AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

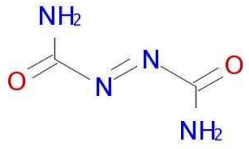
DIAZENE-1,2-DICARBOXAMIDE [C,C-AZODI(FORMAMIDE]

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006[1]

Adopted on 13 December 2012

This agreement concerns

Substance name:	**Diazene-1,2-dicarboxamide [C,C-azodi(formamide), ADCA]**
EC number:	**204-650-8**
CAS number:	**123-77-3**
Molecular formula:	**$C_2H_4N_4O_2$**
Structural formula:	

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Austria presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2012, submission number CW014643-26) on identification of *Diazene-1,2-dicarboxamide [C,C-azodi(formamide)]* as a substance of very high concern due to its respiratory sensitising properties (serious effects to human health that give rise to an equivalent level of concern as CMRs).

The Annex XV dossier was circulated to Member States on 3 September 2012 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 19 November 2012 and was discussed in the meeting on 10-13 December 2012 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

Diazene-1,2-dicarboxamide [C,C-azodi(formamide), ADCA] **is identified as a substance of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with respiratory sensitising properties for which 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 of REACH.**

UNDERLYING ARGUMENTATION

FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Effects to the human health:

Diazene-1,2-dicarboxamide [C,C'-azodi(formamide), ADCA] is classified as respiratory sensitiser with Resp. Sens. 1 according to Reg. (EC) No 1272/2008, Annex VI, Table 3.1[2].

There is scientific evidence that ADCA induces occupational asthma with initial symptoms like rhinitis, conjunctivitis, wheezing, cough followed by symptoms like chest tightness, shortness of breath and nocturnal asthmatic symptoms, with a possible delay of symptoms up to years. Prolonged exposure to ADCA may result in persistent symptoms of bronchial hyperresponsiveness lasting for years. Respiratory diseases including occupational asthma after exposure to ADCA have been recorded at national level in some Member States.

Equivalent concern:
The inherent properties of ADCA give rise to equivalent level of concern because:

- A prevalence study on occupational asthma was carried out among a group of 151 workers at a factory manufacturing ADCA. The findings showed that:
    - At the time of the investigation, airborne concentrations of ADCA ranged between 2 and 5 mg/m³, as 8-h time-weighted averages.
    - The prevalence of workers diagnosed as having developed asthma because of ADCA was 18.5% (28).
    - Of the 28 workers diagnosed as sensitised, over half developed asthma within 3 months of first exposure and 21/28 (75%) within 1 year.
    - Of 13 workers remaining exposed to ADCA for more than 3 months after development of symptoms over half developed sensitivity to previously well tolerated irritants.
    - In 5 individuals sensitivity persisted for over 3 years although exposure to ADCA was stopped. Two of these still had exercise-induced asthma after seven years, i.e. at the time the study was terminated.

The study results, together with scientific evidence from additional studies provided in the Support Document show that ADCA is a strong respiratory sensitiser that can cause severe and persistent adverse effects on human health at relatively low exposure levels.

On the basis of the available data for ADCA the derivation of a safe concentration is not possible.

Therefore, severe health effects cannot be excluded. Overall, these findings show that the impacts caused by ADCA on the health of the affected individuals and on the society as a whole, are comparable to those elicited by category 1 carcinogens, mutagens and reproductive toxicants (CMRs).

In addition, available information on workplace air concentrations (dust, fine dust, ADCA) provides evidence that the highest reported values are well within the range of the exposure concentrations that elicited the adverse effects described in the studies.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Conclusion:

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 is 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.

Reference:

1. Support Document *Diazene-1,2-dicarboxamide [C,C-azodi(formamide)]* (Member State Committee, 13 December 2012)