

General Regulatory Statement – Sunlam Solventbased and Solvent-free Lamination Adhesive Products

The following general regulatory statement covers Sun Chemical Solventbased Lamination Adhesive 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 adhesives and associated coatings. Key requirements are:

Article 3 (General Requirements) requires that 'Materials and articles shall be manufactured in compliance with good manufacturing practice, and following the information/recommendations of the supplier, 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 have a role to play in its overall attainment. To this end Sun Chemical uses the following criteria and procedures:

Exclusion of hazardous materials

Sun Chemical Sunlam Solventbased Lamination Adhesive Products, are formulated to exclude the following categories of raw materials¹:

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, unless evaluated and included in the (EU) No 10/2011 Plastics Regulation Union list.

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. Substances included in the Candidate List as Substances of Very High Concern (SVHC) according to REACH Regulation EC 1907/2006

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.

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;
- Testing for intermediates and finished products.

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

¹ with the exception of the polymer processing aids, which are selected in accordance with the requirements of Council of Europe Resolution AP(92)2 On control of aids to polymerisation (technological coadjuvants) for plastics materials and articles intended to come into contact with foodstuffs.

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 (EC) No 2023/2006 for coatings and adhesives 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.

Although the European Commission has confirmed that the above legislation relates to plastic packaging rather than to inks, coatings and adhesives, Sun Chemical can, following the signing of a confidentiality agreement, provide adequate information (statement of composition) covering products supplied so as to support packaging manufacturers in meeting their obligations under the legislation.

The Packaging and Packaging Waste Directive 94/62/EC, again relating to finished packaging rather than to inks, coatings or adhesives, it 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.

The only environmentally hazardous substances which are likely to be released into the environment, meeting conditions (a) and (b) above, are the catalysts and polymerisation process aids. Where used, they would be indicated both in section 3 of the Safety Data Sheet and also included in the adequate information / Statement of Composition. 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.

Lamination adhesives 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 adhesive and substrate, ensuring adequate drying, curing, 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. Migration risk assessment could involve worst case calculations, migration modelling or migration testing.

Sun Chemical

Regulatory Affairs and Product Stewardship

11 July 2014