

European Chemicals Agency ("ECHA") Identify 4,4'-Methylenebis(2-Chloroaniline) ("MOCA") Pursuant to REACH as a Substance of Very High Concern

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By way of background, in 2010 the International Agency for Research on Cancer ("IARC") published a monograph that evaluated the carcinogenic risk by MOCA to humans. IARC's conclusion was that MOCA is Group I-carcinogenic to humans. This is an upgrade from the previous IARC classification of MOCA as Group 2A—"probably carcinogenic to humans."

In Europe, Member States Competent Authorities or the European Chemicals Agency (ECHA), on request of the European Commission prepares Annex XV dossiers for the identification of Substances of Very High Concern ("SVHC"). SVHCs are defined in Article 57 of Regulation (EC) No 1907/2006 ("the REACH Regulation") and include substances which are:

- Carcinogenic, Mutagenic or Toxic to Reproduction (CMR)—classified as 1A or 1B
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)
- Identified, on a case-by-case basis

ECHA prepared an Annex XV dossier for MOCA (a copy of the dossier is available from the PMA office). As stated in the dossier "The substance [MOCA] is proposed to be identified as a substance meeting the criteria of Article 57(a) of Regulation (EC) 1907/2006 ("REACH") owing to its classification as carcinogen 1B which corresponds to classifications as carcinogen category 2 ("may cause cancer")." It is feasible to conclude that IARC's classification of MOCA as carcinogenic to humans has increased ECHA's interest in MOCA as a carcinogen. The MOCA dossier goes into detail regarding uses of MOCA, including by the polyurethane industry; releases from uses; and current knowledge of alternatives. ECHA notes potential uses for MOCA include use as a curing agent in resins and in the production of polymer articles and also for the manufacture of other substances.

SVHCs are gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set unless the company is granted an "authorisation." There is no tonnage threshold for SVHC to be subject to authorisation.

The authorisation process consists of four steps as noted by ECHA.

Step 1: Identification of SVHC

ECHA published its proposal on August 29, 2011 to identify 20 chemicals as SVHCs and thus as possible candidates for authorisation. MOCA was one of the 20 chemicals identified as a candidate on the Candidate List. Comments by the public on the proposals were requested by ECHA to focus primarily on the hazardous proper-

ties that qualify the chemicals as SVHCs and also the uses, exposures and availability of safer alternative substances or techniques. The comment period ended on October 13, 2011.

Step 2: Prioritization process (by authorities)

The substances on the candidate list are then prioritized to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process, similar to Step 1. PMA is currently preparing a submittal of information and written comment.

Step 3: Applications for authorisation (by industry)

An application for authorisation needs to be conducted within the set deadlines for each use that is not exempted from the authorisation requirement. The "Guidance on the Preparation of an Application for Authorisation" is available from the PMA office.

If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how the applicant intends to replace the substance by the alternative. The Agency will provide expert opinions on the applications and the applicant can comment on those opinions.

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The "adequate control route" does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.

If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies. PMA's MOCA Safe Use Guidance document and Dr. Hogan's MOCA study for dermal exposure control work practices evaluating the PMA's MOCA Safe Use Guidance practices, will be of significant value for an authorisation submittal.

Users, including downstream users, may only use the substances for uses which have been authorized. For this they must either:

- "obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorized substance."
- "apply themselves for authorisations for their own uses."
- ECHA provides a summary of obligations from inclusion in the Candidate List for SVHCs for authorisation (also available from

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the PMA office). “Companies may have legal obligations resulting from the inclusion of substances in the Candidate List. These obligations refer not only to the listed substances on their own or in mixtures, but also to their presence in articles.”

For SVHC in articles, ECHA provides requirements in two categories “From the date of inclusion” and “From 2011.” Note that notification of ECHA may not be required under the “From 2011” category if the SVHC has been registered; MOCA has been registered with REACH. For substances “on their own” and substances “in mixtures” there are also requirements.

In conclusion, it appears MOCA is in Step 2 of the authorisation process. However, it is important to note that the appropriate authorities:

- determine whether the substance is subject to authorisation.
- which uses of the substances will not need authorisation.
- the “sunset date” by when a substance can no longer be used without authorisation.

Going Light Green

By David Welch, Everchem Specialty Chemicals

Solar Furnace

Heating costs getting out of control? Investigate installing a simple version of a solar furnace to heat your office space. First introduced in the 1970s, this version uses 1-inch diameter rock as a heat storage media and air as the working fluid and a fan to move the air. There are no liquids or valves to contend with. The rock is contained in a triangular-shaped box covered with a special solar glass that lets heat in but not out. A fold down reflective cover improves efficiency as well as protection when it is closed during warmer months. It takes about 1 week to “charge” the system at the start of the heating season, and there is enough thermal storage in the rock mass to last 4-5 days during episodes of cloudy weather.



Call for 2012 Technical Papers

Due Friday, December 30, 2011

The Polyurethane Manufacturers Association (PMA) is soliciting Technical Papers for presentation during the 2012 PMA Annual Meeting, April 21-24, 2012, to be held at the Sheraton New Orleans, New Orleans, LA.

Presentation date will be the afternoon of Tuesday, April 24, 2012. Abstracts are due Friday, December 30, 2011. Selected abstracts will be notified in January, and completed papers are due March 2, 2012.

If you or someone you know is interested in presenting or have any questions, please contact the PMA office immediately at (414) 431-3094 or info@pmahome.org.

Abstracts can be submitted using the instructions on the downloadable PDF, or online: <http://www.pmahome.org/callfortechpapers.html>