REACH NEWSLETTER

SGS

WELCOME

Dear Reader,

The UK REACH e-bulletin brings you every month 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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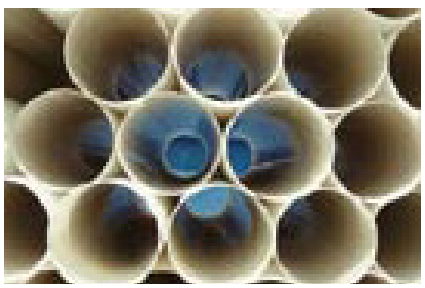
SIX AUTHORISATIONS GRANTED FOR BIS(2-ETHYLHEXYL) PHTHALATE (DEHP)



On 16 June 2016, the European Commission granted six authorisations for the following substance:

1. Bis(2-ethylhexyl) phthalate (DEHP) [CAS No 117-81-7]

The authorisations have been granted to three companies and concern two authorised uses:

1. Formulation of recycled soft PVC containing DEHP in compounds and dry-blends
2. Industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles

DEHP is 1 of 31 substances currently included in the authorisation list (Annex XIV of REACH). Substances on the authorisation list cannot be placed on the market or used after their so-called 'sunset date', unless the company has been granted an authorisation.

Article source: ECHA.Europa.eu
http://ECHA.europa.eu/en/view-article/-/journal_content/title/ECHA-weekly-13-july-2016

CHANGES IN REGULATIONS CONCERNING BPA

Classification of BPA as carcinogenic, mutagenic, reprotoxic (CMR) 1B comes into force in 2018.

The revised EU mandatory classification of bisphenol A (BPA) as a category 1B substance toxic for reproduction will come into force on 1 March 2018. This follows the publication of a Regulation in the EU Official Journal.

The new classification brings BPA into the CMR category 1 group for the first time. It is significant because such chemicals can be nominated, according to REACH Article 57(a), as a substance of very high concern (SVHC) and be added to the REACH candidate list. This in turn could lead to uses requiring authorisation if they are to stay on the market.

Category 1 CMRs can also be banned from use in consumer products in the EU via a simplified procedure.

EU member state officials backed the new classification in February.

The revised classification is included in a Regulation published on 20 July. This sets out a raft of changes to Annex VI of the Caracal (CLP) Regulation, which lists all mandatory classifications.

Article source: Chemicalwatch.com
https://chemicalwatch.com/48728/classification-of-bpa-as-cmr-1b-comes-into-force-in-2018#utm_campaign=48615&utm_medium=email&utm_source=alert

COMMISSION ADVANCES PLAN TO RESTRICT CMRs IN TEXTILES

The European Commission plans to draft its proposed fast-track restriction of 286 substances in consumer textiles in two phases.

A document describing the Commission's approach was discussed during the closed session at a recent meeting of Competent Authorities for REACH and CLP.

The first phase will limit the scope of the restriction to articles that may come into direct contact with the skin. This will mean that only proposed substances which are most relevant for such articles will be included.

Such articles include clothing, footwear and interior textiles articles, such as bed-linen, that may come into direct and prolonged contact with the skin.

Clothing accessories, such as buttons or zippers, interior textiles with no or infrequent contact with skin and footwear made of real leather will be excluded.

A wider scope of articles and inclusion of additional CMRs will be considered in a second phase.

These may include:

- Floor coverings
- Carpets
- Upholstery
- Clothing accessories; and
- Leather articles

The proposed restriction aims to cover articles, or parts of articles, that consist of at least 80% of textile fibres by weight.

The two phases will go through the fast track process - Article 68(2) of REACH - separately. This means the REACH restricted substances list – Annex XVII – will be amended, and substances identified for the first phase will be included in a specific appendix. The same process will then apply to the substances identified for the second phase.

The fast track process still requires the assistance of the REACH Committee in determining which substances to restrict. However, substances that meet CMR category 1 and 2 criteria bypass further steps of the process, such as preparation of a restriction dossier and opinions from ECHAs Risk Assessment and Socio-economic Analysis Committees (RAC and SEAC).

SUBSTANCES

The Commission will establish four lists of 1A and 1B CMR substances to restrict in the first and second phases. These will be split into substances that are:

- Potentially present in clothing and are relevant for the restriction
- Not present in clothing
- Less likely to be present in clothing, or less likely to be released, to be further assessed in a second phase; and
- Substances that were not present in the initial list, but suggested during the public consultation, also to be further assessed in a second phase.

Substances that will not be considered in the first phase will be those that are:

- Only present in accessories
- Not released from articles
- Petroleum and coal stream derivatives; and
- Substances that might be present only as impurities at levels below detection limits.

