SSS Regulatory Newsletter | Issue 1 | 2014

Sustainability Support Services (Europe) AB

One Stop for 'ACCREDITED' Chemical Regulatory Compliance Services & Solutions

Developments related to the REACH regulation between Jan' 2014 to June' 2014

1. **Harmonized classification and labelling**

The classification and labelling of certain hazardous chemicals must be harmonized to ensure adequate risk management throughout the European Union.

Harmonized classification is a standard classification that has been finalized after due discussions and deliberations amongst all the relevant stakeholders of a particular chemical. One cannot use a classification different from the Harmonized classification on the packaging and labels as it is considered to be against the CLP regulation and might invite Evaluation by the CLP enforcement authorities.

Member States, manufacturers, importers and downstream users may propose a harmonized classification and labelling of a substance. Member States can also propose a revision of an existing harmonization.

Harmonized classifications and labelling are mandatory for the suppliers of respective substances so that users are better informed about their potential hazardous effects and how best to make use of them safely.

Another classification of substance is the "Registered classification" which refers to the classification that has been submitted by the Lead Registrant (LR) while Registering a chemical with ECHA. It is expected that other players dealing with the same chemical shall modify their "self classification" to match the "registered classification".

Certain companies demand a lower classification; but if that chemical happens to have a Harmonized Classification or has already been Registered within REACH, then using a different (lower) classification can have implication on the non-European company as well as on the European buyer.

Non-European manufacturers of formulations exporting to Europe - Kindly note that the deadline for revising the classification and labelling of Mixture/Formulation according to the requirement of the CLP Regulation will be 1 June 2015.

If you need assistance with the above mentioned service, please note that Sustainability Support Services (Europe) AB shall be glad to offer the same to your organization!

Details on the Process of Harmonized Classification and Labelling

1. The harmonized classification and labelling process (CLH) includes a period of public consultation that lasts 45 days.
2. Anyone can comment on a proposed harmonization. Those most likely to be interested are companies, organizations representing industry or civil society, as well as individual experts.
3. Comments are welcomed from the EU or beyond.
4. After the consultation period the Risk Assessment Committee (RAC) will prepare a scientific opinion on the proposal taking into account the received comments.
5. RAC will examine the available evidence for all hazard classes proposed and may consider another category more appropriate for the classification of the substance after having examined the available information.
6. The RAC opinion has annexed a background document and a response to comments table based on the comments from the public consultation.
7. When the opinion is adopted, it will be published on ECHA's website together with the background document and the response to comments.
8. ECHA will forward this opinion and any comments to the Commission. If the Commission finds that the proposed harmonized classification and labelling is appropriate, it will submit a draft decision concerning the inclusion of that substance in Part 3 of Annex VI to CLP.
9. After its inclusion, all manufacturers, importers and users of the substance in the EU should classify the substance accordingly, enabling the users to be better informed about the substance, its potential effects and how best to make use of it safely.

2. ECHA updates the SVHC list

The European Chemicals Agency has added 4 new substances to the Candidate SVHC list in June 2014 that includes cadmium chloride, a phthalate and two boron substances. **Thus the SVHC list today contains 155 substances.**

Legal obligations that companies may have resulting from the inclusion of substances in the Candidate List apply to the listed substances on their own, in mixtures or in articles. Producers and importers of articles, containing any of the four substances included in the Candidate List by 16 June 2014, have six months from today to notify ECHA if both of the following conditions apply:

- The substance is present in those articles in quantities over one ton per producer or importer per year, and
- The substance is present in those articles above a concentration of 0.1% weight by weight.

There are exemptions from the notification obligation if the substance is already registered for the use or when exposure can be excluded.

Chemicals on the SVHC list can be continued to be used in the manufacturing of articles. However, if they exceed the quantities mentioned within the REACH regulation, an exporter of a chemical containing SVHC or an exporter of "article" **may have to fulfill additional obligations of "Notification" and/or "Communication". There is also a possibility of the SVHC chemical requiring an "Authorization"** if the SVHC chemical qualifies for the same as per the clauses stipulated for "Authorization".

More….

