AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

ETHYLENEDIAMINE (EDA)

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 1 June 2018

This agreement concerns

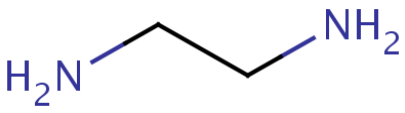
Substance name: ethylenediamine (EDA)

EC number: 203-468-6

CAS number: 107-15-3

Molecular formula: $C_2H_8N_2$

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

ECHA presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (01 March 2018, submission number SPS-013056-16) on identification of *ethylenediamine* as a substance of very high concern due to its respiratory sensitising properties.

The Annex XV dossier was circulated to Member States on 8 March 2018 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 22 May 2018 and agreed in the written procedure of the Member State Committee with closing date of 1 June 2018.

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

Ethylenediamine is identified as a substance meeting the criteria of 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 gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 REACH.

UNDERLYING ARGUMENTATION

FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Equivalent level of concern:

Ethylenediamine (EDA) is covered by index number 612-006-00-6 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified as a respiratory sensitiser.

EDA 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 gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of REACH Regulation.

The inherent properties of EDA give rise to an equivalent level of concern because there is evidence in the scientific literature (such as the case studies presented in the support document) that a considerable proportion of workers become respiratory sensitised to EDA and do develop serious health conditions such as occupational asthma at airborne concentrations as low as 1 ppm (2.5 mg/m^3). Such effects are very serious and represent permanent impairment of lung function. The observed effects reported in the case studies occurred at a level ten times lower than the current Occupational Exposure Limit (OEL) of 10 ppm (8h TWA) adopted in many EU countries.

Most reports describe both an early onset (type 1) and a late phase (delayed) asthmatic response typical of a type III/IV IgG and cell-mediated allergic response. Symptoms of respiratory tract sensitivity may arise after variable periods of workplace exposure. Respiratory sensitisation is considered to be the major health effect of concern.

The available data do not allow either elucidation of dose-response relationships or identification of the thresholds for induction of the sensitive state or provocation of an asthmatic response. On the basis of the available data for EDA it is not possible to derive a no effect level, meaning that a safe concentration cannot be derived.

Permanent impairment of lung function due to EDA induced occupational asthma, as a worst case example, can lead to a decreased quality of life and a requirement for long-term medication. In most cases, the need to eliminate exposure means that the person can no longer work in their chosen profession. Both of these effects therefore limit the person's possibility of living a normal working and private life.

Health effects caused by respiratory sensitisers can lead to permanent disability, which can be viewed as a concern within society. There can also be a significant cost of treating affected individuals in society, in addition to retraining and unemployment support. For example, many workers who develop occupational sensitivity to EDA exposure decide to leave their place of employment or get relocated to prevent continuing symptoms.

There are no data directly describing the economic or societal costs associated with EDA sensitisation. Specifically there are no data describing the costs that could be attributed solely to EDA-induced occupational asthma. A number of studies have investigated the economic costs of respiratory sensitisation in the workplace as an overall societal burden or in relation to other substances. This information, in association with data on prevalence of sensitisation within the general public may however be useful and relevant in the assessment of the impacts of EDA.

The full economic burden of a disease includes not only the direct and indirect costs, but also the psychosocial consequences that cannot be translated into

monetary terms (i.e. intangible costs). It has been shown that even after removal from the offending exposure, the quality of life is less satisfactory in patients with occupational asthma than in those with asthma unrelated to work who were matched for clinical and functional indices of asthma severity.

Considering the type and severity of the health effects mentioned above, the irreversibility of such effects, their impacts on the person's quality of life and the overall societal concern, EDA can be regarded as giving rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of REACH Regulation.

In conclusion, the substance *ethylenediamine* meets the criteria 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 gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document on *ethylenediamine* (Member State Committee, 1 June 2018)