

**June 2021**

## **European General Regulatory Statement Sun**

### **Chemical liquid ink food packaging products**

The following general regulatory statement covers those Sun Chemical liquid ink and coating products intended for general food packaging use.

Please refer to the product technical data sheet for intended end use applications and restrictions.

#### **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.

#### **EuPIA (CEPE) Exclusion Policy**

Sun Chemical products are formulated in accordance with with this exclusion policy as per the latest issue of November 2016.

A copy of the full document accompanies this statement but may also be downloaded from:

[http://www.eupia.org/uploads/tx\\_edm/2016-11-17\\_Exclusion\\_Policy\\_for\\_Printing\\_Inks\\_and\\_Related\\_Products\\_3rd\\_ed.pdf](http://www.eupia.org/uploads/tx_edm/2016-11-17_Exclusion_Policy_for_Printing_Inks_and_Related_Products_3rd_ed.pdf)

Sun Chemical's raw material selection and approval procedures ensure compliance with this policy.

**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 all applicable health and safety laws, regulations, and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in line with EU food contact legislation and as a result take adequate risk management measures to protect food consumers. Since the application and conditions of use are beyond our control the information provided does not represent a guarantee of any kind. The product's performance and its suitability for the customer's purpose depend on the particular conditions of use and the material being printed. 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.

### **Odour and Taint**

- Raw materials are selected for their low odour and taint potential from reputable suppliers with a knowledge of the food packaging end uses in which their product will be used.

### **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.

In line with its position in the supply chain, Sun Chemical products are formulated and manufactured 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 Practice (GMP) Printing Inks for Food Contact Materials".

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)**

The European Commission has confirmed the above legislation to relate to plastic packaging rather than to inks and associated coatings and adhesives.

In line with its position in the supply chain, current EuPIA guidelines and legal requirements on those placing of finished packaging on the market, Sun Chemical supplies adequate information concerning potentially migratable and dual use substances along with the Swiss Ordinance status of the product via a statement of composition (SOC). These formulation-specific documents are available to customers following the signing of Sun Chemical's mutual confidentiality agreement.

The 15th Amendment has reduced the SML (Specified Migration Limit) of 22 Primary Aromatic Amines (PAAs), associated with azo pigments, which are listed in entry 43 of Appendix 8 of the REACH regulation, from 10ppb to 2ppb. Sun Chemical applies this new lower limit for PAAs on its SOC's.

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**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 specific heavy metals present in packaging and additionally require that certain dangerous substances be minimized. This results from the desire to minimize 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.
- Sun Chemical does not systematically test its products for heavy metal content but random analyses indicate that typical levels are below 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 the CLP Regulation (1272/2008) and its amendments as dangerous for the environment with pictogram (dead fish, dead tree).
- 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 in certain specialty products, the main environmentally hazardous substances which are potentially 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 minimizing microbiological deterioration. Their use is kept to a minimum consistent with the required technical performance.
- Please consult the Sun Chemical products safety data sheet concerning disclosable levels of biocides or other potentially environmentally hazardous substances.
- 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.

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**Heavy metals and metalloids:**

- Except in specific and disclosed circumstances (e.g. PMTA-type complexes and food dyes), 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

- Please also refer to the section 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.
- CONEG Regulation - This US legislation identifies the same heavy metals as does 94/62/EC. The combined 100ppm limit is also the same.

Printing inks and associated coatings are only constituents of the finished food packaging. As per Regulation (EC) No 1935/2004, printers, converters, packers and brand owners 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 appropriate packaging design and structures, minimising contamination, using the correct ink and substrate, ensuring adequate drying 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.

On behalf of Sun Chemical Neil Terry



Regulatory Affairs and Product Stewardship Sun  
Chemical Ltd.

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