Details of the 4 chemicals put on the Candidate SVHC list in June' 2014

S. No	Substance name	EC number	CAS number	SVHC property
1.	Cadmium chloride	233-296-7	10108-64-2	Carcinogenic, Mutagenic & Toxic for reproduction Equivalent level of concern having probable serious effects to human health
2.	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Toxic for reproduction
3.	Sodium peroxometaborate	231-556-4	7632-04-4	Toxic for reproduction
4.	Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	-	Toxic for reproduction

3. New batch of SVHCs identified for Authorization

ECHA has recommended a new batch of 5 chemical substances for authorization to the European Commission. Four of the chemicals have hazardous properties for human health being classified as carcinogenic, toxic for reproduction or respiratory sensitizers. The fifth entry comprises an SVHC which has effects to the environment due to its degradation to a substance with endocrine disrupting properties.

The authorization regime is one of the core mechanisms of REACH for the protection of human health and the environment. Making these substances of very high concern (SVHCs) subject to authorization makes sure that their risks are properly controlled and that the substances are progressively replaced with suitable alternative substances or technologies.

The final decision on the inclusion of the substances in Annex XIV of the REACH regulation and on the dates by which companies will need to apply for authorization to ECHA will be taken by the European Commission in collaboration with the Member States and the European Parliament.

More… The recommended substances, including examples of their uses in the scope of authorization, are:

S. No	**Substance name and SVHC property**	**Uses in the scope of Authorization (examples)**

1.	N,N-dimethylformamide (DMF) *(toxic for reproduction)*	Solvent for synthesis and for production of coated textiles and synthetic fibres
2.	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) *(equivalent level of concern due to its respiratory sensitising properties)*	Blowing agent in the rubber and plastics industry
3.	Aluminosilicate Refractory Ceramic Fibres (Al-RCF) *(carcinogenic)*	Insulation for high-temperature industries; ceramic and metal composite reinforcement; electrical and acoustic insulation
4.	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) (*carcinogenic)*	Insulation for high-temperature industries; ceramic and metal composite reinforcement; electrical and acoustic insulation
5.	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO) *(equivalent level of concern due to its degradation to a substance with endocrine disrupting properties)*	Paints and coating products, emulsion polymerisation

Chemicals on the Authorization list

S. No.	Substance Name	EC Number	CAS Number	Sunset date	Latest application date
1.	Ammonium dichromate	232-143-1	7789-09-5	21/09/2017	21/03/2016
2.	Potassium chromate	232-140-5	7789-00-6	21/09/2017	21/03/2016
3.	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	7738-94-5, 13530-68-2	21/09/2017	21/03/2016
4.	Chromium trioxide	215-607-8	1333-82-0	21/09/2017	21/03/2016
5.	Potassium dichromate	231-906-6	7778-50-9	21/09/2017	21/03/2016
6.	Sodium chromate	231-889-5	7775-11-3	21/09/2017	21/03/2016
7.	Sodium dichromate	234-190-3	7789-12-0; 10588-01-9	21/09/2017	21/03/2016
8.	Trichloroethylene	201-167-4	79-01-6	21/04/2016	21/10/2014

9.	Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9, 247-148-4	3194-55-6, 25637-99-4, 134237-50-6, 134237-51-7, 134237-52-8	21/08/2015	21/02/2014
10.	2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	21/08/2015	21/02/2014
11.	Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8	21/08/2015	21/02/2014
12.	Diarsenic pentaoxide	215-116-9	1303-28-2	21/05/2015	21/11/2013
13.	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	21/05/2015	21/11/2013
14.	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	21/05/2015	21/11/2013
15.	Diarsenic trioxide	215-481-4	1327-53-3	21/05/2015	21/11/2013
16.	Lead chromate	231-846-0	7758-97-6	21/05/2015	21/11/2013
17.	Benzyl butyl phthalate (BBP)*****	201-622-7	85-68-7	21/02/2015	21/08/2013
18.	Bis(2-ethylhexyl) phthalate***** (DEHP)	204-211-0	117-81-7	21/02/2015	21/08/2013
19.	Dibutyl phthalate (DBP)*****	201-557-4	84-74-2	21/02/2015	21/08/2013
20.	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	21/02/2015	21/08/2013
21.	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	21/08/2014	21/02/2013
22.	4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	21/08/2014	21/02/2013

4. Dossier Evaluation Report 2013: results and recommendations from dossier evaluation

ECHA's annual evaluation report 2013 gives recommendations to all registrants on how to improve the quality of their dossiers. As a consequence of ECHA's evaluation decisions, two thirds of evaluated registrations were brought into compliance following an update.

