# 4,4'-Methylene bis (2-chloroaniline)

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## Executive summary

Health Council of the Netherlands





At the request of the Ministry of Social Affairs and Employment, the Health Council of the Netherlands has derived health-based advisory values for 4,4'-methylene bis (2-chloroaniline). This advisory report has been composed by the Dutch Expert Committee on Occupational Safety (DECOS). More information on the tasks of this permanent committee of the Health Council of the Netherlands can be found at www. gezondheidsraad.nl. The members of the Committee are listed on the last page of this report.

## Use of 4,4'-methylene bis (2-chloroaniline)

4,4'-Methylene bis (2-chloroaniline) is primarily used as a curing agent for polyurethane prepolymers in the manufacture of castable urethane rubber products. Particularly workers in the plastic and rubber industry can be exposed to this substance.

## Advisory values based on extra risk of cancer

For carcinogenic substances that have been

classified in category 1A or 1B and directly interact with DNA (stochastic genotoxic mechanism), no exposure level can be derived below which no carcinogenic effects can occur. To be able to set occupational exposure limits for these substances, the Minister of Social Affairs and Employment has determined risk levels. These risk levels relate to the extra risk of cancer due to lifetime occupational exposure. As advisory values, the Committee estimates the concentrations in the air that correspond to these risk levels, taking into account 40 years of occupational exposure.

### Target risk level and prohibitive risk level

The target risk level is 4 per 100,000. This means that for concentrations leading up to 4 extra cancer cases per 100,000 occupationally exposed people, no additional protective measures need to be taken. The prohibitive risk level is 4 per 1,000. This means that the concentration leading to 4 extra cancer cases per 1,000 occupationally exposed people, must not be exceeded.

#### Consulted research

There are no studies in humans available on exposure to 4,4'-methylene bis (2-chloroaniline) and the occurrence of cancer that are suitable for deriving health-based advisory values. There are different animal carcinogenicity studies available. The Committee has evaluated these studies and selected the most suitable one. In this study, rats exposed to 4,4'-methylene bis (2-chloroaniline) via feed during lifetime developed different types of tumours. The number of lung tumours has been used by the Committee to derive the health-based advisory values.







The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research..." (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

This publication can be downloaded from www.healthcouncil.nl.

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