

Regulatory Newsletter



Summer 2015

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

THE UNITED NATIONS' GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Over the past few months, Sun Chemical Corporation has been working diligently to ensure compliance with the **United States** Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) 29 CFR 1910.1200, which implements the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Starting in March 2015, Sun Chemical began the transition from existing product labels and Safety Data Sheets (SDS) to the GHS format. The changes include the new GHS pictograms, signal words and warning statements. Other changes include the addition of the National Fire-Protection Agency (NFPA) symbols. The Hazardous Materials Information System (HMIS) will no longer be supported.

While the majority of the label and the 16-Section SDS will look familiar, there are some new elements which aim to help communicate the hazards associated with the product and the safety measures that need to be taken when handling or transporting it. OSHA requires that these six elements appear on all Hazard Communication Standard (HCS) labels: pictograms, a signal word, hazard and precautionary statements, the product identifier, and supplier identification. Supplemental information can also be provided on the label as needed. In addition, chemical manufacturers, distributors and importers are required to provide Safety Data Sheets (SDS) (formerly known as Material Safety Data Sheets or MSDSs) to communicate the hazards of hazardous chemical products. As of June 1, 2015, the HCS requires new SDSs to be in a uniform format, and include the section numbers, the headings, and associated information under each of the 16-headings. Additional information, including frequently asked questions, and guidance can be found on the [OSHA hazard communication website](#).

Sun Chemical Corporation will be fully converted to GHS standards by the deadline of June 1, 2015. The transition to GHS labelling will affect some products sooner than others. Based on the inventory of specific products, Sun Chemical customers may see the old label format for products in the supply chain until inventory is exhausted. Distribution of the new GHS format SDS will be triggered at the time of next ordering the product.

As discussed in previous Newsletters, the **European Union** requires the use of GHS classification and labelling as per Regulation EC No 1272/2008 for mixtures from 1st June 2015. Products already placed on the market or in the supply chain may continue to be supplied until 1st June 2017 without relabelling.



Health **Canada** has issued the final Hazardous Products Regulations (HPR), which implement the Globally Harmonized System of classification and labelling of chemicals (GHS) within the Workplace Hazardous Materials Information System (WHMIS). The transition from the Controlled Products Regulations (CPR) to HPR / GHS will be phased-in, to be completed by June 2017 for manufacturers and importers, and December 2018 for the rest of the supply chain. The HPR will implement the fifth revision of GHS, and align with the US Hazcom 2012 as much as possible. Compared with CPR, there will be a new standardised approach of classifying hazardous chemicals, including physical and health hazards, and amended requirements for labelling and safety data sheets. Bilingual (English and French) labels will be required, and either a bilingual 16-section safety data sheet (SDS), or two separate SDS in English and French. It should be noted that the SDS will no longer have to be reviewed every three years – now updates are required when information changes. The supply label will have a pictogram with a red-bordered diamond, rather than a hatched border, together with a signal word (Danger or Warning) and hazard (H) and precautionary (P) phrases.

Employers are required to establish training and education programmes for workers who might be exposed to hazardous substances in the workplace. In addition, they must ensure that the products are labelled, and that a SDS is readily available for each product. Employees are required to participate in the training, and use the information to help them work safely. They should inform the employer if a label has been removed, or is no longer legible. Sun Chemical is making arrangements to ensure that its products comply with the new labelling and SDS requirements by the deadline of June 2017, and its workforce is adequately trained. During the transition period, both Regulations are in force – individual products may be compliant with either CPR or HPR.

Meanwhile, **Taiwan's** Bureau of Standards, Metrology and Inspection (BSMI) has changed a number of its national standards (CNS 15030 series) to update from the second revision of GHS to the more widely internationally used fourth revision. The Management Regulations for Toxic Chemical Substance Labels and Materials Safety Data Sheets requires that containers and packaging, labels and safety data sheets for toxic chemical substances are identified with labels in accordance with CNS 15030 standards.

Thailand's Food and Drug Administration has notified the World Trade Organisation (WTO) that it intends to adapt its Hazardous Substances Act to ensure that hazardous substance labels are based on the third revision of GHS, and the active ingredient name on the label is in Thai and English. The proposed date of adoption and entry into force has not yet been decided.

CHANGE TO RULES FOR TRANSPORTING ENVIRONMENTALLY HAZARDOUS MATERIALS (UN3082 OR UN3077)



Following the introduction of a special provision for UN3082 and UN3077 to the UN Recommendations on the

Transport of Dangerous Goods 18th edition, these changes have now been added to the latest versions of the IMDG (marine), IATA (air), and ADR (EU road) manuals. Since 1st January 2015, these materials, when transported in single or combination packaging's containing a net quantity per single or inner packaging of 5 l or less for liquids or 5 kg or less for solids, are not subject to any other provisions provided the packaging is suitable. Such products can be classed as not restricted for transport. This means that shippers are not required to mark / label the packages or provide a dangerous goods transport document – a significant reduction in bureaucracy. Sun Chemical has taken advantage of this special provision to avoid unnecessary administration and cost for our customers.

