

## General Regulatory Statement - Liquid Ink and Coating Products

Please find below a general regulatory statement covering Sun Chemical liquid ink and coating products intended for use on food packaging in indirect contact scenarios.

### **The general food packaging safety 'framework' Regulation (EC) No 1935/2004 of the European Parliament (Materials and articles intended to come into contact with food)**

This regulation refers specifically to food contact materials and articles rather than to inks and associated coatings. Key requirements are:

*Article 3* (General Requirements) requires that 'Materials and articles .... shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food which could:

- a) Endanger human health.
- b) Bring about an unacceptable change in the composition of the food.
- c) Bring about deterioration in the organoleptic characteristics thereof.

*Article 17* (Traceability) of Regulation (EC) No. 1935/2004 requires:

- a) The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
- b) ... systems and procedures to allow identification of the business from which and to which materials or articles and, where appropriate, substances or products covered by this regulation and its implementing measures used in their manufacture are supplied.
- c) The materials and articles which are placed on the market in the community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Although the regulation refers to the finished packaging, component suppliers obviously have an important role to play in its overall attainment.

To this end Sun Chemical uses the following criteria and procedures:

#### **EuPIA (CEPE) Exclusion List**

- Sun Chemical products are formulated in accordance with this list as per the latest issue of October 2009. This excludes the use of:

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 VI to the CLP Regulation (EC) No 1272/2008

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 VI to the CLP Regulation (EC) No 1272/2008

c) Pigment colourants based on and compounds of antimony, arsenic, cadmium, chromium (VI), lead, mercury, selenium.

The use of certain dyes, solvents, plasticisers and miscellaneous materials is also excluded. A copy of the document is accompanies this document.

#### **Odour and Taint**

- Materials are selected for their low odour and taint potential from reputable suppliers with an understanding of the requirements of general packaging regulations.

#### **Heavy Metals and other substances:**

##### **Council of Europe Resolution AP 89(1) on the use of colorants in plastic materials coming into contact with food.**

Pigments used for food packaging meet the purity criteria and requirements of the Council of Europe Resolution AP 89(1).

Limits on metals and metalloids soluble in 0.1% hydrochloric acid as a percentage of the actual colourant will not exceed the following levels:

Antimony 0.05%; Arsenic 0.01%, Barium 0.01%; Cadmium 0.01%; Chromium 0.1%; Lead 0.01%; Mercury 0.005%; Selenium 0.01%.

##### **Directive 88/378/EEC on the Safety of Toys and associated European norm BS EN 71.**

Except in very specific and disclosed circumstances, colorants used in food packaging inks are non-bleed pigments which are also suitable for use as colorants in toys as per the Directive 88/378/EEC on the Safety of Toys and the associated European norm BS EN 71. The level of impurities (soluble in 0.1 M hydrochloric acid) in the dried ink will not exceed: Antimony (Sb) < 125 ppm, Arsenic (As) < 25 ppm, Cadmium (Cd) < 25 ppm, Chromium (Cr VI) < 50 ppm, Lead (Pb) < 50 ppm, Mercury (Hg) < 12 ppm, Selenium (Se) < 50 ppm.

- We refer also to the section below concerning the **Packaging and Packaging Waste Directive 94/62/EC** (a combined total of 100ppm specified heavy metals (cadmium, chromium (VI), lead or mercury).
- The individual heavy metals specified in 94/62/EC and their combined limit is identical to those used by the USA via the CONEG Regulation.

In support of the traceability requirement of Article 17, Sun Chemical

- Is ISO 9001 accredited and subject to regular external audit.
- Manufactures according to the general principles of good manufacturing practice.
- Uses procedures including batch traceability of raw materials and of finished products, and unique product and batch codes. Intermediates and finished products are batch tested.

Sun Chemical products are thus formulated so to support compliance of the finished food packaging material with the above regulation.

**Commission Regulation (EC) No 2023/2006 - on good manufacturing practice for materials and articles intended to come into contact with food.**

This legislation applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

The Annex refers to processes involving the application of printing inks to the non-food contact side of a material or article.

