This restriction proposal is currently the subject of consultations between the EU Commission and member states. It currently envisages a temporary (two-year) exemption from the prohibition on use for both pigments. This exemption is also the focus of public debate at the moment. On 15 January 2020, for example, an online petition<sup>6</sup> with the aim of preventing a ban was started and had acquired over 100,000 signatures just two days later.

In light of this restriction proposal and possible bans or exemptions for the pigments Blue 15:3 and Green 7, the German Federal Institute for Risk Assessment (BfR) has investigated the potential adverse health effects and risks posed by these two pigments. This investigation was partially based on the data—where available—that were submitted as part of the REACH registration of these pigments. These data, however, do not offer any directly relevant information for use in tattoo inks. Within the EU, there is no generally applicable legal basis for requesting the submission of data on the use of pigments in tattoo inks.

<sup>3</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

<sup>4</sup> Scientific Committee on Cosmetology, [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/scc\\_o\\_7.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/scc_o_7.pdf)

<sup>5</sup> SCCS: Scientific Committee on Consumer Safety, European Commission

<sup>6</sup> Initiated by the tattoo artist Jörn Eisenbruch: <https://www.openpetition.de/petition/online/tattoofarbenretten-2020>

## 2 Results

In the BfR's opinion, the health risk data currently available for both pigments obtained within the scope of the REACH regulation is incomplete. The available data should be improved for both pigments. Currently available data only show a comparatively low level of toxicity for both substances, though.

**Table 1: Overview of pigments Blue 15:3 and Green 7 in terms of the EU Cosmetics Regulation (CR) and tonnage band according to REACH.**

Pigment	Colour index EC number CAS number	CR annex II	CR annex IV	REACH Tonnage band
Pigment Blue 15:3	CI 74160 EC 205-685-1 CAS 147-14-8	Ref. no. 1367 – when used as a hair dye constituent	Ref. no. 105	10,000–100,000 t/year
Pigment Green 7	CI 74260 EC 215-524-7 CAS 1328-53-6	Ref. no. 1369 – when used as a hair dye constituent	Ref. no. 107 – not to be used in eye products (column G)	1,000–10,000 t/year

In Europe, the annual production volumes (for the coating and dye industries, for example, see table 1) for both pigments exceed one thousand tonnes. The pigments are governed by the REACH regulation and must be registered accordingly. Depending on the quantities produced, the manufacturers must submit toxicological data (standard REACH information requirements) to enable an assessment of the health risks posed by the substances. This can lead to a harmonised classification in a specific hazard class for human health (such as a 'carcinogenic effect') according to the CLP regulation<sup>7</sup>. The toxicological endpoints to investigate include: acute toxicity, skin/eye irritation, allergenic potential (sensitisation), toxicity after repeated exposure (subchronic and chronic toxicity), mutagenic potential (genotoxicity), carcinogenic potential (cancer-causing effects) and toxicity to reproduction (developmental toxicity and toxicity to the human reproductive system). For a reliable scientific assessment, the quality of the available data is decisive (e.g. studies must be conducted according to internationally recognised OECD test guidelines and GLP principles).

The BfR has perused the studies submitted for REACH registration by the registrants for both pigments. For Pigment Blue 15:3, the REACH standard data requirements are not fulfilled in their entirety for any of the toxicological endpoints. For Pigment Green 7, these requirements are fulfilled only for the endpoints of eye irritation and sensitisation. For both substances, the following treatment-related effects have been described *in vitro* as well as in animal experiments:

Both pigments exhibit a low level of acute toxicity. In *in vitro* tests, Pigment Blue 15:3 exhibited no mutagenic effects, while both positive and negative test results are available for Pigment Green 7. These results should be clarified with further tests. In studies utilising animal experiments, no indications of allergenic effects were found for Pigment Green 7, while one of three studies on Pigment Blue 15:3 produced results indicating a weak level of sensitisation, which also requires further clarification. Results are also available indicating a low level of eye irritation and low to moderate skin irritation for Pigment Blue 15:3. A non-standard study performed in mice produced no evidence for Pigment Blue 15:3 as a carcinogen.

