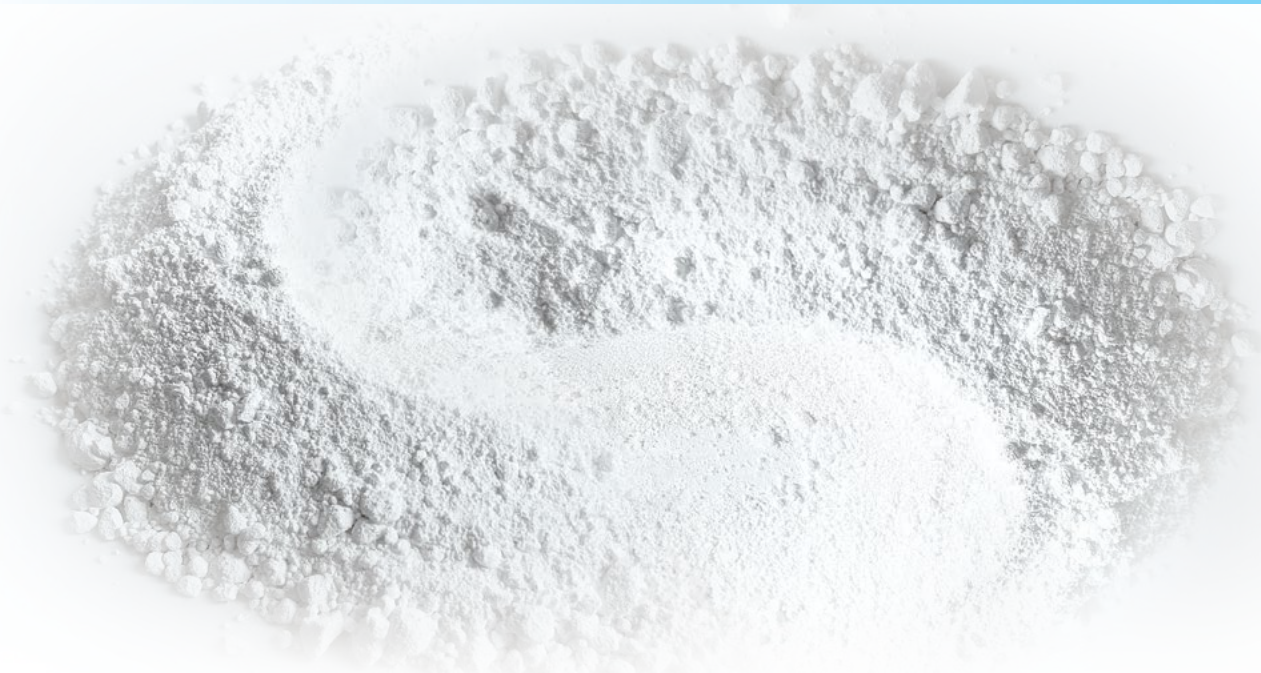


# Regulatory Newsletter

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



After much contentious [discussion](#), a European Union (EU) harmonized classification for titanium dioxide as Carcinogen Category 2 was [published](#) in the 14th adaptation to technical progress (Regulation EU No 2020/217) to the Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008), with the hazard statement H351 (inhalation) "Suspected of causing cancer by inhalation."

Titanium dioxide (CAS number 13463-67-7), also known as Pigment White 6, anatase, rutile and E171, is widely used as a white pigment in many applications such as food, cosmetics, toothpaste, sunscreen, pharmaceuticals, paint, ceramics, paper, plastic and printing inks.

Titanium dioxide in powder form, and mixtures in powder form containing 1% or more of titanium dioxide, will also be classified as Carcinogenic Category 2, with the hazard statement H351 (inhalation) "Suspected of causing cancer by inhalation." However, this classification only applies to the powder form and particles capable of being inhaled.

