REACH NEWSLETTER

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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 European Chemicals Agency (ECHA) and Chemical Watch. Each of our articles are linked back to source for further reading.

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SUBSTANCE ID RULES IN REACH ANNEX NEED REASSESSMENT

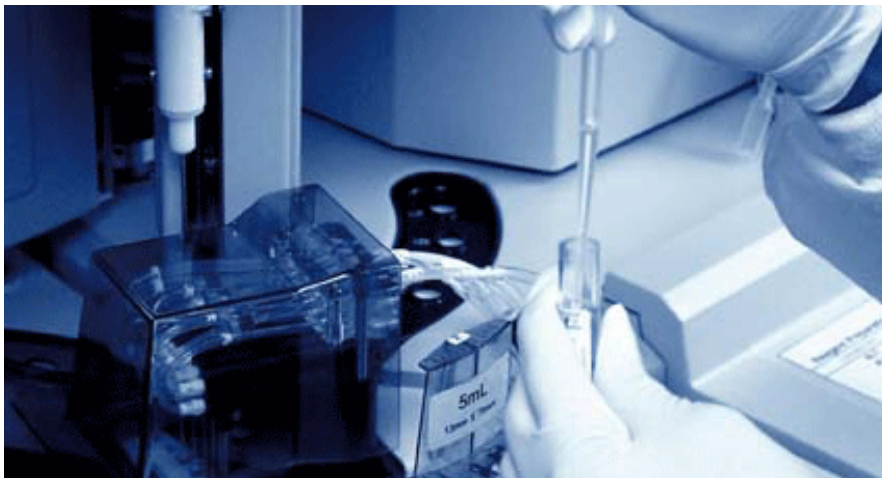
The data requirements for demonstrating a substance's identification under REACH need to be updated or supplemented, says a study for the European Commission.

The study was commissioned in response to the first REACH review in 2013. This identified several challenges for those ensuring the principle of 'one substance, one registration' is met. They include interpreting the definition of substance identity and determining the sameness of substances.

The aim of the study was to identify common issues faced by registrants and good practices in the identification of complex substances, especially those of unknown or variable composition, complex reaction products or biological materials (UVCBs).

It found that more than 2,400 substances – almost a quarter of those registered by 2013 – are complex substances, mostly UVCBs.

A workshop and survey, conducted as part of the study, found that industry bodies stressed the importance of further work to define substance-specific or sector-specific criteria for assessing substance sameness. The substance identity profile template, developed by Cefic (European Chemical Industry Council), was useful, they said, but needs to be modified to work efficiently for UVCBs in addition to well-defined substances.



The study recommends that the Commission consider updating section 2.3 of REACH Annex VI. This lists the analytical data regarded as sufficient to enable substance identification, so that it includes additional, "more appropriate" data, such as those obtained by X-ray diffraction or X-ray fluorescence for inorganic substances. Alternatively, it says a compendium of analytical methods suitable for different groups of substances could be compiled.

Further development of substance identity profiles to help identify UVCBs should also be considered, it says. ECHA, trade bodies and others should continue in their efforts to develop sector-specific guidance for groups of substances.

An annex to the report includes sector-specific substance identity factsheets on:

- Coal-derived substances
- Combustion process products
- Olefins
- Organic pigments and dyes
- Resins
- Substances originating from plants and animals – derivatives
- Zeolites

Article source: ChemicalWatch.com https://chemicalwatch.com/crmhub/48716/substance-id-rules-in-reach-annex-need-reassessment#utm_campaign=48873&utm_medium=email&um_source=alert

RESTRICTION DOSSIER ON LEAD STABILISERS IN PVC

ECHA intends to submit the Annex XV restriction dossier by 16 December 2016, instead of October, as indicated earlier. The extra time is needed to ensure the incorporation of the latest evidence regarding the risks and impacts arising from exposure to lead stabilisers in PVC.

The scope given in the Current Restriction Intentions states:

"Restriction on the placing on the market and use of lead compounds to stabilise PVC and of the placing on the market of PVC articles stabilised with lead compounds. Depending on the outcome of the assessment, the scope of the restriction might be broad or targeted specifically to articles or article groups that are the main contributors to the risks targeted by this proposal".

Article source: Echa.Europa.eu https://echa.europa.eu/registry-of-current-restriction-proposal-intentions

RESTRICTION DOSSIER FOR N,N-DIMETHYLFORMAMIDE SUBMITTED

Italy has submitted a proposal to restrict N,N-Dimethylformamide (DMF) as a substance on its own or in mixtures. ECHA has published the dossier on its website and ECHA's committees will perform a conformity check on the dossier to be finalised at the September plenary sessions of RAC and SEAC.

The six-month public consultation on the dossier is expected to start in mid-September 2016 if the dossier passes conformity.

The scope of the restriction is for the manufacture and industrial use of the substance. The proposed restriction aims to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3%.

The substance is used in the laboratory chemicals and has an industrial use resulting in manufacture of another substance (use of intermediates). This substance is also used in the following areas: scientific research and development and for the manufacture of chemicals, machinery and vehicles.

