

REACH E-NEWSLETTER

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N°34 • MARCH 2019



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SGS

WELCOME

Dear Reader,

The UK REACH e-bulletin brings you key issues relating to the EU REACH (Registration Evaluation and Restriction of Chemicals) regulation.

We bring information on proposed changes, confirmed changes and the possible effects of these changes from a manufacturing, retail and consumer perspective. Opinions from all concerned parties are reported so a full picture of the workings and effects of the regulation are shared.

The information in the following pages is sourced from the European Chemicals Agency (ECHA) and government sources (HSE, DEFRA etc.). Each of our articles are linked back to source for further reading.

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NEW RESTRICTION PROPOSALS

The restriction proposal dossiers for the following substances are now available on ECHA's website. This publication on the web gives stakeholders time to prepare for the public consultations, which are aimed to start in March/April 2019.

- Microplastics
- Formaldehyde and formaldehyde releasers
- Siloxanes D4, D5 and D6: octamethylcyclotetrasiloxane (D4); decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6)

MICROPLASTICS

SUBMITTER(S)

ECHA

DETAILS ON THE SCOPE OF RESTRICTION

Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.

REASON FOR RESTRICTION

The Commission has requested ECHA to prepare an Annex XV restriction dossier concerning the use of intentionally added microplastic particles to consumer or professional use products of any kind.

More detailed information on the background behind this restriction was given in our [issue 32 newsletter](#).

FORMALDEHYDE AND FORMALDEHYDE RELEASERS

SUBMITTER(S)

ECHA

DETAILS ON THE SCOPE OF RESTRICTION

Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses.

REASON FOR RESTRICTION

The Commission has requested ECHA to assess the risk of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses.



PROPOSED RESTRICTION: FURTHER INFORMATION

FORMALDEHYDE (EC NO 200-001-8), (CAS NO 50-00-0)

The proposal is to restrict the placing on the market or the use of all articles releasing formaldehyde at concentrations greater than or equal to 0.124 mg/m³ in the air of a test chamber used under the conditions prescribed in EN 717-1. Formaldehyde released from an article may come from formaldehyde and/or other substances that release formaldehyde (formaldehyde releasers) used in the production process of the article. Articles subject to the CMRs in textiles restriction as well as the use of formaldehyde and formaldehyde releasers as biocide are exempted from the proposed restriction.

Entry into force will be 12 months from publication in the Official Journal.

OCTAMETHYLCYCLOTETRAILOXANE (D4); DECAMETHYLCYCLOPENTASILOXANE (D5); DODECAMETHYLCYCLOHEXASILOXANE (D6)

SUBMITTER(S)

ECHA

DETAILS ON THE SCOPE OF RESTRICTION

Leave on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1% shall not be placed on the market. In addition, wash-off and rinse-off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market.

REASON FOR RESTRICTION

Commission request to ECHA.

REMARKS

The Commission updated the request on 5 February 2018 to include D6 to the previous restriction scope.

PROPOSED RESTRICTION: FURTHER INFORMATION

Proposed restriction wording:

OCTAMETHYLCYCLOTETRASILOXANE

EC Number: 209-136-7

CAS Number: 556-67-2

INCI name: Cyclopentasiloxane or Cyclomethicone

DECAMETHYLCYCLOPENTASILOXANE

EC Number: 208-764-9

CAS Number: 541-02-6

INCI name: Cyclopentasiloxane or Cyclomethicone

DODECAMETHYLCYCLOHEXASILOXANE

EC number: 208-762-8

CAS number: 540-97-6

INCI name: Cyclohexasiloxane or Cyclomethicone

SCOPE OF THE RESTRICTION

- Shall not be placed on the market:
 - As substances.
 - As constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance.
- This restriction shall come into force:
 - On DD/MM/YY [at least 5 years after publication in the Official Journal] for leave-on cosmetic products (as defined in Article 2(1)(a) of regulation (EC) No 1233/2009).
 - On DD/MM/YY [at least 10 years after publication in the Official Journal] for use of D5 in dry cleaning.
 - On DD/MM/YY [at least 2 years after publication in the Official Journal] for all other uses.
- By way of derogation, paragraph 1 shall not apply to:
 - Uses at industrial sites (except for dry cleaning industrial sites), and uses as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of the REACH Regulation are met
 - Medical devices used for the treatment of scars and wounds.
 - Medical devices used for the care of stoma.
 - Use of D5 for dry cleaning in systems where the washing liquid is recycled or incinerated and where there is no release to air or wastewater.
 - [Mixtures used as sealants in construction that contain the substance(s) in a concentration equal to or greater than [x % w/w] of each substance].
 - [Mixtures used as medical devices that contain the substance(s) in a concentration equal to or greater than [y %w/w] of each substance].
- By way of derogation, paragraph 1 shall not apply to the use of D5 for the cleaning or restoration of art and antiques.

