

24 June 2013

Draft background document for Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]

Document developed in the context of ECHA's fifth Recommendation for the inclusion of substances in Annex XIV

Information comprising confidential comments submitted during the public consultation, or relating to the content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name: Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]
EC Number: 204-650-8
CAS Number: 123-77-3
IUPAC Name: Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]

2. Background information

2.1. Intrinsic properties

Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as a respiratory sensitiser, Resp. Sens. 1¹ (H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled"), and was therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

¹ This corresponds to a classification as respiratory sensitiser (R42: "May cause sensitisation by inhalation") in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) N° 1272/2008

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

According to information provided in the registration dossiers, diazene-1,2-dicarboxamide (ADCA) has been registered in volumes in the range of 10,000 - 100,000 t/y. The entire volume of the substance appears to be used in applications in the scope of authorisation. Further information is provided in the confidential annex.

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

ADCA is a low molecular weight amide. It is manufactured predominantly as a yellow/orange powder with a particle size in the 2-10 micron range (Annex XV report, 2012), which is in the respirable range for humans.

2.2.2.2. Uses and releases from uses

The main use of ADCA (as described in the registration dossiers) is as a blowing agent in the rubber and plastics industry:

- Formulation of mixtures, including:
 - o foaming agent
 - o foaming agent blend
 - o extrusion
- Compounding

All these uses appear to be in the scope of authorisation.

This blowing action is caused by gases (N₂, CO, CO₂, NH₃) being released during heat induced decomposition of ADCA (process temp. between 190 and 230°C) (HSE, 1998)². The pure substance is mixed with additives which adapt the decomposition characteristics of ADCA to the needs of the commercial processors, or which alter the supply form.

The substance is mainly used by downstream user sectors such as automotive (sealing, moss and sponge rubber, corrosion protection, artificial leather), construction (cold/hot water pipes, heating pipes, sewage pipes, decking, siding, signal sheets, thermal insulation, vinyl covering), electrical application (cables), shoe soles (standard and medical), sport and leisure products (gymnastic mats, canoes, physiotherapeutic products) (RCOM 2012).

Although the Annex XV report indicated use by professional workers during foaming processes and use by consumers in construction chemicals and air fresheners, many of the registration dossiers have now been updated (April-May 2013), particularly with information on uses. No registration currently identifies

² During processing ADCA is decomposed exothermically to a degree of >99.9%. Possible remaining ADCA (as well as its non-gaseous decomposition products) are embedded in the polymer matrix and are typically not available.

the use of the substance by professionals and consumers, while the majority of registration dossiers submitted for ADCA now advise against these uses.

Processes categories relevant for the use of ADCA such as calendering operations (PROC 6), industrial spraying (PROC 7) and roller application or brushing (PROC 10) are likely to be associated with the highest potential for inhalation exposure levels in comparison to other processes, due to the nature of these activities (e.g. industrial spraying with potential high fraction of inhalable droplets, etc.).

Typical specific industrial processes are powder mixing, co-micronisation, dispersing in liquid carriers, two roll processing, and extrusion. The substance is supplied as powder, low dust powder, liquid (paste) and dust-free solids (granules). In many cases, ADCA is supplied to secondary users, e.g. compounders or formulators.

In conclusion it is assumed that the for the uses of diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] in the scope of authorisation potentially significant exposure to workers cannot be excluded.

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2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

No conclusive information is available regarding the supply chain structure of the uses of ADCA in the scope of authorisation.

However, according to the Annex XV report (2012) the use of ADCA as a blowing agent in the rubber and plastics industry is expected to take place in the entire EU and to result in exposure of workers, particularly in smaller companies.

Regarding the use as a blowing agent, the Annex XV report (2012) describes many different formulations containing ADCA in concentrations between 1 and 95 %. Formulations containing ADCA appear to be prepared in industrial settings and then further distributed to downstream users (Austria, 2012). This suggests a supply chain structure with tens of formulator sites and hundreds of use sites in the EU.

Therefore it appears reasonable to assume that ADCA is used at a high number of sites.

2.3. Availability of information on alternatives³

The Annex XV report (2012) provides further information on the alternatives for ADCA as a blowing agent. It is noted that there are two general classes of blowing agents: chemical and physical.

The Annex XV report (2012) indicates that there are a number of *chemical* substitutes on the market. The applicability of each potential substitute depends on the technical process, the polymer and the result/properties needed. As the production processes for a variety of foamed plastic and rubber products are likely to have been optimised according to the specific technical requirements for the different products, a change in the blowing agent would require an appropriate technical adaptation in the process in order to obtain similar properties of the products.

When selecting alternative substances (chemical blowing agents) the toxicological properties of these substances also have to be taken into account. None of the alternatives listed has a harmonised classification according to Reg. (EC) No 1272/2008 (CLP). However, manufacturers and importers of some of these substances have notified serious classifications concerning human health and environment.

Other alternatives such as the use of *physical* blowing agents (e.g. nitrogen, supercritical carbon dioxide, pentane) have been developed and used with success particularly for extrusion and pressure moulding processes.

However during the public consultation (RCOM, 2012) the ADCA Task Force noted that the serious human health hazards associated with some alternatives proposed in the Annex XV report would discourage customers from using products in pharmaceutical, medical or orthopaedic applications. Furthermore, they noted that some alternatives are explosive.

³ Please note that this information was not used for prioritisation.

The ADCA Task force also stated that during their substitution testing for ADCA that the alternatives tested either do not work or result in far inferior product quality (due to unique properties and blending methods).

2.4. Existing specific Community legislation relevant for possible exemption

There seems to be no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation.

2.5. Any other relevant information (e.g. for priority setting)

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3. Conclusions and justification

3.1. Prioritisation

The substance is used in “very high” volumes in the scope of authorisation. The substance is expected to be used at a high number of sites, in applications where potentially significant exposure of workers cannot be excluded.

Verbal-argumentative approach

On the basis of the prioritisation criteria, diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] gets high priority for inclusion in Annex XIV.

Scoring approach

Inherent properties (IP)	Score		Total Score (= IP + V + WDU)
	Volume (V)	Uses - wide dispersiveness (WDU)	
1 Art. 57 (f);	9 (Very high volume used in the scope of authorisation)	Overall score: $3 * 3 = 9$ Site-#: 3 (Substance is used at a high number of sites) Release: 3 (Significant potential for worker exposure from uses within the scope of authorisation)	19

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] gets high priority for inclusion in Annex XIV.

Therefore, it is proposed to prioritise diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] for inclusion in Annex XIV.

4. References

Annex XV report (2012): Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] (ADCA). Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Submitted by Austria, August 2012.

<http://echa.europa.eu/documents/10162/d9e11c88-481a-47a9-8fff-915b48086ddb>

ECHA (2013): Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]. ECHA's dissemination website on registered substances.

http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c802b65-15b3-5d0f-e044-00144f67d249/AGGR-2dcd48a3-2970-45a8-9d8f-cd90e04ffd97_DISS-9c802b65-15b3-5d0f-e044-00144f67d249.html#section_3_5

RCOM (2012): "Responses to comments" document compiled by Austria from the commenting period 03/09/2012 – 18/10/2012 on the proposal to identify the substance Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] as a Substance of Very High Concern.

<http://echa.europa.eu/candidate-list-table/-/substance/2101/search/+/del/20/col/INCLUSIONDATECL/type/desc/pr e/3/view>