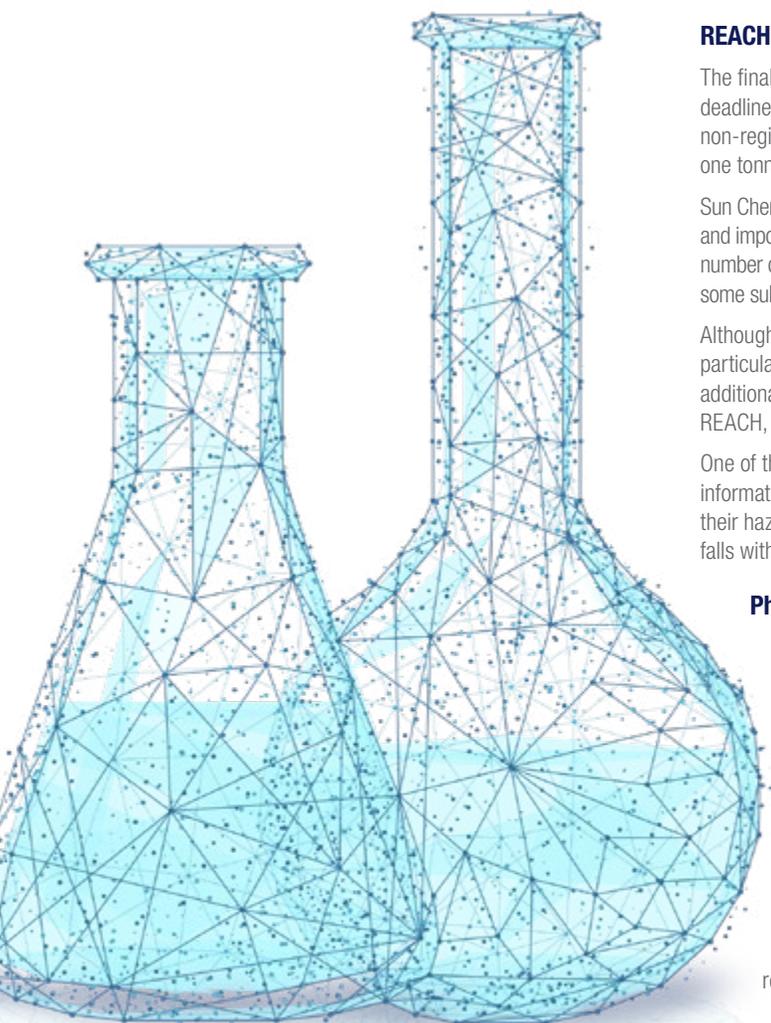


Regulatory Newsletter

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



REACH

The final EU REACH (Registration, Evaluation, and Authorisation of Chemicals) registration deadline for phase-in substances has now passed (end of May 2018). This means that any non-registered substance must be registered before manufacture or import at quantities of one tonne per annum or greater can commence.

Sun Chemical successfully registered all required substances (mainly manufactured colourants and imports) in accordance with the relevant deadline. Unfortunately, the supply of a small number of our raw materials was discontinued due to manufacturers deciding not to register some substances. Affected products have been reformulated using alternative materials.

Although the registration phase is now essentially completed, REACH activities continue, particularly the evaluation of registration dossiers by member states, and requests for additional information, usually involving toxicity testing. We continue to monitor and support REACH, to ensure continued compliance.

One of the consequences of increased toxicity testing and availability of more toxicological information due to REACH is that many substances are being (re)classified with regard to their hazardous properties. In some cases, a raw material may be assigned a hazard which falls within the scope of the EuPIA (European Printing Ink Association) Exclusion Policy.

Photoinitiator reclassifications

Several widely used photoinitiators have recently been reclassified as toxic for reproduction category 1B, and as such are required to be substituted by EuPIA members. The NAPIM (National Association of Printing Ink Manufacturers) Food Packaging Guidance also recommends members adhere to the EuPIA exclusion policy.

Sun Chemical has communicated this information to affected customers and is in the process of updating the labels and safety data sheets for the relevant products. We have also embarked on a substitution programme to replace the affected materials, and new formulations will be made available starting in September in advance of the EuPIA recommended timeframe. The replacement exercise has been complicated by further later reclassifications and exclusion of additional photoinitiators.

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More seriously, the UV industry is currently managing severe shortages of many photoinitiators, including a number of those being used in the reformulation activities. This has meant that implementation plans have had to be modified and delayed in some cases awaiting material availability. Further information can be found in a separate [EuPIA statement](#), and a Sun Chemical customer information note can be obtained from your local representative.

Titanium dioxide classification

EU member states continue to discuss the appropriate harmonised classification to use for titanium dioxide. At issue is whether a chemical hazard classification is appropriate for regulation of dusts, and specifically regarding the physical effects of poorly soluble low-toxicity particulates, such as titanium dioxide.

Questions regarding the scope of the EU CLP legislation (EC No. 1272/2006) and what it is intended to achieve are still not resolved. The latest thinking regarding titanium dioxide is that it will likely be classified as carcinogenic category 2 (due to inhalation of insoluble particulates and overload of the lung clearance mechanism in rats), with an exemption for mixtures where the titanium dioxide particles cannot be inhaled.

