



EXCLUSION POLICY FOR PRINTING INKS AND RELATED PRODUCTS

4th Edition

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Introduction

Since 1996 the printing ink industry in Europe has been committed to compliance with a voluntary common list for the exclusion of certain raw materials (substances and mixtures)¹ from printing inks and related products. This exclusion list of raw materials has been based on hazard classification and/or toxicological evidence available at the time, to protect the health of workers within the printing ink industry and customer facilities as well as to ensure the safe use of printed matter. Based on advances in scientific knowledge it has been progressively updated and maintained in force to grant a consistent safety level at all stages of printing ink manufacturing and use.

Although this hazard-based voluntary approach has been of considerable benefit to printing ink manufacturers, printers and their customers, it is being increasingly superseded by the management of risks from chemicals under REACH². In time, all substances will have been assessed and the most hazardous will be subject to appropriate regulatory controls in Europe; however EuPIA's approach has continued value and has been adapted to ensure it remains fit for purpose.

This industry initiative has been launched and is coordinated by EuPIA, nevertheless it is the individual companies – and not EuPIA as an industry association – that commit to the Exclusion Policy defined in this document.

EuPIA member companies committing to the Exclusion Policy will be listed on the EuPIA website eupia.org.

Principles

The Exclusion Policy concept is applied according to the following principles:

1. The EuPIA Exclusion Policy applies to the manufacture and supply in Europe³ of all types of printing inks⁴ and related products, for use in any application and on any substrate. (Note that for certain applications, further requirements may also apply in addition to the Exclusion Policy.)
2. Although the EuPIA Exclusion Policy does not impose any legal obligations, it has the full support of all EuPIA members. New EuPIA members are strongly encouraged to commit to the Exclusion Policy and will be granted a transitional period of six months to implement it in their operations if they do so. Printing ink manufacturers who are not members of EuPIA are also invited and encouraged to apply the criteria of the Exclusion Policy.
3. The EuPIA Exclusion Policy is supplementary to relevant legislation, and any regulatory control over a substance (e.g. an authorisation or restriction under REACH) will take precedence over the following principles.
4. Raw materials¹ excluded by the Policy, and which must therefore be avoided in the formulation of printing inks, are those substances or mixtures classified in one or more of the CLP hazard classes/categories listed in **Group A and Group B** on the following page. Such materials are considered to represent a risk to health under normal established and foreseeable conditions of use in the manufacture and application of printing inks.
5. Furthermore, the substances in Groups C to G (listed in Annex 1) are excluded for intentional use regardless of whether or not they fall under the hazard criteria of Group A or B as per point 4 above.

¹ Raw materials used in printing inks and related products can be single substances, or mixtures of substances, according to the definition set in Article 2 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('CLP').

² Regulation (EC) No 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals

³ EU, EEA, EFTA

⁴ including digital inks

6. When a raw material currently used becomes included in one of the categories in this Exclusion Policy by reason of re-classification, by default EuPIA members are expected to substitute this material as soon as practicable. A time frame of six months is normally regarded as appropriate.
7. If, after technical investigation, it is found not to be possible to replace a raw material in the short term for a specific application, a temporary exemption from substitution can be granted according to the following rules:
 - a. For hazards listed in **Group A**, the explicit approval of the EuPIA Technical Committee is required. A list of exemptions approved under this procedure is provided in Annex 2 to this document.
 - b. For hazards listed in **Group B** (only), it shall be the responsibility of the individual member company to conduct risk assessment and to demonstrate safe use.
8. Members shall report any use of the exemption procedure in 7a or 7b to the EuPIA Secretariat, who will collate these notifications. Exemptions shall be subject to a default maximum period of one year, monitored by the EuPIA Secretariat and renewable only a maximum of two times, if appropriate justification has been provided.
9. The majority of raw materials used in printing inks are produced under commercial industrial conditions and may contain unavoidable impurities, mostly in small quantities. As some of these impurities may be subject to the criteria of the Exclusion Policy, every effort is made with the supply chain to ensure that they are at a minimum level.
10. For specific technical and performance reasons it may be necessary, in an individual ink, to use a raw material that contains a substance listed in Annex 1 or classified according to Group A or B. The exemption procedure above must be applied unless the concentration of the substance in the raw material is below the limits at which the raw material will be classified and labelled as per point 4 above.
11. Any decision to use a raw material according to paragraphs 7-10 shall be made only:
 - if no suitable alternatives are available or applicable
 - after an appropriate risk assessment has been carried out on the ink manufacturing process
 - after an indicative assessment has been carried out on the application of the ink and end use of the printed product, with risk management advice provided to customers as appropriate.
12. The current criteria of the Exclusion Policy are not retrospective: substances already excluded under previous rules cannot be re-introduced under the above rules.
13. The EuPIA Exclusion Policy, including approved exemptions, will remain under regular review by the Technical Committee and may be amended, where appropriate, in the light of new data on safety, health and environmental matters.

