



## General Regulatory Statement Liquid ink and coating products

The following general regulatory statement covers Sun Chemical liquid ink and coating products intended for use on food packaging materials where the printed or coated layer is not in intentional long term direct contact with the foodstuff.

### **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) require 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.

This regulation refers to finished materials and articles i.e. the finished packaging. In support of the requirements 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 November 2012. This excludes the use of:

A. Substances and preparations/mixtures classified as carcinogenic, mutagenic or 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 or 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 1272/2008.

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 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 1272/2008.

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 full document accompanies this statement.

### **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 metalloids:**

- Except in specific and disclosed circumstances (typically PMTA-type complexes), the colourants used are non-bleed pigments.
- The limits for the following metals (soluble in 0.1 M hydrochloric acid) in the dried ink is as follows:  
Antimony (Sb) < 60 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 the combined total of the specified heavy metals: cadmium, chromium (VI), lead and mercury will not exceed 100ppm.
- 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.

### **Traceability**

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 (as amended).**

Although the European Commission has confirmed the above legislation relates 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 on-going process of review by EFSA and now have an improved basis for use within the EU. Substances used in certain classes of coatings continue to be regulated under National Recommendations such as the German BfR.

**The Packaging and Packaging Waste Directive 94/62/EC (as amended)** relates to finished packaging rather than to inks, coatings or adhesives and places restrictions on the levels of heavy metals present in packaging and require that 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.

- Sun Chemical liquid ink food packaging products do not 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 as amended

Printing inks are only one constituent of the finished food packaging. As per Regulation (EC) No. 1935/2004, printers and converters have a duty to ensure that the finished material or article is fit for its intended purpose as food packaging and to use good manufacturing practices such as using the correct ink and substrate, eliminating contamination, ensuring adequate drying, avoiding set-off, airing if 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  
Global Regulatory Affairs and Product Stewardship  
Sun Chemical Ltd

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**Disclaimer:** The information contained herein is based upon data believed to be up-to-date and correct at the time of writing. It is provided to our customers (and/or analytical contractors) in order that they are able to comply with applicable food packaging legislation. In particular, customers are under an obligation to carry out a risk assessment under relevant good manufacturing practices (GMP) in line with EU packaging legislation and as a result take adequate risk management measures to protect food consumers.

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.

REGULATORY AFFAIRS AND PRODUCT STEWARDSHIP  
SUN CHEMICAL LIMITED. ELIZABETHAN WAY, NEWHEY, ROCHDALE, LANCASHIRE, UK. OL16 4LE  
REGISTERED OFFICE: 3 HIGH VIEW ROAD, SOUTH NORMANTON, DERBYSHIRE, UK. DE55 2DT  
REGISTERED IN ENGLAND No 02647054