

## COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Review of potential risks from 2-MCPD, 3-MCPD and glycidol and their fatty acid esters in the diet of infants aged 0 to 12 months and children aged 1 to 5 years.

### Matter arising

Committee members requested further consideration of the *in vivo* genotoxicity data on 3-MCPD to confirm that it is not genotoxic *in vivo*. Providing this was confirmed, the Committee agreed with EFSA's evaluation of 3-MCPD and its fatty acid esters.

### In vivo genotoxicity of 3-MCPD

The genotoxic potential of 3-MCPD has been investigated *in vivo* in mammals considering various endpoints: gene mutations, chromosomal aberrations, DNA strand breakage and induction of DNA repair (via unscheduled DNA synthesis assay). Several organs were analysed: peripheral blood, bone marrow, liver and also the target organs for cancer: kidney and testis. The genotoxic potential observed in some *in vitro* tests could not be reproduced *in vivo*. These results are summarised in Table 1. Overall, the CONTAM Panel considered that there is no evidence indicating that 3-MCPD is genotoxic *in vivo* (EFSA 2016). In addition, the Committee on Mutagenicity (COM) concluded that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo* (COM 2000).

**Table 1:** *In vivo* genotoxicity data on 3-MCPD (reproduced from EFSA 2016)

Type of test	Experimental test system	End point	Substance tested	Experimental conditions	Result	Reference
Micronucleus test	CrI: Han Wist BR rats Bone marrow	Chromosomal aberrations	3-MCPD	2 days oral gavage. 0 (water), 15, 30 and 60 mg/kg bw per day. Sampling: 24 h after last Administration.	Negative	Robjohns <i>et al.</i> 2003
	Male F344 <i>gpt</i> delta rats		3-MCPD	4 weeks, 5 times a week, gavage. Neg. control: olive oil. 40 mg/kg bw per day. Sampling: 24 h after last Administration.	Negative	Onami <i>et al.</i> 2014
	Mouse		3-MCPD	40–120 mg/kg bw.	Negative	Jaccaud &

						Aeschbacher 1989
	Rat		3-MCPD	2 days, gavage. 0, 15, 30 or 60 mg/kg bw per day.	Negative	Marshall 2000
Comet assay (alkaline)	Male Sprague- Dawley rats Blood leucocytes, bone marrow, liver, kidney and testis	Single strand breaks	3-MCPD	2 days, gavage. 0 (water), 25 or 60 mg/kg bw per day. Sacrifice 3 h after 2-day administration.	Negative	El Ramy <i>et al.</i> 2007
	Male F344 rats Blood leucocytes and testis		3-MCPD	2 days gavage. 0 (water) or 60 mg/kg bw per day. Sacrifice 3 h after 2-day administration.	Negative	El Ramy <i>et al.</i> 2007
Pig-a mutation assay	Male F344 <i>gpt</i> delta rats Red blood cells	Gene mutation	3-MCPD	4 weeks, 5 times a week, gavage. Neg. control: olive oil. 40 mg/kg bw per day. Sampling: 24 h after last administration.	Negative	Onami <i>et al.</i> 2014

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