Source: ECHA

AUTHORIZATION

The RAC and SEAC Committees' opinions on one application for authorization is now available on ECHA's website for one use of chromium trioxide by Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solution Kft; for the passivation of copper foil used in the manufacture of Lithium Ion Batteries for motorized vehicles.

The Commission has granted authorizations for uses of the following substances:

- Formaldehyde oligomeric reaction products with aniline (technical MDA)
 - Polynt Composites France
- 1,2-dichloroethane (EDC)
 - Eli Lilly Kinsale Limited
- 1,2-dichloroethane (EDC)
 - Bayer Pharma AG

- 1,2-dichloroethane (EDC)
 - ORGAPHARM
- 1,2-dichloroethane (EDC)
 - Akzo Nobel Chemicals SpA
- 1,2-dichloroethane (EDC)
 - Microbeads AS
- Chromium trioxide
 - Hansgrohe SE

ECHA has updated the formats for applications for authorization and review reports. The aim is to improve the transparency and efficiency of the application process and to speed up the decision making. Further information and relevant links are available on their website.

Source: *Health and Safety Executive*



COURT ANNULS THE COMMISSION'S AUTHORIZATION DECISION FOR THE USES OF **LEAD CHROMATES YELLOW AND RED**

On 7 March 2019, the General Court of the European Court of Justice issued a judgment annulling the Commission's decision granting an authorization for some uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red. The decision was based on opinions made by ECHA's scientific committees for risk assessment and for socio-economic analysis. Sweden challenged the validity of the Commission's decision on a number of grounds.

The Court upheld Sweden's plea that the Commission made an error during its examination of the absence of

alternatives. The judgment indicates that the burden of proof is on the applicant for authorization to show that there are no suitable alternatives for its uses. The Commission had however granted the authorization without sufficiently verifying all available information to determine that the applicant had satisfied this burden of proof. The absence of such detailed examination means that no authorization should have been granted.

The Commission and the Agency are now analysing this judgment.

Source: *CVRIA*



SWEDISH PROSECUTOR NOTIFIED OF PRODUCT NON-COMPLIANCE FOR **CHEMICALS**

During 2018 the Swedish Chemicals Agency (Kemi) checked 80 companies under its supervisory project and reported 18 companies to the prosecutor for suspected environmental offences following inspections on hazardous substances in goods.

Kemi checked 220 articles mainly made of soft plastic. They included home furnishings, bags, sports gear, interior car electronics, clothing, shoes and mattresses. Out of the 18 reported companies, 11 were selling products non-compliant with restrictions under REACH, the RoHS Directive for electrical and electronic equipment and the regulation on persistent organic pollutants (POPs). The other seven were referred for not providing information on substances on the Candidate List.

The Agency found:

- 14 articles included prohibited substances, including lead and short-chain chlorinated paraffins; and
- 25 articles contained substances that are included on the REACH Candidate List, including phthalates and the substance ADCA.

After Kemi's inspection, the companies immediately removed the affected products from the market.

Kemi has recently been carrying out inspections on products, either alone or in collaboration with other countries. This year a major exercise is underway in Sweden where more than 100 inspectors will check REACH Article 33 compliance. It is also part of a broader joint EU project on substances in articles with 15 other countries.

Source: *Kemi*



HIGH-VOLUME PLASTIC ADDITIVES MAPPED

ECHA and industry have mapped a range of high-volume chemicals that are used as additives in plastic. The information will be used by ECHA to identify substances of priority for further assessment.