As noted in previous newsletters, this effect is not specific to titanium dioxide, and we can expect many other poorly soluble particulate substances or dusts to receive similar treatment in the future.

Cosmetics

The safety of a cosmetic product largely depends on the safety of its ingredients. Many countries have developed their own [regulatory lists](#) of banned or restricted cosmetic ingredients and positive lists.

European Union

Regulation (EC) No. 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products placed on the EU market. The legislation includes restrictions on the substances that may, or may not, be included in cosmetic products.

The Regulation Annexes include lists of banned substances prohibited from use (Annex II), restricted substances that can be used within certain limits (Annex III), and approved lists of colourants (Annex IV), preservatives (Annex V) and UV filters (Annex VI).

If a substance is not on the list of banned or restricted substances, or in a category subject to approval, then it is allowed in cosmetic products provided the manufacturer/supplier has the appropriate safety data to ensure the ingredient and the final product are safe. Further information can be found in [CosIng](#)—the EU's official cosmetic ingredient database.



United States

The U.S. Federal Food, Drug, and Cosmetic Act does not require cosmetic products and ingredients to be approved by the FDA before they go on the market, except for color additives that are not intended for use as coal tar hair dyes. Companies and individuals who market cosmetics have a legal responsibility for the safety of their products and ingredients.



Although it is against the law to use any ingredient that makes a cosmetic harmful when used as intended, the FDA has regulations that specifically prohibit or restrict the use of a number of specific substances, including **chlorofluorocarbon propellants** in cosmetic aerosol products intended for domestic consumption, **chloroform**, **methylene chloride**, **mercury compounds** and **zirconium-containing complexes in cosmetic aerosol products**. Use of the term “sunscreen” or similar sun protection wording in a product’s labelling generally causes the product to be subject to regulation as a drug or a drug/cosmetic, depending on the claims.

Color additives are permitted in cosmetics *only* if the FDA has approved them for the intended use (positive list). In addition, some may be used only if they are from batches that the FDA has tested and certified.

[Color additives subject to certification](#) are derived primarily from petroleum and are sometimes known as “coal-tar dyes” or “synthetic-organic” colors. Except in the case of coal-tar hair dyes, these colors must not be used unless the FDA has certified that the batch in question has passed analysis of its composition and purity in the FDA's own labs.

[Color additives exempt from batch certification](#) are obtained primarily from mineral, plant, or animal sources. However, they still are considered artificial colors, and when used in cosmetics or other FDA-regulated products, they must comply with the identity, specifications, uses, restrictions, and labelling requirements stated in the regulations [21 CFR 73].

China

In China, cosmetics must be tested and approved by the food and drug authority first before they can be marketed. Regulatory requirements on the use of cosmetic ingredients must also be complied with. A list of banned and restricted substances is given in Safety and Technical Standards for Cosmetics ([化妆品安全技术规范](#)).



For special functional ingredients, such as **colorants**, **preservatives**, and **UV filters**, only substances approved and listed may be used. Other ingredients must be listed in the [Inventory of Existing Cosmetic Ingredients in China](#) (China IEIC), otherwise a new cosmetic ingredient registration is required.

Restriction of Hazardous Substances (RoHS)

The members of the Arab Gulf Cooperation states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and United Arab Emirates) and Yemen have notified the WTO of a technical regulation to restrict the use of certain hazardous substances in electrical and electronic equipment.



The regulation is intended to contribute to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste. It limits the concentration of heavy metals (lead, mercury, hexavalent chromium), phthalates (DEHP, BBP, DBP, DIBP), polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) to a maximum of 0.1% by weight, and cadmium to a maximum of 0.01% by weight (in agreement with the EU RoHS limits).

The Brazilian government has also announced plans to introduce a regulation similar to the EU Directive on the Restriction of Hazardous Substances (RoHS) in electrical and electronic equipment (EEE). Currently, public bodies are recommended to purchase products which do not contain hazardous substances above the concentrations specified in the EU RoHS Directive (2011/65/EU).



Meanwhile, China has published its RoHS2 Regulations, which come into force on 12th March 2019. The substances restricted are the same as those in the EU 2003 RoHS Directive (lead, mercury, chromium (vi), cadmium, PBBs, and PBDEs), but the scope of products included is different. Large household equipment, consumer electronics, computing and communication equipment are covered by both, but small household equipment and medical devices are only in the scope of the EU's RoHS, and some applications are exempted from the substance restrictions.

Toys

To further harmonise with the toy safety legislation of the EU, Ukraine has adopted a Technical Regulation on the Safety of Toys, which became effective on 21st September. It establishes requirements on the safety of toys and their placement on the market, and defines the obligations of manufacturers, importers, and distributors.

The regulation diverges slightly from the EU Directive, in that it applies to products that have been developed or intended for children up to 14 years. The EU Directive applies to products designed or intended (whether or not exclusively) for use in play by children under 14 years.