ECHA has till date checked 1 130 dossiers, thereby exceeding the 5 % target of the total number of dossiers submitted for the 2010 registration deadline. In 61 % of the cases concluded in 2013, ECHA found that the dossiers did not comply with one or more REACH information requirements and sent draft decisions to the registrants. Most of ECHA's information requests were related to substance identity, physicochemical properties, sub-chronic toxicity studies, pre-natal developmental toxicity studies and exposure assessment.

The report gives specific recommendations for both future registrants for the 2018 deadline and existing registrants who may need to update their dossiers. The recommendations cover these subjects:

- Improving the chemical safety report to reflect actual uses and risks.
- Knowing how to react to (draft) decisions.
- Keeping the dossier up-to-date.
- Substantiating the reasoning when adapting the standard testing regime.

More….Evaluation Report 2013 Factsheet

5. **Substance Evaluation: Registrants should get ready to comment substance evaluation draft decisions**

Draft decisions on requests for further information about those substances evaluated under the Community rolling action plan (CoRAP) in 2013 will be sent to the registrants for comments at the end of April.

In 2013, the different European Member States have been evaluating 47 registered substances under the substance evaluation process and they have also prepared a draft decision in case further information is needed in order to assess the safety of the substance.

As foreseen by REACH, registrants of these substances will have 30 days to consider and submit their joint or individual comments. A notification letter will contain the deadline by when the comments must be submitted. This deadline will include an extra seven-day period as addressed in the latest update of point 9(d) of the Terms and Conditions of REACH-IT.

The registrants receiving a draft decision on substance evaluation will be those with active registrations on a substance on the date when the draft for the decision is first sent. However, two categories of registrants will be excluded, i.e. registrants who exclusively use the substance as an on-site isolated intermediate and under strictly controlled conditions, and those who have ceased or will still cease manufacture/import of the substance before the decision is adopted by ECHA.

Wherever there are substances of Indian companies registered by SSS (Europe) AB within the CoRAP, SSS professionals are in touch with the respective Member State Competent Authorities (MSCA) and participate in all the meetings wherein; discussions are done relating to the availability of data and the need to conducted any additional testing where existing information is insufficient to prove or negate the hazard

[**More**…Related Factsheet of ECHA]

6. Restriction of chromium VI in leather articles will apply from 1 May 2015

The oldest and most common tanning methods in the leather industry worldwide are chrome-based. A frequently used form is trivalent chromium. Under certain conditions, it can oxidize into hexavalent chromium, which is known for its negative health and environmental impact. Even if chromium VI is only present in small amounts in the leather, it can cause dermal allergies and asthmatic reactions. From 1 May 2015, goods or articles containing leather parts that come into contact with the skin, cannot be placed on the EU market if they contain hexavalent chromium in concentrations of 3 mg/kg by weight or more. Companies importing or manufacturing leather shoes, gloves, clothes, hats and sports equipment as well as furniture, car accessories and straps for watches or bags, may need to change their suppliers or their production process.

The new restriction does not only apply to leather tanneries.

More….Safer Alternative

Sanotan - a new technology which replaces chromium compounds with titanium - has won national and international prizes for protecting the environment and for developing innovative materials for the fashion industry.

Spanish SME Incusa is among those leading the way with a new registered technology, Sanotan, which has effectively replaced chromium compounds with titanium. Titanium-based technology is the future. Another reason is that the natural reserves of titanium are larger than those of chromium. Titanium is also a sub-product of other industries like ceramics, so it will always be available.

Titanium compounds are still more expensive than chromium compounds, but the Sanotan technology has achieved a reduction in chemical consumption, in water and energy consumption, and in CO2 emissions released in the environment. This leads to a productivity gain. Changing the production process was not easy and it took nearly two years to get the new technology ready for market. At first, the quality of the leather was not satisfactory, but the company continued with the research.

The EU-funded project “TiLeather” included laboratory testing for quality, which showed that Sanotan leather meets the European eco-label criteria. It avoids most of the environmental problems caused by traditional tanning. It is hypoallergenic and comfortable for wearing. Using this technology helped us reach a wider range of customers. Incusa are now working with big brands, exporting to the USA and moving to new markets. Some examples are leather straps for Swiss watches, baseball gloves and horse saddles. There has also been interest from the aviation industry.