CHANGES TO PRODUCTS CLASSIFIED AS SEVERE EYE IRRITANTS

Some concerns about products labelled with the corrosive symbol have been raised following the move to the Classification, Labelling and Packaging Regulation EC No 1272/2008 (CLP), which brings the European Union into line with GHS. Under CLP, the symbol for serious eye damage is now the corrosive pictogram, rather than the irritant St Andrews Cross. In addition, the classification thresholds are slightly different according to CLP. Consequently a more severe eye irritant with hazard phrase H318 *Causes serious eye damage* causes a mixture to be similarly classified at 3% or greater, whereas the former risk phrase R41 *Risk of serious damage to eyes*, had a classification threshold of 10%.

Old EU system (DPD)		New EU CLP / GHS system	
	Corrosive (C) – causes (severe) burns		Chemicals corrosive to skin, and/or corrosive to metals (new hazard class)
	Risk of serious damage to eyes		Serious eye damage is now indicated by the “corrosive” pictogram
	Irritant (Xi) Harmful (Xn)		Skin/eye irritation, skin sensitisation and some other acute effects

This means that the labels of several products now show a corrosive symbol, suggesting a more severe hazard than previously seen. However, this is simply a reflection of the different classification system - it does not mean that the products are more hazardous or that there has been a change to the composition or performance. A number of other changes to product classifications and labelling may also be seen following the switch to CLP or GHS, and there are some differences between regions due to implementation of slightly different criteria. This is often confusing for customers, but should not be a cause for alarm.

REACH COMMUNITY ROLLING ACTION PLAN (CORAP)

The European Chemicals Agency (ECHA) has updated its [Community Rolling Action Plan](#) (CoRAP) for 2015 – 2017. The list includes 66 newly selected substances and 68 substances from the previous CoRAP update of 2014. The current intentions are for Member States to evaluate 48 substances in 2015, 48 in 2016 and 38 in

2017, although it can be expected that additional substances may be introduced when the plan is next updated in March 2016. The update includes justification documents, briefly summarising the grounds for the initial concern for the selected substance.

ECHA has also provided a number of [Questions and Answers](#) related to CoRAP and the substance evaluation process under REACH. The CoRAP list is neither a black list nor a sunset list, i.e. it will not cause a substance to be taken off the market. Instead, substance evaluation is a mechanism to evaluate and get more information on the substances listed therein, when there are concerns that the substances may pose a risk to human health or the environment. The evaluation can result in the conclusion that the concern is resolved and thus no further action is needed. If the initial concern is confirmed in substance evaluation, the Member State may consider further risk management options such as harmonised classification and labelling, restriction or authorisation to control that risk for a respective substance. However, that would be subject to a separate process.

Several important substances used in the manufacture of printing inks and pigment products are listed in CoRAP. We continue to monitor and follow developments, and will take appropriate action to ensure that any risks to human health or the environment are adequately controlled.

SOUTH KOREA K-REACH AND CHEMICAL LEGISLATION

The ministerial decree implementing the Act for the Registration and Evaluation of Chemicals (referred to as K-REACH) and the Chemicals Control Act (CCA) has now been published, together with seven implementing regulations published by the National Institute of Environmental Research (Nier). The key requirements include:

- Annual reporting of tonnages for new and existing substances produced or imported in annual quantities of one tonne or more
- Notification of products containing hazardous substances
- A list of existing substances subject to registration will be announced every three years
- Information requirements for applications for exemptions
- Assessment of registration dossiers and requirements for updating
- Joint submission and use of data
- Hazard assessments of registered substances to be carried out by the Ministry of Environment
- Provisions and requirements for Only Representatives

The South Korean Ministry of Environment is offering support to assist small and medium-sized companies, which make up more than 95% of the chemical industry in South Korea, to ensure they comply with the chemical safety regulations (K-REACH and CCA). This includes help with compiling hazard assessment test data, guidance on joint registration and one-to-one consulting service. Sun Chemical's expert team at our REACH Implementation Centre has taken responsibility for K-REACH in addition to (European) REACH, and is currently working to ensure that Sun Chemical meets its obligations and responsibilities as regards products destined for South Korea.

SAFETY DATA SHEETS (SDS) IN TURKEY

The Turkish government has published a [Regulation \(in Turkish\)](#) which aligns the Safety Data Sheets to be used in Turkey with the EU requirements. The new format has 16 sections and 48 sub-sections, although there are some small differences with the EU since Turkey has not yet implemented a version of REACH. Substance manufacturers will have to provide SDS in accordance with the new requirements from 1st June 2015, whereas formulators have until 1st June 2016 to comply for mixtures. The SDS must be provided in Turkish. Sun

Chemical is making preparations to comply with the regulation, including the onerous requirements relating to SDS authors.

