

Reclassification of TPO

Information, declaration, change in raw materials

In brief

TPO, our most widely used photoinitiator for UV inks, is on the SVHC list effective June 14, 2023.

While we will declare TPO in our documentation, as things stand we do not see any need to make changes to the formulations of our UV inks. We detail our reasoning below.

Expansion of the SVHC list

On June 14, 2023, two substances were added to the SVHC list,¹ bringing it to a total of 235. One of these new substances is TPO².

At Printcolor, TPO is used in UV-cured inks developed before 2015 as an effective, efficient photoinitiator. Printcolor UV inks from 2015 are TPO-free.

Declaration, information and notification requirements

Anyone who produces or imports a product with a concentration of more than 0.1% by mass (weight for weight) of a substance on the SVHC list must declare the concentration of the substance. If it cannot be excluded that humans or the environment may be exposed to the product in normal and foreseeable conditions of use, notification of the substance must be submitted to the SCIP database.³ Anyone who is exempt from this notification requirement must give "appropriate instructions"⁴ to the recipient. According to REACH,⁵ "products" refers to finished goods that come into contact with the end consumer (clothing, furniture, jewelry, newspapers, plastic packaging). The end consumer must be informed of concentrations of >0.1%. Printcolor does not manufacture products in this sense, instead it supplies manufacturers of these products. In our view it is unlikely that a product decorated with our inks will have a TPO concentration of >0.1%. We have therefore decided on the following course of action to ensure our customers are equipped with reliable information:

In accordance with the CLP regulation,⁶ Printcolor will declare TPO as having a concentration of >0.1% in the relevant safety data sheets of all affected products in section 3 and paragraph 15. The documentation is currently being updated with the necessary information.

We request that you continue following the processing instructions in the material safety data sheets (MSDS). As things stand, we do not see the need to change the formulations of our UV inks.

Phasing out TPO

Manufacturing toxicologically safe printing inks and thereby protecting users is one of our most fundamental corporate principles.

¹ SVHC: substances of very high concern, administered and updated every six months by the ECHA (European Chemicals Agency)

² TPO: diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (CAS: 75980-60-8)

³ SCIP: database for information on substances of concern in articles as such or in complex objects (products). For details see the SCIP leaflet: https://echa.europa.eu/documents/10162/28213971/scip_leaflet_en.pdf/d1180cae-ae6b-ac9e-55e5-49a4324def40. The reporting requirement only applies within the EU.

⁴ We are working on this basis that the information on personal protective clothing included in the MSDS, on application in the TDS, etc. suffices for exemption from the notification requirement.

⁵ REACH: European Union regulation for protection of human health and the environment from the risks posed by chemicals

⁶ CLP: classification, labeling and packaging of substances and mixtures

TPO is listed in Annex 10, Part A, of Swiss ordinance 817.023.21⁷ and since April 2023 it has been on the Eu-PIA suitability list⁸ of photoinitiators for indirect food contact.

Food contact materials are listed on the basis of evaluated studies drawn from toxicological data and accepted migration threshold values.

From the listings it can be inferred that if the product is properly cured in compliance with processing parameters and handled with appropriate protective measures (in accordance with the MSDS), it can be assumed that in all probability no harm results to humans from the application of printing inks with TPO in accordance with their intended use.

Furthermore, the latest additions to the list are unusual in that substances are usually only placed on the SHVC list when they have been reclassified on the basis of their characteristics. The TPO reclassification from its current category Repr. 2 to the new Repr. 1B⁹ is to be expected – this time, however, we have an unprecedented situation of a substance appearing on the list without a complete reclassification.

It remains to be seen how the classification of TPO will develop in future. If there is a change in classification we will of course fulfill our information requirements again.

We are constantly assessing reclassifications of substances as well as possible new formulations (change in raw materials), new developments and product cancellations, even before urgent action is required. All of our UV inks, developed since 2015, are already TPO-free. At the moment there are few alternative substances to TPO available, and these offer substantially less effective qualities.

For these reasons we will not be phasing out use of TPO for the time being.

We will inform you of any new developments immediately on our website.

If you have questions or concerns, we are happy to provide further information.

Thank you for your attention.

Printcolor AG, November 2023

⁷ Ordinance of the Federal Department of Home Affairs on materials and articles intended to come into contact with foodstuffs

⁸ European Printing Ink Association suitability list of photoinitiators and photosynergists for food contact materials

⁹ There is a REACH registration (REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals) for TPO as well as a harmonized classification under the CLP regulation (CLP – classification, labeling and packaging of substances and mixtures), Annex 6. The current CMR classification for TPO is Repr. 2, H361f (substance is a reproductive toxic agent, suspected of damaging fertility), and the new classification Repr. 1B (substance is a reproductive toxic agent, may damage fertility and/or the unborn child).