

EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS

7th Revised Edition

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April 2011 (corrigendum November 2011)

EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS

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 preparations/mixtures)¹ from printing inks and related products. This exclusion list of materials has been based on health and safety matters in the day-to-day production and marketing of printing inks and associated products employing Good Manufacturing Practices, wherever they are manufactured.

Although this concept is of considerable benefit to printing ink manufacturers, printers and their customers, the following comments need to be emphasised to practically apply the concept.

- 1. Exclusion lists based on selection criteria and individual assessment have been widely used by printing ink manufacturers and their customers. Although they are recommendations and do not have legal obligations, the EuPIA Exclusion List has the full support of all of its printing ink manufacturer members.
- 2. The raw materials excluded by the present list are substances or preparations/mixtures previously used or relevant in the formulation of printing inks that must be avoided in consideration of the selection criteria (sections A to C) or the substances list (sections D to G) and which under normal established and foreseeable conditions of use in the manufacture and application of printing inks would cause a risk to health.
- 3. 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 on the exclusion list, every effort is made to ensure that they are at a minimum level.
- 4. It may be necessary, in an individual ink, to use a raw material that contains a substance classified and labelled T, Toxic according to DSD or classified for acute toxicity category 1, 2 or 3 or STOT SE 1 or STOT RE 1 and labelled with the Hazard Statements H300, H301, H310, H311, H330, H331, H370 or H372 according to the CLP Regulation, for particular technical and performance reasons. Note: this exception does not apply to raw materials that are so classified and labelled, which are already excluded by Point 2 above.

A decision to use a raw material in this category is only made

- if no suitable, alternative raw materials are available
- after an appropriate risk assessment has been carried out on the ink manufacturing process
- after a risk assessment has been carried out, in conjunction with the converter, on the application and end use of the printed product.
- 5. When a raw material currently used becomes included in one of the categories in this Exclusion List by reason of re-classification, then EuPIA members are required to substitute this material as soon as practicable. A time frame of six months is normally regarded as appropriate.
- 6. The EuPIA Exclusion List will be under frequent review by the Technical Committee and may be amended, where appropriate, in the light of new data on safety, health and environmental matters.

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¹ According to the definition set in Article 2 of the CLP Regulation (EC) No 1272/2008

The following categories (selection criteria) and individual substances (substances list) are excluded as raw materials for the manufacture of printing inks and related products supplied to printers:

SELECTION CRITERIA

- A. Substances and preparations/mixtures classified carcinogenic, mutagenic and toxic for reproduction category 1 and 2 and labelled as toxic (T) according to the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC with risk phrases R45, R46, R49, R60, R61 or classified for carcinogenicity, germ cell mutagenicity and reproductive toxicant category 1A and 1B and labelled with the Hazard Statements H340, H350 and H360 according to Annex I to the CLP Regulation (EC) No 1272/2008²
- B. Substances and preparations/mixtures classified and labelled as very toxic (T+) or toxic (T) according to the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC with risk phrases R23, R24, R25, R26, R27, R28, R39, R48 combined with any of the R23, R24, R25, R26, R27 or R28 or classified for Acute Toxicity Category 1, 2 or 3 or STOT SE 1 or STOT RE 1 and labelled with the Hazard Statements H300, H301, H310, H311, H330, H331, H370 or H372 according to Annex I to the CLP Regulation (EC) No 1272/2008².
- C. Pigment colourants based on and compounds of antimony³, arsenic, cadmium, chromium (VI)[,] lead[,] mercury, selenium.

SUBSTANCES LIST

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 1 and 2 according to Directive 67/548/EEC or category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008.

² This criterion applies both to harmonised classifications contained in CLP Annex VI, Table 3.2 or Table 3.1 and to self-classifications assigned in accordance with Annex VI to the Dangerous Substances Directive or Annex I to the CLP Regulation.

³ With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified nor labelled as T or T+.

E. Solvents

2-Methoxyethanol 2-Ethoxyethanol 2-Methoxyethyl acetate 2-Ethoxyethyl acetate Monochlorobenzene Dichlorobenzene

Volatile chlorinated hydrocarbons, such as trichloroethylene, perchlorethylene 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 Tetramethyldiaminobenzophenone (Michler's Ketone) Hexachlorocyclohexane

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