In addition, it proposes two types of limit values: those that are technologically and analytically feasible for substances that can be eliminated from the articles; and those based on hazard, such as CLP specific limit values or Dnels, and/or the lowest "achievable concentration" for substances that cannot be eliminated.

Before finalising the restriction, the Commission intends to consult ECHA's Enforcement Forum on the scope and wording of the restriction, on the availability of testing methods and on the enforceability of the conditions. It will also consult the agency on the specific concentration limits of some substances, and a group of experts on the scope and on the limit values, by organising a technical workshop.

It will additionally launch a second, shorter public consultation on the draft amendment of Annex XVII before the proposal is discussed in the REACH Committee.

This article was updated on 8 July to say that the proposed restriction aims to cover articles that consist of 80% textile fibre.

Article source: Chemicalwatch.com https://chemicalwatch.com/48469/commission-advances-plan-to-restrict-cmrs-in-textiles

COMMISSION ISSUES DRAFT AUTHORISATIONS FOR LEAD PIGMENTS

The European Commission has issued a draft implementing decision granting authorisation for two lead pigments for a range of uses. These include industrial and professional coatings, plastics applications and road markings.

Dominion Colour Corporation (DCC), which submitted the application for lead sulfochromate yellow and lead chromate molybdate sulfate red, says the draft decision confirms and supports the positive opinions issued by ECHA in the RAC and SEAC reports. This said:

- Risk management measures and operational controls described in the application are appropriate and effective in limiting the risk;
- The socio-economic benefits arising from the uses applied far outweigh the risks to human health or the environment arising from those uses; and
- There are no suitable alternative substances or technologies in terms of their technical and economic feasibility.

ECHA's opinions on the RAC and SEAC reports say the authorisations should have review periods of either seven or twelve years. The draft decision gives DCC a review period of seven years, expiring on 22 May 2022, for all uses of the substances in question.

In February some member states said they opposed granting the authorisations, regardless of how

long the review periods were, or what other conditions were included, because alternatives are available. EU paint associations also objected to the authorisation on the same grounds.

SUBJECT TO CONDITIONS

The Commission has granted the authorisations subject to risk management measures and operational conditions that include:

- DCC and the downstream users must implement a programme for selection, appropriate use and maintenance of personal protective equipment and employee training for all uses of the two substances;
- Lead sulfochromate yellow must not be marketed above 2,100 tonnes/year and lead chromate molybdate sulfate red must not exceed 900 tonnes/year;
- DCC must submit a report to the Commission by 31 December 2017 on the status of the suitability and availability of alternatives for its downstream users. This will justify the need to use the substances, including information on performance requirements and national legal requirements; and
- In the report, DCC must also refine the description of the authorised uses, based on information on alternatives provided by downstream users within its supply chain.

DCC points out that the Commission's proposed authorisation of the pigments notes that it is not incompatible with the primary goal of the World Health Organization and the UN Environment Programme's Global Alliance to Eliminate Lead Paint "as the uses applied for do not concern consumers, and should not lead to their exposure to the substances".

Member states are expected to vote on the draft decision at the REACH Committee meeting held from 6-7 July.

Article source: Chemicalwatch.com https://chemicalwatch.com/register?o=48114&productID=1&layout=main

ECHA APPOINTS SENIOR OFFICIAL AS BREXIT 'CONTACT POINT'

ECHA has responded to the Brexit crisis by appointing Andreas Herdina, ECHA's Head of Communications and Outreach Directorate, as its "contact point" for British companies and for its own British staff.

His task will be to ensure that ECHA takes a "single consolidated position" towards British companies and staff and that he acts as a reference point on Brexit matters.

In a statement, ECHA says that, until the withdrawal negotiations (that is, the UK invokes Article 50 of the Treaty of the European Union), the UK remains a member of the EU, with all the rights and obligations that go with it.

The status of UK companies with regard to REACH remains, for the time being, unchanged, it adds. The withdrawal negotiations will determine the extent to which REACH and other EU chemicals legislation will apply in the UK.

Andreas Herdina commented, "At this moment, we cannot draw any conclusions, but, in any case, those British companies that will continue to sell their chemicals and products to the EU will need to comply with EU requirements."

Article source: Chemicalwatch.com https://chemicalwatch.com/48300/ECHA-appoints-senior-official-as-brexit-contact-point

CALL FOR EVIDENCE: FORMALDEHYDE RELEASERS

The European Commission has requested ECHA to investigate formaldehyde releasers and their uses in the EU. The aim of this work is to support the European Commission to decide whether to request ECHA to prepare an Annex XV dossier for restriction on formaldehyde and whether formaldehyde releasers should be part of this restriction dossier.

ECHA is inviting interested parties to submit any information related to formaldehyde releasers to help with the preparation of the dossier. The call for evidence consultation is open until 4 October 2016.