Information on over 400 substances used in the EU as additives in plastics is now available on ECHA's website. The listing is based on the technical functions of additives and data provided by industry on substances manufactured or imported at above 100 tonnes per year. It covers substances used as antioxidants, antistatics, flame retardants, nucleating agents, plasticizers, pigments, heat stabilizers, and UV/light stabilizers. Information on the polymer types that the additives are most commonly found in and the expected concentration ranges is also provided.

The work included the development of a methodology for comparing the potential of additives to be released from plastic articles during their use. Together with information on hazard potential, the use and release information will be used by ECHA and Member States in the prioritization of groups of substances for in-depth assessment under REACH.



Through its results, the project aims to assist industry in identifying what use and exposure information is relevant to determine safe use for substances in articles and hence trigger a need for updating their registration dossiers. This information should be included in registrations and also communicated down the supply chains. Comparing the release potential of additives with the same technical function can also help in the substitution of hazardous substances with safer alternatives.

The project was launched in 2016 and was carried out in cooperation with 21 industry sectors, including both additive manufacturers and downstream users. It contributes to meeting the 2020 goals of the World Summit on Sustainable Development and to the EU's Strategy for Plastics in the Circular Economy.

Source: [ECHA](#)

INSPECTORS CHECKING CONSUMER PRODUCTS FOR HAZARDOUS CHEMICALS

Inspections for two EU-wide enforcement projects are currently under way to identify hazardous chemicals in consumer products. One project focuses on treated articles and chemical mixtures for consumer and professional uses under the Biocidal Products Regulation. The other targets REACH and CLP obligations for imported products and is performed in cooperation with customs authorities.

The inspections under the first enforcement project for biocides (BEF-1) kicked off in January 2019 and will run throughout the year. Carried out in 28 EU and EEA countries, the inspections focus on treated articles for consumer and professional use. Inspected products include, for example, children's and sports clothing, as well as products aimed for professional use such as building products, swimming pool equipment or personal safety equipment. Chemical mixtures such as paints and inks are also covered in these inspections.

Particular attention is paid to illegal use of non-approved active substances and to compliance with the labelling obligations.



For the pilot project under REACH and the CLP Regulation, inspections began in March 2019 and will run until autumn. Inspectors and customs authorities in the 16 participating EU Member States and EEA countries are working together to check whether imported products comply with certain restrictions under REACH regarding hazardous chemicals such as cadmium, nickel or lead. They are also verifying that chemical products are labelled with the required safety information.

Where products are found to be non-compliant, the import will be stopped and they will not be allowed to enter the EU market. The tighter collaboration between inspectors and customs authorities will also further enhance the protection of EU citizens from hazardous substances.

The final report for the pilot project under REACH and CLP is expected around mid-2020. The results of the BEF-1 project on treated articles and mixtures will be published towards the end of 2020.

Source: [ECHA](#)

NEW ECHA PRACTICAL GUIDES

ECHA has published the following new guides:

- [Practical guide on how to report changes in identity under REACH and CLP](#) – this replaces 'Practical guide 8: How to report changes in identity of legal entities'.
- [Practical guide on how to act in dossier evaluation](#) – this explains how ECHA processes dossiers and the steps registrants should take after receiving the draft or adopted decision. The guide clarifies the revised dossier evaluation decision practices, where from 1 January 2019, decisions are sent to all non-compliant registrants of a substance. It also highlights the opportunities and obligations for registrants in making sure that their dossier complies with REACH.



Source: [Health and Safety Executive](#)

THREE PROPOSALS TO IDENTIFY NEW SUBSTANCES OF VERY HIGH CONCERN (SVHCs)

ECHA has announced SVHC proposals for the following substances:

- 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) (EC -, CAS -). The substances are used as a processing aid in the production of fluorinated polymers.
- 2-methoxy ethyl acetate (EC 203-772-9, CAS 110-49-6). The substance is not registered under REACH.
- Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1 % w/w of 4-nonylphenol, branched and linear (4-NP) (EC -, CAS -). TNPP is primarily used as an antioxidant to stabilize polymers.

The deadline for comments is 29 April 2019.

[Participate in the public consultation](#)

Source: [ECHA](#)



WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 97,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your services and value chain by increasing performance, managing risks, better meeting stakeholder requirements and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language and understand the culture of the local market and operate in a consistent, reliable and effective manner.

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WHEN YOU NEED TO BE SURE

