

Minority opinion regarding the classification of reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); MBO

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The minority opinion regarding the classification of MBO is the following:

It is recognised that exposure to MBO may lead to the release of formaldehyde at sites of initial contact with the body and that formaldehyde does appear to have potential to damage the genetic material of such tissues. However, the available evidence on formaldehyde shows that it does not appear to be able to reach the germ cells following conventional oral, dermal or inhalational routes of exposure. Consequently, we are of the opinion that MBO, like formaldehyde itself, does not present a relevant germ cell mutagenicity hazard to humans.

Whilst we recognise that substances may still be classified as suspected germ cell mutagens where there is evidence only of somatic cell genotoxicity, this does not appear to be relevant for formaldehyde and substances that release it at sites of initial contact with the body. The available toxicokinetic information indicates that the germ cells are unlikely to be targeted. We do not agree that the current ECHA guidance on this aspect of the criteria should always be read literally, without the possibility of applying scientific judgement in exceptional circumstances such as this.

In our opinion, MBO should not be classified for the human health hazard endpoint germ cell mutagenicity; it should not be labelled "Suspected of causing genetic defects."