

Regulatory Newsletter

This newsletter is intended to provide an information update on important regulatory issues and developments of interest to Sun Chemical customers.



Food packaging update

The long-expected German printing ink ordinance still remains at the internal consultation phase within the German ministries. The ordinance will cover all printed food contact materials, and considers transient food contact applications, such as napkins, as being direct food contact, requiring manufacture using only positively listed substances (listing in the EU Plastics Regulation is also permitted). Inks which do not come into direct contact with food may be manufactured from substances other than those listed, provided that migration from the printed packaging is not detectable (with a detection limit of 0.01 mg/kg food or 10 ppb).

The next step in the process should be notification to the European Commission, which allows other member states to comment on the potential effect of national legislation on the EU market. The packaging supply chain has prepared a number of arguments to be used in discussions with the member states. Industry, together with several member states, has a strong preference for EU-wide regulation, rather than a piecemeal of different national requirements. In view of the ongoing discussions, the ordinance is not expected to be applicable until 2017 at the earliest. In the meantime, Sun Chemical continues to work with suppliers to ensure that key raw materials are evaluated and included in the positive list.

The latest version of the Dutch regulation on packaging and consumer articles coming into contact with foodstuffs, commonly known as the Warenwet, recently came into force. It contains general rules applicable to all food contact materials, followed by material-specific substance lists and restrictions. Although printing inks are not directly covered, coatings, pigments and colorants are specifically included. Risk assessment, in accordance with internationally recognized scientific principles, can be used for non-listed substances; the threshold of toxicological concern (TTC) approach is mentioned as an accepted method. Sun Chemical regularly uses the TTC approach in the risk assessment of substances which lack adequate toxicity data.

The European Commission has issued two new guidance documents for the EU Plastics Regulation. The first covers [information in the plastics supply chain](#), and describes the purpose and content of the Declaration of Compliance, as well as the roles and obligations within the supply chain. Although a Declaration of Compliance is not required for non-plastic intermediates, such as adhesives, coatings and printing inks, the document also provides recommendations on the content of the Adequate Information that is expected to be provided. Sun Chemical provides this information by way of our Statements of Composition, which give details on the components with a potential to migrate from the print. The second document provides more general [guidance on the Plastics Regulation](#), including explanations regarding the scope and definitions, why substances are included or exempted from the Union List,

working for you.

and information on dual-use additives and biocides. Sun Chemical was an active participant in the working group drafting these documents, and ensured that the description of the expectations and obligations for printing inks accurately reflected the legal requirements.

Sun Chemical is pleased to announce that its groundbreaking best practice guide ([Designing Packaging with Certainty: A Best Practice Guide](#)) has been revised and updated to reflect the latest developments. Now in its fourth edition, this brochure has additionally incorporated narrow web energy curing to complement the guidance on conventional and UV and EB curing offset printing for food packaging and other sensitive applications. It assists readers in understanding how to design, produce and store packaging safely with respect to migration of unwanted contaminants, and provides practical ways to minimize the risks.



Suppliers of packaging to Nestlé or Nestec group companies should be aware that key supplier documents were updated in February. The Nestlé standards on materials in contact with food abstract is now at version 3.0, dated 21 February 2014. This document replaces version 2.2 of January 2013 and describes the applicable restrictions for different types of food contact material. Particular attention should be given to packaging for high-temperature applications, where printed materials are only permitted if the temperature of the printed layer does not exceed 100°C and inner printed materials must not be used. Inner printing (direct food contact printing), including ink jet, is only allowed following specific approval by Nestec. The requirements for packaging inks (printing on the nonfood contact surface) are in compliance with (a) the Swiss Ordinance on packaging inks, (b) trade association Exclusion Lists and (c) the Nestlé Guidance Note on Packaging Inks.

This latter document was also updated to version 02-2014, published 21 February 2014, replacing the previous version of February 2012. As well as

general exclusions there are exclusion lists for pigments, photoinitiators, acrylates and solvents, together with lists of acrylates and solvents that should be minimized. Customers using products for Nestlé work should clearly communicate these requirements to their suppliers. Sun Chemical has excellent contact with the Nestlé corporate packaging experts and many years' experience supplying products suitable for Nestlé work.

Changes to substance classifications

A number of important substances used in the manufacture of printing inks are changing hazard classification. These changes will be seen in the Safety Data Sheet, and may also change the classification, labelling and even the packaging of the product itself.

