6 February 2014

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)] 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. 1[1] (H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled"). Taking into account all available information on the intrinsic properties of diazene-1,2-dicarboxamide [C,C'-azodi(formamide), ADCA] and their adverse effects, it was concluded that the substance can be regarded as substance for which in accordance with Article 57 (f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f) and was

[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

therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

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.

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. As mentioned below (section 2.2.2.2), ADCA is used in the EU in various forms.

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, including:

- Formulation of mixtures, including:
  - foaming agent blend
  - compounding
- Conversion, including:
  - extrusion
  - foaming

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

The blowing action is caused by gases (N_2, CO, CO_2, NH_3) 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, advertising), electrical application (cables), shoe soles (standard and medical), sport and leisure products (gymnastic mats, canoes, physiotherapeutic products), packaging, and household products (RCOM 2012, 2014).

[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.

Although the Annex XV report (2012) 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 the use of the substance by professionals and consumers, while the majority of registration dossiers submitted for ADCA now advise against these uses.

The level of containment during industrial use of ADCA varies among its different processes and sites. Process categories relevant for the use of ADCA such as mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5), transfer / loading (PROC 8), and calendering operations (PROC 6) 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. Based on survey results reported during public consultation (RCOM, 2014), open / semi-open systems concern a considerable part of the sites using ADCA (e.g. closed systems were reported by less than 20% of the respondents in the survey reported by the ADCA Task Force while approximately 85% of the members of EuPC[3] are reported to use closed production systems).

Typical specific industrial processes related to formulation include e.g. powder mixing, co-micronisation, and dispersing in liquid carriers. Conversion may e.g. involve extrusion, foaming (e.g. calendering), spread coating, injection/rotational moulding etc. The substance is imported in the vast majority in pure powder form. Overall in the EU market it is supplied in various forms, such as pure powder, pre-blended powder, powder pre-mixes, low-dust powder, non-dusting preparations, solid masterbatch, liquid dispersions, paste, seal sachets, and dust-free solids (granules, prills) (Annex XV, 2012; RCOM, 2014).

In conclusion it is assumed that 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.

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 has potential 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 (Annex XV report, 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.

[3] the European umbrella association of Plastics Converters

2.3. Availability of information on alternatives[4]

The Annex XV report (2012) provides further information on 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, e.g. p,p'-oxybisbenzenesulfonylhydrazide (OBSH); *p*-toluenesulfonylsemicarbazide (TSSC) and5-phenyltetrazole. 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 in the Annex XV report (2012) has a harmonised classification according to Reg. (EC) No 1272/2008 (CLP). However, manufacturers and importers of some of these substances have notified classifications concerning human health (e.g. carcinogen 1B; mutagen 2) 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 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. The ADCA Task force also stated that the alternatives tested either do not work or result in far inferior product quality (due to unique properties and blending methods).

Some further information in relation to alternatives was provided during the public consultation on the draft Annex XIV Recommendation (RCOM, 2014).

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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[4] Please note that this information was not used for prioritisation.

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

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + 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/pre/3/view

RCOM (2014): "Responses to comments" document for Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]. Document compiling comments and respective answers from commenting period 24/06/2013 –23/09/2013 on ECHA's 5th draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV). http://echa.europa.eu/documents/10162/13640/axiv_5th_recommendation_adca_rcom_en.pdf