Article source: ECHA.Europa.eu http://ECHA.europa.eu/addressing-chemicals-of-concern/restriction/calls-for-comments-and-evidence/-/substance-rev/13967/term

NEW PRACTICAL GUIDE FROM ECHA ADVISES SMEs ON REACH INFORMATION REQUIREMENTS

ECHA says the guide is targeted to managers of small and medium-sized businesses and REACH coordinators who are responsible for gathering the information needed to compile REACH registration dossiers.

The guide clarifies what information on a chemical is needed for registration, how this information can be generated and what kind of help is available. SMEs can benefit from the information when they negotiate with external service providers, such as laboratories or contract research organisations, as they will have a clearer picture of the tests required. Translations of the guide will be available in the autumn.

Article source: ECHA.Europa.eu http://ECHA.europa.eu/documents/10162/13655/pg_sme_managers_reach_coordinators_en.pdf

RESTRICTION DOSSIER FOR N, N-DIMETHYLFORMAMIDE SUBMITTED

Italy has submitted a proposal to restrict N,N-Dimethylformamide (DMF) in articles.

The restriction covers the manufacturing and industrial use of the substance. 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.

Article source: ECHA.Europa.eu http://ECHA.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions

TURKEY TO PASS REACH-LIKE LAW THIS YEAR

Turkey expects to pass into law a modified version of REACH in the fourth quarter of this year, according to the Ministry of Environment and Urbanisation.

The country has been aligning its chemical regulatory system with the EU's chemicals regulations since its membership negotiations began in 2005. The final stage in this process – implementing the REACH-type regulation – has been delayed from an initial end of 2015 deadline. The delay was due to elections last November that resulted in changes in ministerial responsibilities.

However, the ministry says the new regulation will come into force in the last quarter of this year. It has the acronym KKDIK, which stands for chemicals registration, evaluation, authorisation and restriction in Turkish.

"It is envisaged that the draft KKDIK regulation will be published in the final quarter of 2016," the ministry, which is designated as the competent authority for the law, has stated.

A draft version of KKDIK has been available for some time. It has an initial registration window for existing substances, running from 31 December 2015 to 31 December 2018. Registration is required for substances manufactured or imported in volumes over 1 tonne/year. Registration will be a mandatory requirement as the 'no data, no market' rule is incorporated in KKDIK in the same way as in the EU.

Chemical industry experts in Turkey said any further delays from the end of this year would trigger amendments in the draft legislation, causing even more delays.

The draft legislation is almost a mirror image of the EU regulation, albeit with minor changes to reflect the character of the local industry. However, many firms say the infrastructure to enable them to comply with the new law is still insufficient. Many cite a shortage of competent staff to manage the compliance burden as the main problem.

Turkey's chemical exports totalled $14bn in 2015, according to data compiled by the Ministry of Science, Industry and Technology. The EU was the biggest recipient of Turkish exports, with $5.3bn.

Article source: Chemicalwatch.com https://chemicalwatch.com/48103/turkey-to-pass-reach-like-law-this-year

UK GOVERNMENT URGES FIRMS TO PRESS ON WITH 2018 REGISTRATIONS

Following the UK's decision on 23 June to leave the EU, the government is seeking to ensure that there will still be a high level of compliance with the 2018 REACH registration deadline, and that potential disruption to supply chains is kept to a minimum.

The environment ministry (Defra) and the Health and Safety Executive (HSE), which is the UK REACH competent authority, will carry out a number of projects, focusing on the registration deadline, that are additional to its usual business.

These will include research, analysis and targeting of issues and messages, capacity building, SME tools and communications.

The projects will aim to ensure there is a good level of awareness, among chemical manufacturers and importers, of their registration obligations, and that companies understand the need to act early and to work with others to share data and costs. SMEs, which are expected to account for a high proportion of registrants, will be paid particular attention.

Another goal is to minimise the amount of animal testing that is commissioned and to promote alternative test methods, through building understanding among laboratories and pre-registrants.

In addition, government advisory body the UK Chemicals Stakeholder Forum has established a REACH 2018 subgroup, which will help to identify substances and sectors where potential concerns may arise.

Defra says that UK-based companies affected have the legal obligation to register their substances by the 2018 deadline, and that the UK will remain bound by EU law until the agreement for the the country's withdrawal comes into force. Beyond that date, companies wanting to trade with the EU should expect to meet REACH standards.

The period between the UK invoking Article 50 of the EU Treaty and triggering the start of withdrawal negotiations, and the country's eventual exit is two years, unless the other member states agree to extend it.

Article source: Chemicalwatch.com https://chemicalwatch.com/48577/uk-government-urges-firms-to-press-on-with-2018-registrations#utm_campaign=48493&utm_medium=email&utm_source=alert

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