

## Minority opinion regarding the classification of chloroform

by Alicja Andersson, May 2011

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

1. Based on the weight of evidence evaluation, the available data do allow a conclusion to be drawn about the mutagenicity of chloroform.
2. The main basis of this conclusion are the results from the positive studies in somatic cells (Fujie *et al.* 1990, Hoechst *et al.* 1988, Shelby and Witt 1995) that included repeated positive experiments with dose-response relationship, which implies that the effects did not occur by chance. Therefore, it can be concluded that chloroform is a mutagen in somatic cells.
3. According to CLP, Annex I 3.5 the classification in Category 2 is based on:

Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:

– **Somatic cell mutagenicity tests *in vivo*, in mammals;** or

– Other *in vivo* somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays

Note: Substances which are positive in *in vitro* mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, shall be considered for classification as Category 2 mutagens.

4. Since chloroform is able to induce micronuclei and chromosome aberrations in somatic cells *in vivo*, the substance meets the criteria (in bold above) for Muta Cat 2 classification.