PERSISTENT ORGANIC POLLUTANTS (POPS)

The [EU Regulation](#) on persistent organic pollutants (POPs) has been amended to implement the commitments made under the Stockholm Convention on Persistent Organic Pollutants and the Protocol to the Convention on Long-Range Transboundary Air Pollution on POPs. Hexachlorobutadiene (HCBd), polychlorinated naphthalenes (PCNs), short-chain chlorinated paraffins (SCCPs) and endosulfan have been added to the list of controlled substances. In addition, maximum concentration limits have been set for two previously listed entries, brominated diphenyl ethers (BDPEs) and perfluorooctane sulfonic acid and its derivatives (PFOS). The EU has also announced that it intends to submit a proposal to add perfluorooctanoic acid and its compounds (PFOA) to the POPs Convention. Sun Chemical does not use restricted persistent organic pollutants, including perfluorooctane sulfonic acid, or perfluorooctanoic acid and their compounds.

FOOD CONTACT MATERIALS

No visible progress has been seen regarding the draft **German** printing inks Ordinance – the version of July 2014 is still the latest public draft. However, we understand that German Members of Parliament, having been briefed by members of the food and packaging supply chain, have expressed concerns about the potential costs, competitiveness and impact on the German market. In response, we understand that the German government has stated that it would much prefer to see a Union-wide regulation, and has asked the European Commission to start work on this. Unfortunately, the Commission complains that it has insufficient resource, and is fully occupied with its existing commitments and priorities. We continue to follow and monitor developments.

The **Malaysian** Ministry of Health has issued a draft regulation, notified to the WTO, introducing limits to metals which could potentially migrate from plastic food contact materials to food.

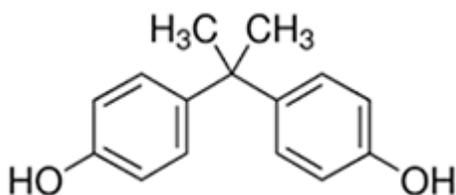
Metal	Migration limit (mg/kg)
Barium	1
Cobalt	0.05
Copper	5
Iron	48
Lithium	0.6
Manganese	0.6
Zinc	25

A number of other substances have also been assigned maximum migration limits. Interestingly, these limits are consistent with those in the European food contact Plastics Regulation EU No 10/2011. Plastic materials and articles should be tested in accordance with Malaysian Standard MS2234: Plastic materials and articles intended to come into contact with food.

Following a number of food safety scandals, **Taiwan** has introduced several new requirements in its revision of the Food Safety and Sanitation Regulation Act. Large listed companies are required to set up their own

laboratories and self-test raw materials, including food contact materials, and products. Producers or importers of containers or external packaging for raw food materials and food products must ensure they have comprehensive labels in Chinese including origin of production and production systems used. In addition to improved traceability in the supply chain, and substantially increased financial penalties, food or food additives may no longer be manufactured in the same factory as non-food products.

One of the most extensively studied substances on the planet, **bisphenol A (BPA)**, continues to provoke heated discussion. The **US Food and Drug Administration (FDA)** experts completed a four year review of more than 300 scientific studies and concluded that there was no information in the evaluated studies to prompt a revision of the FDA's safety assessment of bisphenol A in food packaging at this time. The [FDA reiterated its position](#) that bisphenol A is safe for the current approved uses in food containers and packaging. It will continue to review the available information and update its BPA safety assessment, if warranted.



The **European Food Safety Authority (EFSA)** [concluded](#) that current exposure levels to bisphenol A pose no risk to human health, following its comprehensive re-evaluation of BPA exposure and toxicity. The Tolerable Daily Intake (TDI) was proposed to be lowered to 4 µg per kg bodyweight per day because of new data and refined methodologies, but the highest exposure estimates from a combination of dietary and non-dietary sources (such as cosmetics, thermal paper, air, dust and toys) were still three to five times lower than this new limit. The opinion has also addressed the considerable uncertainties in the non-dietary exposure estimates and potential health effects in the assessment. The TDI will be reassessed in two to three years following the completion of a long term study on rats by the US National Toxicology Program (NTP), which is expected to resolve some of the uncertainties regarding BPA's toxic effects. Unsurprisingly, these opinions were warmly welcomed by members of the food packaging supply chain, and strongly criticised by NGO groups.



MORE PHTHALATES BANNED IN CHILDREN'S TOYS

The US Consumer Product Safety Commission (CPSC) has notified the World Trade Organisation of its intention to ban the use of five additional phthalate plasticisers in children's toys and childcare articles. Following assessment of the risks of 14 phthalates, di-iso-butyl phthalate (DiBP), di-n-pentyl phthalate (DnPP), di-n-hexyl phthalate (DnHP) and dicyclohexyl phthalate (DCHP) were recommended to be permanently excluded from use in children's toys and childcare articles at greater than 0.1%. It was considered that the toxicological profiles of these phthalates is sufficiently similar to other anti-androgenic phthalates that they contribute to the cumulative risk. In addition, the temporary ban on the use of di-iso-nonyl phthalate (DINP) will be made permanent. The Consumer Product Safety Improvement Act (CPSIA) introduced a permanent ban on di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and butyl benzyl phthalate (BBP) in 2008, together

with interim prohibitions on di-n-octyl phthalate (DNOP) and di-iso-decyl phthalate (DIDP), as well as DINP.

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

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