Article source: ECHA.Europa.eu https://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions

NEW GUIDANCE DOCUMENTS AVAILABLE FROM ECHA

Sector-specific support on essential oils:

The European industry associations for essential oils has published new guidance on environmental assessment for essential oils. The aim is to help companies fulfil their legal requirements for the environmental assessment of natural complex substances. Further information and a link to the guidance is available on ECHA's website. Essential oil producers may wish to seek further help through the European Federation of Essential Oils (EFEO) and International Fragrance Association (IFRA).

Article source: ECHA.Europa.eu https://echa.europa.eu/view-article/-/journal_content/title/guidance-on-environmental-assessment-for-essential-oils-now-available

New advice on skin and eye irritation testing:

ECHA has published advice on using new or revised Organisation for Economic Co-operation and Development (OECD) test guidelines related to serious eye damage/eye irritation and skin corrosion/irritation. This helps reduce animal tests and ties in with the non-animal testing approach to gather information. In addition, the OECD test guidelines are relevant for many registrants preparing for the 2018 registration deadline. The guidance is available on ECHA's website.

Article source: ECHA.Europa.eu https://echa.europa.eu/view-article/-/journal_content/title/advice-on-skin-and-eye-irritation-testing-helps-reduce-animal-tests

ECHA ASKED TO EXAMINE WHETHER CERTAIN SUBSTANCES IN TATTOO INKS SHOULD BE RESTRICTED IN THE EU

Tattoo inks and permanent make up may contain hazardous substances – for example, substances that cause cancer, genetic mutations, toxic effects on reproduction, allergies or other adverse effects on health. The European Commission has asked ECHA to assess the risks of these individual substances on human health and to examine the need for EU wide restrictions on their use in tattoo inks.

In this analysis, ECHA will also assess the availability of alternatives and the socio-economic impact of a possible restriction. ECHA is not being asked to ban tattooing or tattoo inks – their work is to examine individual substances that the inks may contain.

ECHA and some Member States are currently planning how best to share the work. An official announcement will be made in the Registry of Intentions on ECHA's website in the near future and the public will be invited to submit any relevant information to assist in this work. If it is found that a restriction is needed, a formal proposal to restrict the substances (a restriction dossier) will be submitted within one year to initiate the restriction process.

The objective is to ensure that people in all EU Member States could get tattoos or permanent make up without concerns for their health

Article source: ECHA.Europa.eu https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf

EU ALIGNS ITS CHEMICALS CLASSIFICATION, LABELLING AND PACKAGING REGULATION TO THE 5TH REVISION OF UN GHS PUBLISHED ON: 14/06/2016

The EU has aligned its chemicals classification and labelling regulation to the 5th revised edition of the United Nations' Globally Harmonised System (GHS) for the classification and labelling of chemicals.

On 19 May 2016, the European Commission adopted Commission Regulation (EU) 2016/918 amending Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the ‚CLP Regulation'). It is commonly referred to as the '8th ATP to CLP'.

The CLP Regulation sets rules on the hazard classification of chemicals, how these hazards are communicated through labelling and how the chemicals are packaged. CLP labels provide important hazard information to consumers and workers through pictograms (in the shape of a red diamond), hazard and precautionary statements and other labelling elements.

The CLP Regulation is based on the United Nations' Globally Harmonised System for the classification and labelling of chemicals. It is therefore expected to facilitate worldwide trade in chemicals, while ensuring a harmonised basis for the protection of human health and the environment.

The GHS is revised every two years to reflect scientific progress or to improve implementation. This 8th ATP to CLP implements the 5th revised edition of GHS. The European Union is thereby one of the first regions to implement this revision.

This revision includes changes related to classification rules, such as a clarification of classification criteria for some hazard classes and a new test method for oxidising solids, as well as the labelling provisions, such as a rationalisation of the list of precautionary statements.

Manufacturers, importers and downstream users are required to follow the new rules. In order to ensure that companies have sufficient time to adapt and to avoid the need for suppliers to re-label products at short notice, a transitional period of 18 months is provided after entry into force.

The 8th ATP to CLP entered into force on 4 July 2016. Application of the new rules becomes mandatory from 1 February 2018, although they can be applied voluntarily before this date.

Article source: ECHA.Europa.eu http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8853&lang=en

UK CHEMICAL STAKEHOLDER FORUM HEARS BREXIT CONCERNS

The UK Chemical Stakeholder Forum, which is a Defra organised forum for industry, NGOs and government departments, met recently to discuss UK chemical policy, and a key issue was REACH and the UK`s vote to leave the EU.

The environment department (Defra), which is the UK lead ministry for chemicals policy, has made it clear that those UK-based companies affected must register their substances by the 2018 deadline, and that the UK will remain bound by EU law, until the agreement for the country's withdrawal comes into force.

Beyond that date, companies wanting to trade with the EU should expect to meet REACH standards.

Officials told the forum that the government will create a new EU unit, comprised of officials from various ministries, and that Defra's top official will represent it on an "EU Exit Board" that will consider the policy issues for affected ministries.

Defra has put out a call for initial industry views on what they think the overarching objectives of UK chemicals policy should be, during the Brexit negotiations and beyond; and, in the event of the UK not remaining part of the single market, what should be the scope of the management or regulation of chemicals in the UK.

Article source: ChemicalWatch.com https://chemicalwatch.com/48850/uk-chemicals-forum-hears-brexit-concerns

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 85,000 employees, SGS operates a network of over 1,800 offices and laboratories around the world.

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