Exclusion criteria

Substances and mixtures classified in the following hazard classes/categories⁵, shown with their respective hazard statement codes, are excluded as raw materials for the manufacture of printing inks and related products supplied to printers:

⁵ Applies both to harmonised classifications contained in CLP Annex VI Table 3 and to self-classifications assigned in accordance with Annex I to the CLP Regulation.

GROUP A

Acute Toxicity Cat. 1 & 2 [H300, H310, H330]

Acute Toxicity Cat. 3 (inhalation)
[H331]

Carcinogen or Mutagen Cat. 1A & 1B
[H350, H340]

Toxic to Reproduction Cat. 1A & 1B [H360]
(non-threshold substances)

STOT Single Exposure Cat. 1 [H370]

GROUP B

Acute Toxicity Cat. 3 (oral, dermal)
[H301, H311]

Toxic to Reproduction Cat. 1A & 1B [H360]
(if threshold exists)

STOT Repeated Exposure Cat. 1 [H372]

Operating Rules and Procedures

1. EuPIA complies with European competition rules and will therefore share commercial information only in aggregated and anonymised format to Member Companies, which should refrain from engaging in any discussions on their company-specific data.
2. Access to confidential information contained in application or notification files is restricted to the EuPIA Secretariat and will not be shared with the Technical Committee and/or with EuPIA members (or non-members) in any way.
3. The name of the companies submitting an exemption notification/application or requesting a renewal of their exemption, as well as the details of these individual notifications/applications/renewal requests will not be shared with EuPIA members.
4. A member wishing to apply for an exemption for a group A substance, is invited to submit the application file to the EuPIA secretariat in an anonymised format. The secretariat will share the anonymised file with the EuPIA Technical Committee for their review and approval.
5. The Secretariat reports regularly to the EuPIA Technical Committee about the status of temporary exemptions in an aggregated and anonymized way.
6. The members of the EuPIA Technical Committee will declare their independence, impartiality and respect for the confidentiality of information provided.
7. An appeal mechanism is established in the event companies would want to challenge a negative decision taken by the Technical Committee for exemption or renewal.

**Annex 1: substances explicitly excluded for intentional use
(irrespective of hazard classification)**

Group

C. Pigment colorants based on and compounds of antimony⁶, arsenic, cadmium, chromium (VI), lead, mercury, selenium.

D. Dye colourants:

| | | |
|-----------------|------------------|-----------|
| Auramine | (Basic Yellow 2 | CI 41000) |
| Chrysoidine | (Basic Orange 2 | CI 11270) |
| Fuchsine | (Basic Violet 14 | CI 42510) |
| Induline | (Solvent Blue 7 | CI 50400) |
| Cresylene Brown | (Basic Brown 4 | CI 21010) |

Other soluble azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of Category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008.

E. Solvents:

2-Methoxyethanol
2-Ethoxyethanol
2-Methoxyethyl acetate
2-Ethoxyethyl acetate
Monochlorobenzene
Dichlorobenzene
Volatile chlorinated hydrocarbons, such as trichloroethylene, perchloroethylene and methylene chloride
Volatile fluorochlorinated hydrocarbons
2-Nitropropane
Methanol

F. Plasticisers:

Chlorinated naphthalenes
Chlorinated paraffins
Monocresyl phosphate
Tricresyl phosphate
Monocresyl diphenyl phosphate

G. Various compounds:

Diaminostilbene and derivatives
2,4-Dimethyl-6-tertiary-butylphenol
4,4'-Bis(dimethylamino)benzophenone (Michler's Ketone)
Hexachlorocyclohexane

⁶ With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified and labelled as per the exclusion criteria.

Annex 2: exemptions approved by EuPIA Technical Committee under this Policy

1. **Formaldehyde** in micro-encapsulation for scent varnishes, provided that the residual formaldehyde content does not exceed 0.5% w/w in the microcapsules and 0.1% w/w in the final varnish (determined according to EN ISO 14184-1).