Regulatory Newsletter

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

Changes to classification, labelling and safety data sheets

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) requires a number of changes to the classification, labelling and Safety Data Sheets for our products in North America and Europe. In order to meet the implementation date of June 2015, Sun Chemical will introduce these changes in production starting in December. The most noticeable impact will be on the label, with the introduction of hazard diamonds replacing the HMIS ratings in the USA, and the orange hazard boxes in the EU. Other changes, including the text of hazards and precautionary measures, will also be seen, following the prescribed wording of GHS. In addition, the GHS classification system uses some different hazard criteria and concentration threshold limits, so new hazards may be indicated on products. Whilst these might cause concern, particularly if a product was previously not classified, it is important to note that the products themselves have not changed, and the new information is a result of the change to the legislation.

The British Coatings Federation is running a CLP webinar for downstream companies in the supply chain on 29th January at midday to explain these changes to mixtures. They are offering a 25% discount to customers of Sun Chemical (please indicate if you are interested). North America will see some differences between GHS implementation in Canada and the U.S. The U.S. implementation is based on the third edition of the UN Purple Book, whereas Canada will follow the latest fifth edition; this will introduce some differences in the precautionary statements. In addition, Canada is expected to require bilingual (English and French) safety data sheets. Canada will also adopt a number of non-GHS hazards that have been adopted by the U.S., e.g., combustible dust.

Multinational customers should note that there is some leeway permitted in the adoption of classification thresholds in GHS, and there are already some significant discrepancies between the EU and the U.S., such that an identical mixture may be classified differently according to each region's implementation of GHS.

The OECD aspires to move to a common classification for substances. A pilot project, covering just four substances, indicates that it is difficult for assessors from different countries to arrive at a common classification, even using the same set of data. This is supported by a recent Japanese study comparing the GHS classification of CMR (carcinogenic, mutagenic or toxic for reproduction) substances in Japan and the EU, which found that nearly one fifth (61/359) were significantly different (classified in one region and not classified in the other). So there is still a long way to go before we have a truly globally harmonized system, but at least we are starting the journey.

working for you.

SunChemical®
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REACH (Registration, Evaluation and Authorisation of Chemicals)

The European Chemicals Agency (ECHA) has indicated that it will use a different strategy for checking the compliance of REACH registration dossiers, based on the experience over the past five years. The most important substances, including those with wide exposures and high volumes, and the critical hazard endpoints, will be prioritised to identify where risk management efforts should be directed.

Another 65 new substances have been added to the 69 previously published in the latest draft of the Community Rolling Action Plan (CoRAP) to be evaluated under REACH between 2015 and 2017. Substances are prioritised for inclusion on the basis of proposals by Member State authorities, reflecting a suspicion or concern about their risks (hazards, volume, exposure potential) with relevance for the health of citizens or protection of the environment in Europe. Inclusion of a substance in CoRAP does not automatically imply any prohibition or restriction on its use, but only that a targeted assessment is required in order to clarify its situation. Substance evaluation can result in a number of different outcomes, including the conclusion that risks are adequately controlled with the measures already in place.

Substance evaluation selection criteria:

Hazard-based criteria	Suspected or known persistent, bioaccumulative or toxic (PBT) substance or very persistent and very bioaccumulative (vPvB) substance or close to meeting criteria or structural similarities
	Suspected endocrine disruptors (reproductive effects, structural similarities)
	Suspected or known carcinogenic, mutagenic or reprotoxic (CMR) substances (or based on structural similarities)
	Suspected or known sensitisers (or based on structural similarities)
Exposure-related criteria	Wide dispersive use
	Number of using sites
	Consumer use and/or exposure of sensitive subpopulations (e.g., children)
	Aggregated tonnage
Risk-related criteria	Risk assessment in the Chemical Safety Report indicates that the Risk Characterisation Ratio (RCR) for human and/or environmental exposure is not significantly below one
	Cumulative exposure from structurally related substances with critical properties

The inclusion of a substance in CoRAP should not be seen as a reason for alarm or immediate action. Sun Chemical actively monitors the evaluation of substances in CoRAP and will take prompt action in the event of any justified concern being identified about the use.

One of the aims of REACH is to reduce testing of chemicals on animals. The Competent Authorities for REACH and CLP (Caracal) recently supported proposals from the European Commission to make skin and eye irritation testing *in vitro* a standard requirement, with *in vivo* testing only in exceptional circumstances. There was also discussion about using in vitro methods to predict skin sensitisation, but many Member States preferred a more cautious approach and the current *in vivo* method was retained.

