EUROPEAN TYRE & RUBBER manufacturers' association

COMMENTS TO ECHA DRAFT RECOMMENDATION

ETRMA response to the EU public consultation on ECHA recommendation to include ADCA in Annex XIV

Brussels, 23 September 2013

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Substance name: **Diazene-1,2-dicarboxamide (C,C`-azodi(formamide)) (ADCA)**
EC Number: **204-650-8**
CAS Number: **123-77-3**

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I. Personal information

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II. Organisation

- Type of organisation/institution: Industry association
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III. Comments

GENERAL COMMENTS

General comments on the recommendation to include the substance in Annex XIV, including the prioritisation of the substance:

ETRMA questions the prioritisation of ADCA for inclusion in Annex XIV. ETRMA **considers the defining the use of ADCA as "wide-dispersive" is incorrect, as is the statement that the substance is "expected to be used in applications where a significant exposure of workers cannot be excluded"**.

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ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is therefore not consistent with what is described in the Annex XV dossier itself. Uses of articles manufactured with ADCA do not result in significant releases of the substance. **ADCA use may be considered only as 'widespread' but not as 'wide-dispersive'.**

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Potential inhalation exposure is limited to only early stages of rubber article manufacturing processes (namely: storage and weighing)*. ADCA is handled in powder form only by a limited number of workers (for example, in a plant of 217 workers only 7 handle ADCA in power form). Following the mixing phase, potential inhalation exposure disappears because the substance gets embedded in the polymeric matrix.

ADCA in rubber manufacturing plants is handled in strict compliance with the specifications contained in the extended Safety Data Sheets, which are considered to be sufficient to avoid human health risks during the manufacturing of rubber goods, according to the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protection measures are required, as reported in the REACH registration dossier**.

- Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure.
- Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended.
- Eye protection: Safety glasses
- Body protection: Protective work clothing

TRANSITIONAL ARRANGEMENTS (Application date(s) and Sunset date(s))
Comments on the proposed dates:

Industrial validation tests on alternative substances have been conducted by several companies. For most existing applications, there are currently no known alternatives which meet the required product specifications for the automotive and aerospace applications, for example. The main problem is that the volume of air generated is lower, and thus the density of the final material is not good. The vulcanization kinetics are also different.

Individual companies find that most of the alternatives proposed in the Annex XV dossier do not give satisfactory results: low decomposition temperatures, generation of holes that worsen a vehicle's resistance to corrosion. Additionally, certain identified substances (TSH, TSSC, DNPT) pose serious health hazards, and sometimes, risks of explosions.

Reformulation is critical and products with new formulations might need to be, in most of the cases, "requalified" without the guarantee that they will meet the necessary safety performances.

There is currently great uncertainty on the possibility to find available alternatives and on the timeline necessary for substitution.

Hints:

- *for more details on the approach used by ECHA for determining the proposed Application dates and Sunset dates, see the document approach for preparing draft Annex XIV entries – section "Transitional arrangements"*
- *please note that the present lack of alternatives to (some of) the uses of a substance or the time estimated to change industrial processes and finalise transition to alternatives is no viable reason for prolonging the application dates or sunset dates for the substance or some of its uses. Such information is however important information to be included in a potential authorisation application, if the substance is included in Annex XIV.*

USES (OR CATEGORIES OF USES) EXEMPTED FROM THE AUTHORISATION REQUIREMENT
(including product and process oriented research and development (PPORD) and maximum tonnage for that)
Comments on uses that should be exempted, including reasons for that:

Considering the current impossibility to substitute the use of ADCA, and the absence of human health exposure risk, as indicated above, we find an exemption from authorisation is needed and necessary for the manufacturing of rubber articles, including:

- Sealing gaskets
- Sealing components
- Expandable mastic for insulation and soundproofing
- Tyres foam filler
- Parts of anti-vibration rubber components
- Expandable polymer for thermal insulation for aerospace applications.

Such rubber applications are very important within a vehicle since, among others benefits, they prevent the leakage of liquids, and contribute to shock absorption, both in normal vehicle use conditions and in the case of accidents.

Major identified risk in case it becomes impossible to use ADCA in rubber goods manufacturing, or due to costs associated with the REACH authorisation procedure: delocalization of manufacturing outside EU to satisfy the current market demand.

Hints:

- *mention clearly the **use(s)** or categories of uses that are proposed to be exempted*
- *mention the **Community legislation** which is considered to justify the proposed exemption(s)*
- *please note the explanations on **preconditions** to fulfilled for considering exemption of uses from authorisation (see the document on approach for preparation of draft Annex XIV entries – section "Uses or categories of uses exempted from the authorisation requirement")*
- *if the proposed exemption regards product and process oriented research and development (PPORD), first check whether the use falls indeed under the definition of **PPORD**, and if so include the maximum tonnage proposed to be exempted and provide a justification for your proposal*
- *if a use falls under the **generic** exemptions from authorisation, there is no need to propose an additional specific exemption.*

REVIEW PERIODS FOR SPECIFIC USES

Comments on uses for which review periods should be included in Annex XIV, including reasons for that:

None

Hints:

- *please note that all authorisation decisions will include a case specific review period, based on concrete case specific information provided in the applications for authorisation*
- *if you consider that review periods for certain use(s) should already be included as entry in Annex XIV and not decided upon case by case, then mention clearly the respective use(s), the proposed review period(s), and sufficient information justifying the setting of an upfront review period*

IV. Attachment (additional non-confidential information)

General Rubber Goods manufacturing *

V. Confidential Attachment

None.

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