<sup>7</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

However, in consideration of the study quality and the incomplete status of the overall data available, the BfR does not consider these findings to be robust enough to complete a conclusive risk assessment concerning the use of both pigments in tattoo inks. Accordingly, the BfR instead recommends that the European Chemicals Agency (ECHA) reviews the available data on both pigments in terms of the standard REACH data requirements. This approach would enable missing data to be requested and indications of risks to human health to be clarified. However, even after completing the data sets in this way, the use of Pigment Blue 15:3 and Green 7 in tattoo inks would still not be the subject of a risk assessment conducted according to REACH, since this assessment covers only uses registered under REACH.

As a result of these issues with the available data, the BfR is unable to complete a definitive risk assessment of the use of the two pigments in tattoo inks at this stage.

However, the BfR also is of the opinion that an assessment of the two pigments should also account for the fact that both pigments have been used in tattoo inks for over ten years without any obvious adverse effects. This applies in particular to the sensitisation endpoint. The literature offers no reports of allergies or irritation caused by these pigments. Allergies to tattoo inks described to date have been generally ascribed to the use of red or black colourants (Laux et al., 2016).

As regards further work in this area, the BfR notes that a ban of these pigments could result in less well-investigated substances being used instead. Substitute substances for Pigment Blue 15:3 and Pigment Green 7 could be more harmful to health while simultaneously lying outside the scope of the restriction. Targeted chemical modifications could be used to develop new pigments whose adverse effects are unknown. Evidence for pigments of this kind has already been provided by a study for the European market (Hauri, 2014). The authors identified the partially brominated Pigment Green 36 (CAS 14302-13-7, CI 74265), which is used as a substitute for Pigment Green 7, with a frequency of 3.5 % among all pigments analysed. This pigment was not detected in an earlier market surveillance study conducted in 2009 (Hauri et al., 2009). Research on Pigment Green 36 has been sparse to date and it cannot therefore be viewed as a less harmful alternative to the chlorinated Pigment Green 7.

A number of key scientific committees have assessed the pigments Blue 15:3 and Green 7 in the past (SCC, 1986; OECD SIDS, 1997; BG-RCI, 1995<sup>8</sup>). These committees were unanimously of the opinion that the pigments exhibit a low level of toxicity and do not present an unacceptable risk to human health. Accordingly, further studies and assessments were considered to be of a low priority. In 1995, the German Social Accident Insurance Institution for the raw materials and chemical industry (BG-RCI) did not consider occupational health measures necessary in connection with Pigment Green 7 (BG-RCI, 1995). Nor did the European Commission's Scientific Committee on Cosmetology had any objections to the pigments being listed as permitted colourants in the EU Cosmetics Regulation (SCC, 1986), other than noting that the available data on mutagenicity and sensitisation should be improved for Pigment Blue 15:3. As is apparent from OECD-SIDS (OECD SIDS, 1997), this work was indeed completed for the mutagenicity endpoint: based on the available data, Pigment Blue 15:3 was considered being non-mutagenic.

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<sup>8</sup> German Social Accident Insurance Institution for the raw materials and chemicals industry (in German: Berufsgenossenschaft Rohstoffe und chemische Industrie, (BG-RCI))

### 3 Risk management options/measures

On the basis of the data currently available, an argument can be made for a temporary exemption of pigments Blue 15:3 and Green 7 from the proposed restriction.

The BfR therefore recommends the following:

- Any decision to exempt the two pigments from the restriction should consider the risk posed by potentially more harmful substitutes being used in their place.
- The ECHA should review the completeness of the REACH regulation data submitted for both pigments as part of the dossier evaluation and missing data should be requested.

#### Further information on tattoo inks is available from the BfR website

Tattoo inks FAQ

[https://www.bfr.bund.de/en/faq\\_about\\_tattoo\\_inks-201880.html](https://www.bfr.bund.de/en/faq_about_tattoo_inks-201880.html)

All BfR publications about tattoo inks

[https://www.bfr.bund.de/en/a-z\\_index/tattoo-130164.html](https://www.bfr.bund.de/en/a-z_index/tattoo-130164.html)



BfR 'Opinions app'

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### **About the BfR**

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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