

Questions and Answers on the EuPIA Exclusion Policy for Printing Inks and Related Materials

It is recommended that the [EuPIA Exclusion Policy](#) be consulted in conjunction with this Q&A for a full understanding.

Q1. Why is there a EuPIA Exclusion Policy?

The European Printing Ink Association (EuPIA) promotes the highest possible standards of health and safety in its self-regulating Exclusion Policy, protecting workers and end users by excluding the most hazardous raw materials from printing ink formulations.

After several revisions and due to the introduction of the Regulation (EC) No 1907/2006 of 18.12.2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) which reinforces the risk assessment approach, the EuPIA Technical Committee decided to replace the previous Exclusion List by a new Exclusion Policy, which maintains the hazard-based approach from the former list and introduces more elements of exposure-based risk assessment and management which shall apply in cases where an existing raw material is re-classified in line with more recent scientific evidence and thus fulfils exclusion criteria. For these raw materials, rules are defined on how the procedures of substitution may be handled or, if not replaceable in the short term, under which circumstances a safe continued use may be possible (time limited where appropriate). In this way negative impacts on customers' processes or business continuity can be mitigated, whilst still striving to uphold the highest standards of health and safety.

Q2. How are members informed about the new classification of a substance?

EuPIA members may receive the information on a new substance classification by different channels. It could be an information letter or an updated Safety Data Sheet (SDS) from (a) supplier(s), information on a legislative proposal, or an official information from EuPIA or National Associations or from European or national authorities.

Q3. When does the 6 months substitution period start?¹

Members shall launch the substitution process when the most reliable suppliers begin to use the classification, or when a legislative proposal (draft ATP amending CLP Annex VI) receives a favourable vote in the REACH Committee, whichever comes first. In general, the EuPIA Secretariat will formally confirm the start of the substitution period according to the EuPIA Exclusion Policy to all EuPIA members and affiliated National Associations.

¹ Affected printing inks or related products will be re-classified and re-labelled according to the CLP Regulation, irrespective of the timing of substitution.

Q4. What happens when the recommended 6 months transition period is over?

As the Exclusion Policy is a self-commitment of the EuPIA members, there is no legal obligation to stop the use of the concerned raw material after the 6 months recommended period.

However, if after technical investigation, it is found impossible to replace a raw material in the short term for (a) specific application(s), the Exclusion Policy temporarily allows for continued use provided that safe use can be demonstrated by adequate risk assessment.

In such cases, an exemption notification must be addressed in written form by EuPIA members to the EuPIA Secretariat. This application for exemption has to be done by each individual EuPIA member company who requires additional time for finalizing the substitution.

Q4.1 Is the printer involved in the risk assessment?

The involvement of a printer in the process of assessing the risk of exposure may be individually decided by an ink manufacturer, case by case depending on the exposure scenario which has to be assessed. However this does not replace the obligation for the printer to do his own risk assessment.

Q4.2 Is the printer notified of the results?

Ink manufacturers have an obligation – already by chemical legislation – to describe the conditions under which their material can be safely used downstream, and to propose risk management measures. This information shall be communicated to the printers by the means of an updated SDS or other equivalent document.

Q5. How will customers be informed about any extension of the substitution period?

It is the responsibility of each individual EuPIA member to inform its own customers.

For a substance belonging to the Group A exclusion criteria, this will be added, after approval of the exemption by the EuPIA Technical Committee, in the Annex 2 of the Exclusion Policy with a description of the scope of the exemption, i.e. final application, maximum concentration in the finished product, etc.

For a substance belonging to the Group B exclusion criteria, approval of the exemption application by the EuPIA Technical Committee is not required. By consequence the customer information has to be done by the individual company who has applied for the exemption to the EuPIA Secretariat.

Q6. What happens when a substitution is found within 6 months but the printer needs more time to qualify the new products?

In order to allow the printer to finalize the qualification of the new product free of the excluded substance, the ink supplier has the possibility to apply the same exemption notification as described in Q4.

Q7. Is it possible for printers to use remaining stocks still containing the excluded substance after the end of the substitution period?

Printers have no legal obligation to follow the EuPIA Exclusion Policy.

However they have to fulfil their legal obligations with regards to the chemical regulations, including applying the risk management measures recommended by the ink manufacturer in the safety data sheet of their concerned products, and assessing the risks to the end users of printed material.

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