Liquid and solid (non-powder) mixtures containing 1% or more of titanium dioxide particles will not be classified as carcinogenic, but must be labeled with additional warning statements: "Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist." (EUH211); or "Warning! Hazardous respirable dust may be formed when used. Do not breathe dust." (EUH212).

There is a transition period of 18 months with a deadline September 9, 2021, although use of the new classification on a voluntary basis in advance of the deadline is encouraged.

Since the hazard is linked to inhalation of titanium dioxide particles, and once dispersed into a liquid and incorporated into a printing ink, the titanium dioxide is embedded in a matrix and no longer available to be inhaled, it is our belief that Sun Chemical products can [continue to be used safely](#). A customer statement has been prepared providing further details and is available on request.

working for you.



## Cosmetics

### European Union

In response to the EU [reclassification](#) of titanium dioxide as Carcinogenic Category 2 (Suspected of causing cancer by inhalation), the Scientific Committee on Consumer Safety (SCCS) was [asked](#) to reconsider the safety of titanium dioxide in cosmetics.

Currently, under the EU Cosmetic Products Regulation, titanium dioxide is authorized for use as a colorant, and as a UV filter at a concentration of up to 25%. The substance is also used as a filler in cosmetics, but this use is not subject to any specific restriction under the regulation.

According to the Cosmetic Products Regulation, a substance with a Category 2 or higher carcinogenicity, mutagenicity or reproductive toxicity classification under the EU Classification, Labelling and Packaging of substances and mixtures (CLP) Regulation is automatically banned from use in cosmetics, unless an exemption applies. Use of a Category 2 substance is permitted if the SCCS has evaluated it and found it can be used safely.

In its final [opinion](#), the SCCS determined that the use of titanium dioxide was safe for general consumers when used in face products in powder form up to a maximum concentration of 25%. For hair-styling aerosol spray products, the maximum safe concentration was 1.4% for general consumers and 1.1% for hairdressers. The Cosmetic Products Regulation will be amended accordingly.

The European Commission has published three amendments to the Cosmetic Products Regulation EC No 1223/2009. [Two substances used in nail products](#) have been added to Annex III and restricted to professional use only due to the potential for causing skin sensitization.

[Three substances](#) have been added to Annex II, prohibiting their use in hair and eyelash dye products, and maximum concentrations for [six hair dye ingredients](#)

have been introduced in Annex III, including one restricted to professional use only.

[One UV filter](#) has been added to Annex IV, setting a maximum concentration limit and prohibiting use in applications that may lead to exposure of the end-user's lungs by inhalation.



### China

China's State Council has published the final legal text for China's overarching cosmetics regulation, which took effect on January 1, 2021. The Cosmetics Supervision and Administration Regulation replaces the Regulations Concerning the Supervision and Hygiene of Cosmetics, which took effect in 1990.

Under the changes, cosmetics ingredients and products will both be categorized according to the degree of risk as either general use or special use (for higher-risk ingredients and products). Previously, this risk-based approach was only applicable to cosmetic products. The regulation focuses on improving supervision measures, quality and safety, and increasing the punishments for violations.

A company is required to register and gain approval for special-use ingredients before they are permitted for use on the Chinese market. General-use ingredients only require notification. After a company has submitted safety information to the authorities and obtained a record-keeping certificate, it is allowed to use the ingredient in China.

Similarly, notification is all that's required for general-use cosmetic products, whereas all special-use cosmetic products require registration and must be approved before they can be marketed. While the ingredients and products covered by the terms "general" and "special use" are still to be determined, hair dye and skin-whitening products will be considered as special-use products.



### Indonesia

Indonesia's National Agency of Drug and Food Control (BPOM) has published an updated version of the 2010 regulation on cosmetics notification, which took effect on June 24, 2020. Companies looking to market cosmetics in Indonesia must first notify authorities about the product and its ingredients to receive approval. Before notification, cosmetics manufacturers must obtain a production license from the Ministry of Industry, and importers must have an importer identification number from the Ministry of Trade. The revised Criteria and Procedure for Submission of Cosmetics Notification applies to the entire supply chain of the Indonesian cosmetics industry.