Sun Chemical products are manufactured in accordance with the EuPIA "Good Manufacturing Practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food (GMP)"

Sun Chemical Ltd has supporting ISO 9001-accredited quality systems, procedures and batch traceability as outlined above.

**Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.**

**Plastics Directive 2002/72/EC as amended up to and including 2008/39/EC and Regulation (EC) No 975/2009.**

Although the European Commission have confirmed the above legislation to relate to plastic packaging rather than to inks and their associated coatings, Sun Chemical can, following the signing of a confidentiality agreement, provide a statement of composition covering products supplied so as to support packaging manufacturers in meeting their obligations under the legislation.

Some substances used in coatings but not in plastics particularly certain biocides and surfactants have been subject to the ongoing process of review by EFSA and now have an improved basis for use within the EU. Substances used in coatings continue to be regulated under National Recommendations such as the German BfR (see below).

**The Packaging and Packaging Waste Directive 94/62/EC**, again relating to finished packaging rather than to inks, coatings or adhesives, places restrictions on the levels of heavy metals present in packaging, and requires certain other dangerous substances to be minimised. This results from the need to minimise the environmental impact of packaging waste, particularly when such species are present in emissions or ash when packaging is incinerated or in leachate when packaging is landfilled.

- None of our products intentionally contain those heavy metals (cadmium, chromium (VI), lead or mercury) as specified in the Directive. The total content of these four metals present in a dried ink or coating will be less than the 100ppm limit.
- We do not systematically test our products for heavy metal content but random analyses indicate that typical levels are significantly lower than the 100 ppm limit.

The requirement relating to dangerous substances is elaborated in European Standard EN 13428 *Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction*.

This necessitates determining whether:

- a) any packaging constituents contain substances which are classified according to Annex I of the Dangerous Substances Directive (67/548/EEC) as dangerous for the environment with symbol 'N' (dead fish, dead tree); and,
- (b) whether such substances are likely to be released into the environment from ashes, emission or leachate resulting from incineration or landfilling of the packaging after use.

If conditions (a) and (b) are met, then only the minimum adequate amount of the dangerous substance with regard to its functional purpose is permitted to be used.

- Apart from certain speciality niche products, the only environmentally hazardous substances which are likely to be released into the environment, meeting conditions (a) and (b) above, are the biocides which are used in water-borne products. Biocides are added to prolong the shelf-life of the product by minimising microbiological deterioration. Their use is kept to a minimum consistent with the required technical performance.
- The volume and weight of packaging used for our products is the minimum adequate amount required to maintain the necessary level of safety, technical performance and acceptability for the customer.

As a result, Sun Chemical products will support finished printed packaging materials in meeting with the requirements of Articles 9 and 11 of Directive 94/62/EC.

Printing inks are only one constituent of the final food packaging. As per Regulation (EC) No 1935/2004, printers and converters have a duty to ensure that the finished article is fit for its intended purpose as food packaging and to use good manufacturing practices such as eliminating contamination, using the correct ink and substrate, ensuring adequate drying, avoiding set-off, airing where appropriate etc. If there is any doubt as to the suitability of the product for the intended food packaging application, we would advise that the printer/converter carries out appropriate organoleptic and migration tests on the finished article to ensure compliance with the relevant legislation.

Stephen Hesketh  
Regulatory Affairs and Product Stewardship  
Sun Chemical Ltd  
UK Packaging Division.

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**Disclaimer:** Sun Chemical products are intended for sale to professional users. The information herein is general information designed to assist customers in determining the suitability of our products for their applications. All recommendations are made without guarantee, since the application and conditions of use are beyond our control. We recommend that customers satisfy themselves that each product meets their requirements in all respects before commencing a print run. There is no implied warranty of merchantability or fitness for purpose of the product or products described herein. In no event shall Sun Chemical be liable for damages of any nature arising out of the use or reliance upon this information. Modifications of the product for reasons of improvements might be made without further notice.