

## September 2023

### Regulatory information note on perfluoroalkyl 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.

One potential source of PFAS (depending on the definition used) are PTFE-based waxes used in inks, coatings and varnishes to protect the printed surface from damage when in contact with other surfaces, by providing slip properties and excellent rub and scratch resistance. Whilst PTFE wax does not have the same toxicity concerns as some other PFAS, they still retain the same issues regarding persistence.

It should be noted that the supply and use of these waxes continue to comply with all current EU chemicals legislation including the REACH Restriction for perfluorooctanoic acid (PFOA) and its salts, and legislation relating to food contact applications, such as the Swiss Ordinance Part A and the Plastics Regulation (EU) 10/2011.

PTFE waxes were widely used in the past in the European printing ink industry. Sun Chemical are actively looking to reformulate to remove PTFE waxes from our products. Sun Chemical will support customers by providing on request details of all intentionally added PFAS, principally PTFE waxes. Sun Chemical is also able to offer ink ranges for many applications that have been reformulated or newly developed that do not intentionally contain PFAS and PTFE waxes.

There may be other less-obvious potential sources for per- and polyfluoroalkyl substances in printing inks, including certain specialised additives that may be present in small quantities (<<1%) in the raw materials that printing ink manufacturers purchase (such as fluorinated pigments). However, fluorine-containing binders, such as FEVE or PVDF-based polymers, are not used in the printing ink sector (unlike the paints and coatings industry, where these are used for long-term durable protective coatings applications).

### PFAS restrictions in Europe

Several PFAS are currently restricted in the EU. Examples include:

- Perfluorooctane sulfonic acid and its derivatives (PFOS) and Perfluorooctanoic acid (PFOA) is restricted under the EU's Persistent Organic Pollutants (POPs) Regulation.
- Perfluorobutane sulfonic acid (PFBS) and its salts, and 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (HFPO-DA) are substances of very high concern under REACH.
- Perfluorooctanoic acid (PFOA), ammonium pentadecafluorooctanoate (APFO) and others have a harmonised classification and labelling under CLP.
- PFAS as a group are limited to 0.5 µg/l under the Drinking Water Directive.

**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.

The national authorities of Denmark, Germany, the Netherlands, Norway, and Sweden have submitted a proposal to ECHA regarding PFAS under REACH. The member states argue that high persistence is the main concern for all PFAS along with concerns resulting from a specific combination of properties. The dossier submitters propose a total ban over time on the use of all PFAS in all applications, which also includes the ban of materials like PTFE wax.

The proposal to restrict all PFAS has gone into a 6-month public consultation period where industry will comment, and which will end on the 25<sup>th</sup> of September. The next steps according to the Restriction Process mean that ECHA's scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) will check the proposed restriction, taking the consultation input into account. Once finalised, the SEAC's opinion, together with the opinion of the RAC will be sent to the European Commission, which will draft the legal text. The Annex XV restriction proposal prepared by the Danish, Dutch, German, Norwegian and Swedish authorities is expected to be adopted and enter into force in 2025.

### **PFAS restrictions in the US**

In the last few years, State laws have been introduced that ban the use of food packaging that contains PFAS as intentionally added substances. State law definitions of "intentionally added" vary, however, most states consider the use of PFAS in packaging or packaging components to achieve a functional effect to be an intentional addition. Sun Chemical inks containing PTFE have this included intentionally, and using a conservative interpretation of the laws, this use of PFAS may fall within the "intentionally added" definition.

The state laws define "packaging" to mean packaging and components of packaging. Thus, in certain states, inks, on the non-food contact side of a package, fall within the definition, however, some states define the term "food packaging" to include only packaging and packaging components that are intended for use in "direct food contact." Only specific Sun Chemical products are recommended for direct food contact. Sun Chemical packaging inks are intended for application to the non-direct food contact surface of the food packaging.

Sun Chemical cannot control how inks are used in food packaging applications by downstream customers. We recommend that customers make their own, independent determinations as to whether their products made with Sun Chemical's inks comply with state PFAS laws.

On behalf of Sun Chemical



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