EXCLUSION POLICY FOR PRINTING INKS AND RELATED PRODUCTS

7th 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has been of considerable benefit to printing ink manufacturers, printers and their customers, it is being increasingly superseded by the management of risks from chemicals under REACH[2]. 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 https://www.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 Europe[3] of all types of printing inks[4] 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. 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.

3. Raw materials[1] 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.

4. 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 3 above.

5. 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.

6. 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:

[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

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 included 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.

Members shall report any use of the exemption procedure in 6a or 6b 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.

7. Under exceptional circumstances, specific exemptions for Group B substances for specified applications may be extended for time periods exceeding three years, where there is sufficient justification. This justification procedure includes the comprehensive review of risk assessment dossiers (prepared by the exemption applicants) by the Exclusion Policy Advisory Panel (EPAP). These exemptions will continue to be monitored and reviewed on a regular basis. A list of exemptions approved under this procedure is included in Annex 2 to this document

8. 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.

9. For specific technical and performance reasons it may be necessary, in an individual ink, to use a raw material that <u>contains</u> 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 3 above.

10. Any decision to use a raw material according to paragraphs 6-9 shall be made <u>only</u>:

- 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.

11. The current criteria of the Exclusion Policy are not retrospective: substances already excluded under previous rules cannot be re-introduced under the above rules.

12. 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/categories[5], 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	GROUP B
Acute Toxicity Cat. 1 & 2 [H300, H310, H330]	Acute Toxicity Cat. 3 (oral, dermal) [H301, H311]
Acute Toxicity Cat. 3 (inhalation) [H331]	Toxic to Reproduction Cat. 1A & 1B [H360]
Carcinogen or Mutagen Cat. 1A & 1B [H350, H340]	STOT Repeated Exposure Cat. 1 [H372]
STOT Single Exposure Cat. 1 [H370]	Endocrine Disruptor for Human Health Cat.1 [EUH380]

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 antimony[6], 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 andmethylene 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

Please note:
These time-limited exemptions are granted only to EuPIA member companies formally committed to the Exclusion Policy and who have successfully completed the exemption application procedure, with the explicit approval of EuPIA's Technical Committee.
These are not exemptions for general use by EuPIA members.

1. Butyl Glycol (CAS #111-76-2, Group A substance, see paragraph 6a)

2. Benzophenone (CAS #119-61-9, Group A substance, see paragraph 6a)

3. N-Vinyl Caprolactam for use in digital inks (CAS #2235-00-9, Group B substance see paragraph 7), for those members who have had their dossier approved by the EPAP (January – March 2023). This exemption has a final expiry date of 31st December 2025.[7]

4. Solvent Black 29 dye for use in digital inks, (covering all substances, which after a thorough evaluation of the chemical structure are falling under the description of Solvent Black 29 e.g. CAS Numbers 117527-94-3 and related EC numbers, as well as EC 938-781-3, Group B substance see paragraph 7), for those members who have had their dossier approved by the EPAP (January – March 2023). This exemption has a final expiry date of 31st December 2025. Applications from members submitted after March 2023 may also be considered for inclusion in this exemption.[7]

ANNEX 3

Exemptions for substances with occupational concern (Inhalation exposure to Poorly Soluble Particles)

No substance falling under this hazard category is currently used.

By default raw materials classified as STOT Single Exposure Cat. 1 [H370] and STOT Repeated Exposure Cat. 1 [H372] should not be used in printing inks.
However, Poorly Soluble Particles (PSP) are considered to have low systemic toxicity due to missing bioavailability. The effects observed include a pulmonary immune response triggered by particles, wherein the deposited dose overwhelms clearance from the alveolar region, reducing the lung's ability to remove particles. There is ongoing scientific discussion on whether the exposure to particulate matter through inhalation justifies a STOT-RE hazard classification. The EU CLP Regulation does not explicitly acknowledge "lung overload," making classification of observed effects challenging.

As long as Occupational Exposure Limits listed in the Explanatory note are respected the use of such substances is possible. Regular checks at EuPIA's ETC will take place.

[7] *Note: Digital / ink-jet inks are usually developed jointly together with the equipment manufacturers' printhead and application technology and tailored to have specific characteristics to meet precise performance requirements and tolerances. This results in more extensive challenges to substance substitution, from both the ink technology itself and the equipment perspective, in comparison with other printing processes.*