**South Korea**

South Korea's Ministry of Food and Drug Safety is amending its Regulation on Safety Standards of Cosmetics to bring most of its rules on cosmetic ingredients in line with those of the EU. The safety standard applies to all cosmetics that are imported, manufactured and distributed in the country. Changes are made to permitted levels of preservatives and allowed hair dye ingredients.



**India**

India's standards bureau has published a revised draft standard on colorants in cosmetic products. Colorants are defined as substances that are mainly and exclusively intended to color a cosmetic product used on the body as a whole or in part, by absorption or reflection of visible light. It also applies to precursors of oxidative hair colorants.



The standard deals with cosmetic raw materials in two parts: (1) a GRAS (Generally Recognized as Safe) list for dyes, colors and pigments; and (2) a GNRAS (Generally Not Recognized as Safe) list of raw materials and adjuncts, other than dyes, colors and pigments.

The update applies to the part one GRAS list to bring it in line with the latest version of the EU Cosmetic Products Regulation (EC) No 1223/2009, and now contains 153 substances.

**Toys**

**European Union**

The European Commission has published two amendments to the EU Toy Safety Directive (2009/48/EC), lowering the aluminum content permitted in toys and adopting specific limit values for formaldehyde.

The limits for aluminum have been reduced from 5,626 to 2,250 mg/kg for dry, brittle, powder-like or pliable toy material. The limits were reduced from 1,406 to 560 mg/kg for liquid or sticky toy material and from 70,000 to 28,130 mg/kg for scraped-off toy materials.



Since children are exposed to aluminum/formaldehyde through sources other than toys, only a certain percentage of the tolerable daily intake is allocated to the exposure from toys. The limit values for formaldehyde range from 0.1 ml/m<sup>3</sup> (emission limit) in resin-bonded wood toy material, 1.5 mg/l (migration limit) in polymeric toy material, and from 10 mg/kg to 30 mg/kg (content limit) in water-based, paper, textile or leather toy materials.



The new limits will apply from May 2021. The European Printing Ink Association has revised its statement on [printing inks and related products for the manufacture of toys](#), warning of the potential for printed silver ink layers (which contain aluminum flakes as the pigment) to exceed the new limit, depending upon coverage.

**India**

India's Ministry of Commerce and Industry has published a quality control order covering toys, with the goal to improve their quality, reliability and consistency, and to better protect human health and the environment. The Toys (Quality Control) Order defines toys as any product or material designed or clearly intended, whether or not exclusively, for use in play by children under 14 years of age. It specifies that toys must conform to the eight-part standard (IS 9873: Safety Requirements for Toys). A certificate of conformance is required for imported toys.

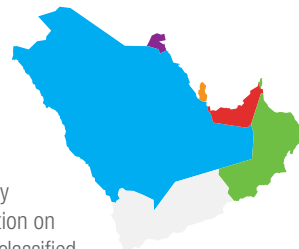
**Israel**

Israel has proposed to update its toy standards with new migration limits for 19 elements to match the latest revisions made by the EU (EN 71-3:2019 Safety of Toys—Part 3: Migration of Certain Elements) and the international standards organization (ISO). The standards cover toys with a reasonable risk of being put into a child's mouth. These include those intended for use close to or inside the mouth, such as cosmetics, writing implements classified as toys, and all toys or parts of toys aimed at children under six years old.



**GCC Standardization Organization**

The GCC Standardization Organization (GSO), covering Saudi Arabia, Qatar, Kuwait, Oman, Bahrain and the United Arab Emirates, is similarly updating its chemical migration limits to align with the EU toy safety standard EN 71-3. The Gulf technical regulation on toy safety also prohibits the use of substances classified as CMR (carcinogenic, mutagenic or toxic for reproduction) and restricts the use of several phthalate plasticizers.