Alternative validated *in vitro* test methods for irritation and corrosion:

Skin corrosion	Transcutaneous electrical resistance test method (TER)	OECD 430
	Reconstituted human epidermis test method (Rhe)	OECD 431
	In vitro membrane barrier test method	OECD 435
Skin irritation	Reconstructed human epidermis test method	OECD 439
Eye irritation	Bovine corneal opacity and permeability test method	OECD 437
	Isolated chicken eye test method	OECD 438
	Fluorescein leakage method	OECD 460

The European Commission, in cooperation with ECHA, has clarified the relationship between the marketing ban on cosmetics ingredients that have been tested on animals and the REACH information requirements. Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints, with the exception of tests that are done to assess the risks to workers exposed to the substance. Workers, in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users handling cosmetic products as part of their business (e.g., hairdressers). Registrants of substances that are used for a number of purposes, and not solely in cosmetics, are permitted to perform animal testing, as a last resort, for all human health and environmental endpoints. Therefore, the testing and marketing bans in the Cosmetics Regulation do not apply to testing required for environmental endpoints, exposure of workers and noncosmetic uses of substances under REACH. Registrants of substances registered exclusively for cosmetic use will still have to provide the required information under REACH wherever possible, by using alternatives to animal testing (such as computer modelling, read-across, weight of evidence, etc.).

Sun Chemical avoids animal testing wherever possible, and we are working to minimise and eliminate such testing for our use. Our policy is to prevent any unnecessary duplication of testing by relying on information already generated by our supplier industry and recognised organisations. We will only initiate any necessary testing if we have insufficient or suspect information, to allow us to meet our legal obligations, with regard to risk assessment, classification and labelling of our products. Considerable progress has been made in understanding toxicological mechanisms; however, there are still only a limited number of validated alternatives to animal testing at this time. There are no recognised substitutes for the majority of tests for which animals are required. Sun Chemical encourages research into the development of suitable alternatives to animal testing, such as in-vitro assays and the use of cell culture systems. We will

continue to follow developments in toxicity testing that avoids the use of animals, and will encourage the use of such methods where they have been properly validated. Sun Chemical supplies a number of pigment products to the cosmetics industry; these products have not been tested on animals for cosmetics purposes.

Other international chemical legislation

The Turkish version of REACH, known locally as KKDIK, will accept registrations between 31st December 2015 and 31st December 2018, according to the latest draft out for public consultation. Companies exporting chemicals to Turkey can appoint an Only Representative to submit the registration on their behalf, as in the EU. Sun Chemical has two main manufacturing sites in Turkey, and is following these developments closely.

The Australian government has recently announced a number of measures to cut red tape and promote a business-friendly environment with less regulation and lower costs. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) will develop criteria to accept more international standards and risk assessments conducted by trusted regulatory authorities. Australian regulators should not impose additional requirements for domestic approval unless a good reason for doing so is demonstrated.

Food contact materials

A fifth draft of the German Printing Ink Ordinance was made available in the summer, but the proposed legislation has still not been notified to the European Commission, or to the World Trade Organization (WTO). These delays mean that compliance with the ordinance is not now expected until mid-2017 at the earliest. In the meantime, Sun Chemical continues to work with the authorities to achieve a workable outcome.

An inspection of Swiss manufacturers of plastic food contact materials found a number of examples of noncompliance, according to a report from the Food Safety Authority of the Canton of Zurich. It found that there were failures to demonstrate the safety of substances potentially migrating into food, and supporting documentation and evidence could not be provided.

The United Arab Emirates has notified the WTO of a control scheme for materials intended to come into contact with food. The scheme will not apply to packaging materials that do not directly touch the food.

Taiwan has issued a number of revised testing methods and procedures for a range of food utensils, containers and packages, which will take effect from 1st February 2015. Heavy metals, including lead and cadmium, together with methacrylate and polymethylmethacrylates, are principally affected.

FoodDrinkEurope has recently published a guidance document on printed cartons, intended to illustrate best practice in ensuring the legal compliance of printed cartons intended for packaging food products. It is aimed at individuals who have responsibility for ensuring the compliance of printed cartons with food contact legislation, for example packaging managers or technologists, technical managers or packaging buyers. It includes sections on regulatory background, responsibilities for food safety compliance along the supply chain and good practice guidance for the procurement and manufacture of printed cartons.

