

Health Council of the Netherlands

Ethylene glycol

Executive summary



At the request of the Ministry of Social Affairs and Employment, the Health Council of the Netherlands evaluated the effects of ethylene glycol on reproduction. Based on this evaluation they made a recommendation for classification. The advisory report was drafted by the subcommittee on the Classification of Substances Toxic to Reproduction of the Dutch Expert Committee on Occupational Safety (DECOS) of the Health Council. More information about the committee and its task can be found at healthcouncil.nl.

Use of ethylene glycol

Ethylene glycol is a colourless liquid mostly used for the production of polyester fibres, polymers, and polyethylene terephthalate (PET) resins. It is also used for its antifreeze and coolant properties as a de-icing fluid for aircrafts and windshields for cars. Additionally, it can be used as solvent in paints and as a softening agent in the manufacture of plasticisers. Occupational exposure can occur through inhalation, and skin and eye contact. For example, workers involved in airport de-icing operations can be exposed when ethylene glycol vapour and mist is generated by spraying de-icing formulation through the air.

Classification based on strength of evidence

To assess effects on reproduction, the committee evaluates the available literature on the effects on male and female fertility and on the development of offspring. Moreover, the committee considers effects of a substance on lactation and on the offspring via lactation. If the data indicate hazardous properties, the committee recommends classification into a hazard category. Classification is performed according to EU-regulation (EC) 1272/2008 (see text box). When there are indications that a substance has hazardous properties, the committee recommends classifying the substance into hazard categories that indicate the strength of the evidence for hazardous effects (see text box). For category 1, the strength of evidence is highest, and largely based on studies in humans (1A) or animals (1B). For category 2, evidence is limited, and the substance is categorised as a suspected toxicant. The committee can also recommend not classifying a substance because of insufficient data or because the substance is probably not hazardous for reproduction.

A recommendation for classification reflects the strength of evidence for the hazardous properties of a substance, but it does not reflect the health risk for workers. The health risk is based on the level of exposure to the

substance in the workplace. The committee does not have sufficient data on these exposure levels.

Reviewed literature

No human data were available for the evaluation of adverse effects of ethylene glycol on fertility, development and lactation. The committee based their evaluation on animal studies only.

Fertility

Overall, no consistent effects on fertility were observed across studies. Several studies in mice showed potential adverse effects on fertility in terms of lower litter sizes and lower number of live pups. However, definite conclusions cannot be drawn as it is unclear whether these effects can be attributed to fertility or development. One study in rats and one in mice found no functional fertility effects. Other studies are of limited quality, or are not optimally designed to assess fertility. Overall, the studies on reproductive organs are very limited in design. The committee considers the available data to be too limited and of too low quality to allow a definite conclusion on fertility.

Development

Studies in rats and mice clearly showed that exposure to ethylene glycol caused adverse effects on development. The effects were mainly related to foetal body weights, skeletal malformations, post-implantation loss and

lower numbers of live foetuses per litter. No adverse effects were found in rabbits up to dose levels causing maternal toxicity. This could be because of differences between rodents and rabbits in foetal accumulation of ethylene glycol and its metabolite glycolic acid, which is the primary toxicant causing developmental toxicity. However, the committee did not find conclusive evidence that shows that the rabbit model would be a more appropriate model for evaluating the effects of ethylene glycol in humans. Therefore, the rodent studies were not excluded from the evaluation. The committee concludes that based on the clear evidence for an adverse effect on development, classification in Category 1B is warranted.

Lactation

Due to a lack of relevant data, adverse effects of exposure to ethylene glycol on or via lactation cannot be evaluated.



Recommendations to the ministry

Based on the available scientific data, the committee recommends:

- not to classify ethylene glycol for reproductive toxicity, due to inconsistent and insufficient data;
- to classify ethylene glycol in Category 1B, H360D, for developmental toxicity;
- not to classify ethylene glycol for effects on or via lactation, due to a lack of data.

Classification for substances toxic to reproduction

The Health Council performs classification and labelling of substances according to the guidelines of the European Union (Regulation (EC) 1272/2008). The hazard categories described below indicate the strength of the evidence for hazardous properties of the substance. The substance is also labelled with an EU hazard statement code that can be used on packaging.

Classification for reproduction (fertility (F) and development (D)):

- Category 1: Known or presumed human reproductive toxicant - Causes adverse effects on fertility or the unborn child (Hazard statement code H360(F/D)).
- Category 1A: Known human reproductive toxicant – Substances that are known to be toxic for human reproduction, largely based on human studies (H360 (F/D)).
- Category 1B: Presumed human reproductive toxicant – Substances that are presumed to be toxic to human reproduction, largely based on animal studies (H360 (F/D)).
- Category 2: Suspected human reproductive toxicant – Can possibly affect fertility or the unborn child. Evidence from animal and/or human studies is limited (H361(f/d)).

Classification for lactation:

- Effects on or via lactation (H362) – Substances which have been proven to affect lactation or which are present in breast milk in such quantities that there is reason for concern for the health of the breastfed child.

Implications for the workplace

According to the Dutch Working Conditions Act, employers are legally required to prevent or minimize the health and safety risks of working with hazardous substances as much as possible. Based on the Health Council's recommendations

for classification, the Minister of Social Affairs and Employment can decide to add substances to the official list of substances that are carcinogenic, mutagenic or toxic to reproduction. This list includes carcinogenic and mutagenic substances in categories 1A and 1B, and substances toxic to reproduction in categories 1A, 1B and 2. Depending on the classification, the government asks the employer to take additional measures to protect employees.

This publication can be downloaded from healthcouncil.nl.

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