As a consequence of the REACH regulation, a number of raw materials and substances used in the manufacture of energy-curing (UV and EB) products have been subjected to additional toxicological and ecotoxicological testing. The outcome of these tests is that many of these materials, previously not classified for environmental effects, are now being classified as dangerous for the environment. These substance reclassifications carry through into the formulated products, such that a number of these inks and coatings will now be classified as dangerous for the aquatic environment, with the dead fish/dead tree hazard symbol. This hazard means that the product is also considered dangerous for transport, requiring the use of specific UN-approved packaging, limits on combined quantities and the UN3082 transport label.

It is important to remember that the products themselves have not changed, and there will be no difference in performance. The hazardous components are listed in Section 3 of the Safety Data Sheet. In addition, our general advice not to discharge down drains or into watercourses still applies. A number of energy-curing products have been similarly classified as dangerous for the aquatic environment for some years, so you may have already experienced using and handling such materials.

Gold-effect metallic inks are typically formulated with gold "bronze" pigments (though strictly the pigment is an alloy of copper and zinc, i.e., brass). Following testing, copper is now to be classified as harmful and dangerous for the aquatic environment. Zinc already has a dangerous for the aquatic environment classification. According to the European CLP Regulation, alloys are considered to be mixtures, hence the gold bronze pigments must be classified as dangerous for the aquatic environment. This means that the classification of metallic gold inks will also change, and the dead fish/dead tree symbol will appear on the label. The reclassification may alter the transport classification, although if the ink is already classified (e.g., as flammable), the change may not be obvious.

Another substance, N-vinylcaprolactam (NVC), is used as a reactive diluent in a number of our screen and digital UV-curing printing inks. As a result of toxicological testing required for REACH, the classification of NVC has changed from harmful to toxic, due to specific effects on the liver and respiratory tract following repeated exposure. NVC has been assigned a

particularly low Derived No Effect Level (DNEL) for worker inhalation (essentially equivalent to a workplace Occupational Exposure Limit). Sun Chemical has undertaken exposure monitoring and re-examined our risk assessments and control measures to ensure that this material can be used safely. We have informed our customers about this new information and advised them about appropriate handling measures and controls.

Since NVC reacts to form part of the crosslinked print matrix during the UV-curing process, exposure from the cured print should not be a concern. However, because the revised hazard classification now means that NVC falls within the scope of the exclusion criteria of the [EuPIA Exclusion List](#) for printing inks and related materials, Sun Chemical has embarked on a programme to identify alternative materials with a lower hazard. We anticipate that replacement will not be easy, and there are likely to be some differences in technical performance when the alternative products become available.

The Netherlands has informed the European Chemicals Agency (ECHA) of its intention to submit a dossier for a harmonized classification of cobalt and cobalt compounds. The classification proposed is Carcinogenic Category 1B; H350 *May cause cancer* and Reprotoxic Category 1B; H360F *May damage fertility*. The Dutch Competent Authorities consider that in view of the solubility of various cobalt compounds it seems that read-across with respect to the cobalt salt is a logical approach for a harmonized classification. A number of cobalt salts and compounds can be used as driers to promote the development of technical properties in oxidation-drying inks. Sun Chemical recognized the potential toxicological concern regarding cobalt compounds many years previously, and in accordance with its product stewardship principles, removed cobalt driers from product formulations several years ago.

Globally Harmonized System of Classification and Labelling (GHS)

The Globally Harmonized System for Classification and Labelling of Chemicals (GHS) is being implemented by Canada, and this alignment will change WHMIS-related laws (the Hazardous Products Act and Controlled Products Regulations). The final regulations are expected to be published in 2014, with the goal to be in force by June 2015. In force means that suppliers may begin to use and follow the new requirements for labels and safety data sheets (SDS) for hazardous products sold, distributed, or imported into Canada at that time. A transition period is expected, but the dates have not yet been announced. The measure will facilitate international trade, reduce costs to businesses and consumers, and enhance worker health and safety through improved and consistent hazard identification.

Meanwhile, the U.S. Environmental Protection Agency (EPA) is considering changes to the Protection in the Workplace (40CFR721.63) and Hazard Communication Program (40CFR721.72) regulations to align with GHS according to the Hazard Communication Standard (29CFR1900.1200). Classification and labelling according to GHS is required from June 2015 in the U.S. for both substances and mixtures. This date also sees GHS

apply to mixtures within the European Union. Further information regarding national implementation of GHS in different countries is provided in the table.

Sun Chemical is already shipping products classified and labelled in accordance with local GHS legislation to Brazil, China and other Asian countries. We are well prepared for the substantial forthcoming impact of the requirements in 2015 for the U.S., the European Union (mixtures) and other countries. As we approach this deadline, you may begin to see selected product ranges labelled with the GHS red diamond symbols and hazard statements as we start to phase in these changes.