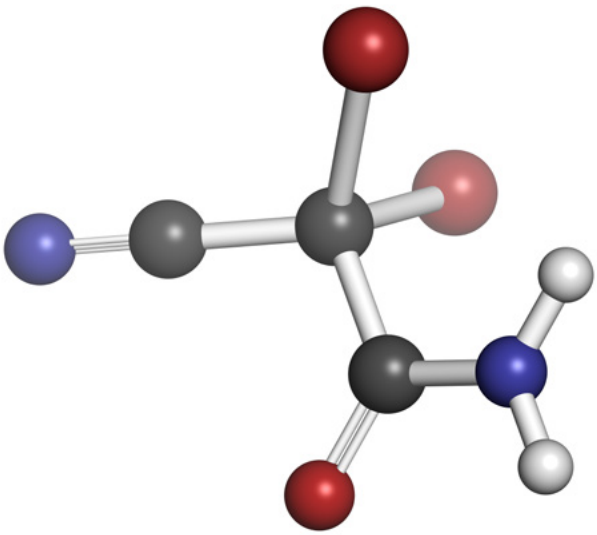
Sun Chemical's low migration best practice guide can still be obtained via our website.

FoodDrinkEurope has also updated its guidelines on the safe use of paper and board made from recycled fibres for food contact use, which illustrate best practice in relation to the use and selection of recycled paper and board for food contact packaging. It includes general requirements for risk evaluation, functional barriers, microbiological and quality considerations, legislative references and specific substances for consideration such as di-isobutyl phthalate and mineral oils.

N-vinyl caprolactam

The European Printing Inks Association (EuPIA) has issued an updated customer information note on N-vinyl caprolactam (NVC). The REACH assessment of NVC produced a very low Derived No Effect Limit (DNEL) for workers of 0.17 mg/m3, together with a new Category 1 classification for Specific Target Organ Toxicity on Repeated Exposure. This new classification means that NVC now falls within the criteria of the EuPIA Exclusion List, and EuPIA members were expected to find a replacement. In addition, only uses where the DNEL is not exceeded are permitted. The EuPIA Technical Committee has agreed that screen inks containing NVC will not be supplied after 31st March 2015.

The other area of use is in digital inkjet inks requiring good adhesion and high cure speeds; here a temporary exemption has been granted, providing safe use can be demonstrated, since substitution is not currently feasible. Following an extensive investigation, Sun Chemical has been able to replace NVC in its screen inks, and these alternative products are now being introduced onto the market. In digital inkjet printing, the interaction between the printhead and the ink is critical to performance and quality, and at this time no satisfactory alternatives could be found to meet the demanding performance requirements. Products without NVC are already available for less challenging applications. Sun Chemical will continue to work with equipment manufacturers and raw material suppliers to investigate alternative approaches. Workplace monitoring indicated that the exposure to NVC was considerably below the DNEL during manufacture and printing activities.



Biocides

Many products used by consumers require in-can preservation against bacteria, yeasts and fungi. A number of these biocides and other preservatives are also used in water-based paints and printing inks. There has been considerable media interest in the use of methyl isothiazolinone (MIT) following high increases in the numbers of allergic reactions reported by clinics in several countries. Whilst the use of MIT in cosmetics may be the principal cause of skin sensitisation, the presence of MIT in paints and printing inks could be sufficient to cause an allergic response in already sensitised individuals. The use of MIT in cosmetics is being reviewed, and much lower limits and/or restrictions in certain types of products are expected. This should reduce the numbers of new cases of sensitisation, but there will still be a significant population already sensitised to MIT.

One of the criticisms of the paint industry has been that the presence of MIT in consumer paints is not mentioned. The levels currently used are below the legal requirements for labelling, yet still high enough to be of concern for affected individuals. As a consequence, CEPE has recently issued guidance on labelling of decorative paints to inform consumers of the presence of skin sensitising biocides. Although Sun Chemical's products are not sold to the general public, we recognise that printers and convertors are also consumers and may already be sensitised to biocides such as MIT. Consequently, in accordance with our product stewardship principles, we will provide an appropriate hazard warning in our Technical Data Sheets for affected water-based printing inks and related products.

Azo-dyes

The Japanese Ministry of Health, Labour and Welfare (MHLW) will regulate the use of azo-dyes in household products and textiles. Azo-dyes that can break down to release one of 24 listed aromatic amines must not contain more than 30 µg/g (parts per million) aromatic amine when used in household products that would be in prolonged contact with skin or could be placed into a child's mouth. This restriction is very similar to that introduced in the European Union in 2002 and now incorporated in REACH Annex XVII.

For more information on these regulatory issues, please contact the Regulatory Affairs team in **North America** or **Europe**.

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