

European Regulatory statement for SunPak FSP EcoPace inks (FEPxx, FEBnn)

Intended use:

SunPak FSP EcoPace is a series of low migration sheetfed offset process and base inks for sensitive (food, cosmetics, healthcare, pharmaceutical and tobacco) packaging, suitable for paper and board designed for modern high speed printing presses in all formats.

Please refer to the specific product technical data and regulatory information for more detailed intended end use applications and / or restrictions.

Regulation (EC) No 1935/2004 of the European Parliament (Materials and articles intended to come into contact with food)

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:

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

Although this regulation refers to the finished packaging, component suppliers have an important role to play in its overall attainment. In order to meet the requirements of Regulation (EC) No 1935/2004 Sun Chemical observes the following criteria:

- Materials are selected for their low odour and taint potential from reputable suppliers with an understanding of the requirements of food contact regulations and who are aware of the importance of good manufacturing practice in assuring odour and taint remains within acceptable limits.
- Sun Chemical is ISO 9001 accredited and, in addition to the above, we manufacture according to the principles of good manufacturing practice (see comments under Article 17) including tests on incoming raw materials and on finished products. These measures, combined with converter and end user tests on the finished printed articles, ensure the organoleptic requirements of the directive are met.

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.

- Sun Chemical products are manufactured in accordance with good manufacturing practices.
- Sun Chemical fully implements EUPIA Good Manufacturing Practice (GMP) at all sites manufacturing inks intended for food contact applications to ensure we formulate and produce inks to allow the production of compliant Food Contact Materials.
- Our raw materials screening and approval process follows the principles outlined in section 7.3.1 of the EUPIA Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials (4th version March 2016).

EUPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in Printing Inks for food contact materials

Where regulatory compliance is required, NIAS with relevant SML or group migration limit values will be shown on a Statement of Composition (SoC). Where no SML or Group Migration Limit values exist then we will employ EUPIA's Risk Assessment process. Where we have used the EUPIA Risk Assessment process then we will indicate in the SoC.

EuPIA (CEPE) Exclusion Policy

Sun Chemical products are formulated in accordance with the latest edition of the EUPIA Exclusion Policy (5th edition, June 2023). Sun Chemical's raw material selection and approval procedures ensure compliance with this policy.

CMRs and ECHA SVHC Substances

This information is valid for the Candidate List found on ECHA's current homepage as well as substances listed on the Authorisation list.

The Sun Chemical stewardship program does not accept listed candidate SVHC's and our products intended for the EU market do not contain any known amounts of Substances of Very High Concern (SVHCs) at more than 0.1% (or the lowest concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification as a SVHC), and which could be subject to potential future authorization process (as outlined in REACH Art 56).

Information on substance use restrictions will continue to be communicated as part of our SDS.

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (as amended up to and including 16th amendment)

This legislation relates to plastic materials and articles rather than to inks, coatings and adhesives. As a consequence certain substances used exclusively in coatings may not be listed in the above legislation. This includes substances listed and approved by EU member state legislation for use in direct food contact materials.

A Statement of Composition (SOC) as per Regulation (EC) No. 10/2011 is provided by Sun Chemical and this includes information on the source and value of substance (s) migration restriction.

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.

Swiss Ordinance

Provided that the SunPak FSP EcoPace range is used according to the information given in the Technical Data Sheet and correctly processed, and provided that the food packaging is designed in a way that there is no intended direct food contact with the print, we hereby confirm that they will allow for compliance of the final product with the Ordinance of the FDHA 817.023.21, Annex 10.

Polyfluoroalkyl Chemicals (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are a large and diverse group of synthetic chemicals that are used in a wide range of consumer and industrial products.

All PFAS are highly persistent in the environment due to their stability and are known to persist longer in the environment more than other synthetic substances. The combination of the prevalence of PFAS usage and their persistence in the environment means that there is an ever-increasing level of environmental contamination, especially in groundwater and drinking water.

The SunPak FSP EcoPace range does not knowingly contain any PFAS chemical.

Nestle St 80.001-01 Printing Inks for Food Packaging

The SunPak FSP EcoPace range fully complies with the conditions outlined by Nestle St 80.001-01 Printing Inks for Food Packaging (Dated 02/04/2024).

Abstract of Nestle Standards on Materials in Contact with Food

The SunPak FSP EcoPace range fully complies with all the applicable sections in the Abstract of Nestle standards on materials in contact with food (Version 6, January 2024).

Mineral Oils

By definition, mineral oil saturated hydrocarbons (MOSH) consist of linear and branched alkanes, and alkyl-substituted cyclo-alkanes. Mineral oil aromatic hydrocarbons (MOAH) include alkyl-substituted aromatic and polyaromatic hydrocarbons.

Article 112 of the French Decree No. 2020-1725 on the 'Fight Against Waste and the Circular Economy' regulates the use of mineral oil on packaging and free advertising. The article prohibits mineral oil containing substances that interfere with waste recycling and provides the following definitions:

MOH = Mineral Oil Hydrocarbons

MOAH = Mineral Oil Aromatic Hydrocarbons consisting of 1 to 7 aromatic cycles

MOSH = Mineral Oil Saturated Hydrocarbons consisting of 16 to 35 carbon atoms

The first restrictions come in from 01/01/2023 and run till 01/01/2025 wherein MOH containing more than 1% of MOAH is banned. Then from 01/01/2025 MOH containing more than 0.1% of MOAH (1-7 aromatic cycles) (or more than 1 ppm of MOAH (3-7 aromatic cycles)) or more than 0.1% of MOSH (C16-C35) is banned.

To the best of our knowledge, the SunPak FSP EcoPace range is fully compliant to the thresholds for MOSH and MOAH for 2023 and 2025.

Whilst the French mineral oil decree does not provide clear guidelines for testing and certifying compliance, there are ongoing efforts to develop better analytical techniques that can accurately determine compliance to the French requirements. However, there are still limitations in existing analytical techniques which can make it difficult to accurately test for compliance. Therefore, in the absence of a reliable testing method, our compliance with the decree is based on declarations from our raw material suppliers and the chain of custody approach wherein their information is based on information they have received from upstream.

Moreover, there are no analytical methods currently able to determine the source of any substances that are detected that are chemically identical to MOSH/MOAH (e.g., rosin and rosin derivatives, PE waxes, polyolefin saturated hydrocarbons (POSH), etc.), which can lead to misidentification of substances from non-mineral oil sources as MOSH/MOAH.

Finally, whilst other mineral oil regulations cover mineral oils on printed products and packaging, the French decree is only focussed on the mineral oil content of printed inks. Therefore, if a MOSH/MOAH substance is detected in the testing of a printed product, it would not be possible to determine whether the ink or the substrate or another component was the source.

Discussions are underway between AFEI (the French ink association) and the French authorities to resolve this and which will hopefully provide more clarity regarding these points.

Due to their ubiquitous use in industry and beyond, the presence of traces of mineral oils arising from impurities, or from processing or other adventitious contaminants cannot be excluded.

Food Allergens (as per EU Directive 2003/89/EC as amended)

The above listed products in the SunPak FSP EcoPace range do not knowingly contain any allergens present within 2003/89/EC.

Additional specific allergens statements are available if requested.

Packaging and Packaging Waste Directive 94/62/EC (as amended)

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.

- The above listed products in the SunPak FSP EcoPace range 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 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.

Printed Packaging Compliance

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

Callum Parkins
Global Regulatory Affairs and Product Stewardship
Sun Chemical Ltd.

May 2024

Disclaimer:

Sun Chemical products are intended for sale to industrial 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.

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