## Miscellaneous

### REACH

In response to the REACH [restriction on di-isocyanates](#), which specifies that only professionals who have successfully completed training on safe use will be permitted to work with di-isocyanates beginning in August 2023, the isocyanate producer trade associations ISOPA and ALIPA have started work on a [package of training materials](#) that workers will eventually be able to complete via e-learning or in a classroom. The level of training depends on the specific uses, with higher risk of exposure requiring more in-depth training. Each employee has to be trained once every five years.



### European Chemicals Agency

The European Chemicals Agency (ECHA) has released an [EU chemicals legislation finder](#) (EUCLEF) containing



35 pieces of legislation, including chemicals in food contact materials, toys, cosmetic products, and electrical and electronic equipment. As obligations from different EU laws can apply to the same chemical, EUCLEF acts as a central searchable [portal](#) and will bring clarity to companies, especially small- and medium-sized enterprises, on which pieces of legislation apply to their substances. The free online tool, which is integrated into the ECHA chemicals database, will eventually house a further 16 pieces of legislation, due to be added later in the year.

### Market Regulation and the Standardization Administration of China

The State Administration for Market Regulation and the Standardization Administration of China has approved five new standards that limit the volume of volatile organic compounds (VOCs) and other substances that can be used in adhesives, printing inks, cleaning agents and various types of coatings.

The new standards limiting VOC content in cleaning agents (GB 38508) and adhesives (GB 33372) took effect on December 1, 2020, with the printing ink standard (GB 38507) taking effect on March 1, 2021. The new standard for adhesives replaces the voluntary technical standard GB/T 33372.

### United States Environmental Protection Agency

The United States Environmental Protection Agency has [proposed](#) to retain the 2015 National Ambient Air Quality Standard (NAAQS) for ozone of 70 ppb (parts per billion), which was a reduction from 75 ppb in the 2008 standard. This means states that have already attained the existing standard would not need to impose new regulations on emission of volatile organic compounds (VOCs) or nitrogen oxides (NO<sub>x</sub>)—two substances which contribute to the formation of ground-level ozone.



### California Office of Environmental Health Hazard Assessment (OEHHA)

The OEHHA has adopted [new reference exposure levels](#) (RELs) for toluene of 5,000 µg/m<sup>3</sup> for infrequent one-hour, 830 µg/m<sup>3</sup> for repeated eight-hour and 420 µg/m<sup>3</sup> for chronic long-term exposures.



### UK REACH

The UK government has extended the deadlines for full data submissions under its independent REACH legislation, giving businesses up to six years to complete registration dossiers. [UK REACH](#) took effect on January 1, 2021, the day after the Brexit transition period ended. An initial grandfathering of EU-held registrations, which only requires very basic information, must be completed for existing EU REACH registrations by April 30, 2021.

The detailed information underpinning those registrations will be staggered over a six-and-a-half-year period, with high-tonnage substances and those with particularly hazardous properties being registered first. The UK government is seeking to align its data and information-sharing mechanisms with those of the EU and provide access to the ECHA database as part of a chemicals annex linked to a post-Brexit trade agreement.

**CEFLEX**

The organization CEFLEX (A Circular Economy for Flexible Packaging) has published [Designing for a Circular Economy \(D4CE\) guidelines](#) which provide the flexible packaging value chain with practical advice and support to design flexible packaging to be compatible with a circular economy. They focus on polyolefin-based flexible packaging, as these materials make up the largest proportion of flexible packaging in the post-consumer waste stream (estimated to be 70%–80%).

Advice and information on the key elements of a flexible packaging structure—including the materials used, barrier layers and coatings, the size and shape, inks and adhesives—have been provided. Limits have been set for some of these elements so that their use does not adversely impact the sortability and recyclability of the packaging, while maintaining the functionality needed for product protection. Another key part of the guidelines is providing insight into end-of-life processes for flexible packaging.

Explaining what happens to flexible packaging in sorting and recycling processes will help the value chain to make better design decisions and understand the “why” and the direct impact the materials and other elements have.



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

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