Coatings

Authorities in several Chinese cities have ordered industries to replace solvent-based coatings with water-based alternatives. This follows a commitment that government-backed construction projects should not use solvent-based coatings or adhesives. Shanghai has banned such coatings from construction projects approved after 30th April.

In Tianjin, the vehicle maintenance industry has been told it must replace the coatings by 1st October. In March, Zhongshan announced draft standards that would phase out organic solvents with high volatile organic compound (VOC) content, and the use of solvents containing more than 20% VOC, from 1st October. It will offer financial incentives to replace solvent-based coatings.

Zhongshan already prohibits the production of paints for interior decoration with more than 200 g/l of VOC, and solvent-based wood furniture coatings cannot exceed 700 g/l. Restrictions are already in place in other cities, including Shenzhen, Taizhou, and Nanjing. Nanjing's focus has been on getting the automotive industry to replace VOCs with environmentally friendly alternatives.



Workplace safety

NFPA 652 is a standard issued by the U.S. National Fire Protection Association that provides the basic principles of, and requirements for, identifying and managing the fire and explosion hazards of combustible dusts and particulate solids. It applies to all industries (i.e., facilities and operations manufacturing, processing, blending, conveying, repackaging, generating, or handling combustible dusts or combustible particulate solids).

NFPA 652 is intended to ensure occupants and adjacent properties are reasonably protected from the effects of a fire, flash fire, or explosion; limit damage from a fire, flash fire, or explosion; and ensure facilities and processes are designed to prevent or mitigate fires and explosions from causing failures to adjacent buildings, properties, life safety systems, or the facility's structural elements.



The standard is effective from 7th September 2015 and enforceable after three years (for scheduling and completion of Dust Hazard Analyses (DHAs) for existing processes and facility compartments), or five years (for scheduling and completion of DHAs for bucket elevators, conveyors, grinding equipment, spray dryer systems, and dust-collection systems).

Compliance begins with:

- Understanding the standard and associated standards
- Understanding your materials
- Evaluating your process for compliance or potential exposure (hazard identification)
- Managing your risks (using the hierarchy of controls, starting with engineering controls, elimination, and/or substitution where feasible)
- Maintaining documentation

Determination of exposure:

1. Dust Testing:
 - a. Determination of Combustibility (UN Test N.1 (4.1))
 - b. Determination of Explosibility (ASTM E1226 and ASTM E1515)
2. Dust Hazard Analysis*
3. Documentation of DHA and five-year revalidation

**Note: The DHA is a retroactive requirement and must be completed within three to five years of the effective date of NFPA 652 (9/7/15), as stated above.*

Prevention and mitigation measures:

- Housekeeping—Must be a written plan that includes cleaning methods, frequency, training/PPE, etc.
- Ignition Source Control—Use of hot work permits, controlling hot surfaces and bearings, utilizing proper hazardous area classifications
- Ensuring electrical equipment complies with NFPA 70 Article 502 and 503 for classified areas
- Electrostatic Discharge Control—Utilizing non-conductive tools and equipment
- Open Flames—Ensuring fuel-fired space heaters are not used in Class II locations
- Industrial Trucks—Ensuring they are properly rated for the electrical classification of the area they are used in
- Self-Heating—Materials susceptible to self-heating must be managed to control the self-heating or have detection equipment put in place.
- Friction and Impact Sparks—Foreign materials (that could act as an ignition source) need to be controlled to prevent them from entering the process stream, and equipment with high-speed moving parts must be periodically checked or equipped with vibration monitors/alarms.

The European Agency for Safety and Health at Work (EU-OSHA) has released an animated [video](#) outlining how best to manage dangerous substances in the workplace. It illustrates in an engaging way the common presence of dangerous substances in many workplaces and sectors across Europe, and highlights the importance of establishing a culture of risk prevention by promoting risk assessment to manage dangerous substance effectively.



European Agency
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at Work

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The video also aims to raise awareness of groups that might be at higher risk, including women as well as migrant, temporary, and young workers. Visitors to the website might also like to watch the related video [dust at work](#) starring Napo.

Sustainability

Sun Chemical has released its Corporate Sustainability report for 2017, detailing the work it is doing to increase its use of bio-derived raw materials and showing positive progress on its eco-efficiency goals.

The report outlines Sun Chemical's sustainability road map, which uses a phased approach to improve the eco-efficiency of each production and non-production facility's processes and products by monitoring key metrics to understand and manage their environmental impacts. Its internal key metrics measure energy consumption/conservation, energy carbon footprint, process waste reduction, water consumption, material safety, and employee safety.

Highlights from the report focus on the development of eco-friendly solutions, including:

- Solvent-based liquid inks using resins responsibly sourced from certified forests
- Water-based liquid inks using bio-derived resins that do not impact ink performance
- Printed bio-sensor technology to detect levels of pyruvate in onions to determine pungency
- Bio-based food colorants using spirulina derived from photosynthetic bacteria
- Mirror-Tech inks which reduce waste by replacing metallised board with printable metallic ink

The sustainability report is available to customers and can be requested [online](#).



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

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