GHS Implementation Dates

Country	Obligatory from		GHS Revision
	Substances	Mixtures	
Australia	1/1/2017	1/1/2017	3
Brazil	27/2/2011*	1/6/2015	4
Canada	Technical consultations ongoing		
China	1/5/2011*	1/5/2011*	2
European Union	1/12/2010*	1/6/2015	4
Indonesia	12/7/2013*	31/12/2016	4
Japan	1/1/2011*	1/1/2011*	4
Korea	1/7/2010*	1/7/2013*	
Malaysia	TBA	TBA	3
Mexico	Voluntary		
New Zealand	1/7/2006*	1/7/2006*	4
Norway	2011*	1/6/2015	4
Philippines	21/3/2014*	21/3/2015	4
Russian Federation	Voluntary		
Serbia	1/10/2011*	1/6/2015	2
Singapore	2012*	mid 2015	4
South Africa	Voluntary		
Switzerland	1/12/2012*	1/6/2015	4
Thailand	12/3/2012*	12/3/2017	3
Turkey	1/6/2015	1/6/2016	3
Uruguay	1/1/2013*	1/1/2013*	
USA	1/6/2015	1/6/2015	3
Vietnam	30/3/2014*	30/3/2016	

*GHS already required

SDS user guide

The Chemical Hazards Communication Society (CHCS) has announced the publication of the second edition of the [Safety Data Sheet \(SDS\) User Guide](#), which is available free of charge on its website. As well as a section-by-section guide to the content of the SDS, the SDS User's Guide also contains useful appendices such as a glossary of common terms and links to further information. This second edition has been thoroughly updated to take account of all the changes that have been introduced by such initiatives as REACH and CLP regulations.

Chemical exposure webtools

The U.S. Occupational Safety and Health Administration (OSHA) has introduced Internet-based tools to help reduce worker exposure to hazardous chemicals. One is a [safer chemicals toolkit](#), which is intended to provide information and guidance to either eliminate hazardous chemicals or make informed substitution decisions in the workplace by finding a safer chemical, material, product or process. A second, [annotated Permissible Exposure Limit \(PEL\) tables](#), provides a side-by-side comparison of different exposure limits: OSHA PELs, California Division of Occupational Safety and Health (Cal/OSHA) PELs, National Institute of Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs) and American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs). Since many of the OSHA PELs have not been updated for many years, they may be inadequate for ensuring protection of worker health. OSHA recommends that employers consider using the alternative occupational exposure limits, because exposures above some of these alternative limits may be hazardous to workers, even when the exposure levels are in compliance with the relevant PELs.

Nanomaterials

Belgium has introduced a national requirement for a nanomaterials register. Individual nanomaterials will have to be registered from January 2016, and mixtures from January 2017. Note that registration is required before placing on the market. Registration of nanomaterials in articles is being considered, subject to evaluation. Fortunately, the Belgian authorities have recognized the issue of pigments potentially being covered by nanomaterial definitions, and have provided a specific exclusion from the scope of the decree; consequently pigments, printing inks and printed or pigmented articles will not require registration.

In response to the growing number of member states considering or implementing nanomaterial registers at national level, the European Commission has launched an impact assessment with the aim of identifying and developing the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials (i.e., whether to have an EU nanomaterial inventory and, if so, in what form). Since the likely administrative burdens could be

very significant, and particularly considering that typical pigments, powders and other ink components are long-established substances with underlying toxicological data to demonstrate safe use, Sun Chemical is working through various trade associations to ensure that any requirements remain proportionate and in accordance with the aims and benefits of such inventories.

The National Institute for Occupational Safety and Health (NIOSH) has issued guidance on the use of engineering measures to control worker exposure, entitled "[Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes](#)." The document provides a summary of available technologies and recommended controls for different processes, including weighing, handling, cleaning and maintenance, as well as information on exposure monitoring and evaluating the performance of the control measures.

Sustainability Report 2013

Sun Chemical has published its [Corporate Sustainability Report 2013](#). It provides information about our sustainability performance and describes the different indicators which reflect the various pillars upon which we build our sustainability. The latest version of the report introduces Eco-Track, a new internal web-based data-collecting system, which enables continuous monitoring, gives more transparency and improves data quality check capabilities of the seven key metrics. A number of renewable and safety projects are highlighted in the report.



For more information on these regulatory issues, please contact the Regulatory Affairs team in [North America](#) or [Europe](#).

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