3-Monochloropropane-1, 2-diol (3-MCPD) Esters in Edible Oils and in other Foods: Is There a Need for Concern?

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INTRODUCTION

In today's global demand for healthy and safe foods, consumers are looking for foods without or with least contaminants. Foods produced from either small farms or large corporations are as much subjected to the same growing consumer demands for healthy, nutritious foods. Convenient foods have led to continuous improvement of existing food processing techniques, all designed to produce safe foods, while maintaining nutritional and sensory qualities. These developments require a more structured approach for the safety evaluation of foods and food ingredients. In the production of edible oils and fats from the crude oils, most oils are refined to remove free fatty acids, peroxides and other oxidative compounds which contribute to the aroma of the oil. These processing techniques have now been found to also result in processed-based contaminants, which are not present in the natural oils. Chloropropanols are groups of chemical contaminants that are formed in certain food ingredients during processing.

OCCURRENCE OF 3-MCPD ESTERS IN OILS AND FOODSTUFFS

Free chloro3-chloropropane-1, 2-diol (3-MCPD) has been known as a processing contaminant for decades especially in hydrolysed vegetable protein (HVP) where it was first found, and in soya sauces. According to the European Union (EU) legislation, the tolerable daily (TDI) intake of free 3-MCPD is 0.02 mg kg^{-1} for HVP and soya sauces. It is also used by the Scientific Committee on Food (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Recently, free 3-MCPD has also been detected in foods like bread, toast, noodles and smoked products. Interestingly however, bread and noodles could be important contributors to the total daily intake especially for their strong consumption rather than for their content in 3-MCPD but the same TDI value seems to be applied.

Many studies or surveys have been carried out on free 3-MCPD in foods, until recently, where 3-MCPD esters have been found in oils and fats. Various papers have documented the presence of free and 3-MCPD esters in many food products, such as cereals, roasted coffee, malts, breads, *etc.* (Hamlet and Sadd, 2004; Dolezal *et al.*, 2005; Divinová *et al.*, 2007). Reported values are between 0.2 and 6.6 mg kg^{-1} in most analysed foodstuffs and the levels of bound 3-MCPD are generally much higher than the free form. Salami and other meat products also recorded high values of up to 6.4 mg kg^{-1} (Reece, 2005; Svejkovská *et al.*, 2004; Zelinková *et al.*, 2006).

Oils and fats are deemed to have a higher potential of forming 3-MCPD esters upon high thermal treatments, especially during deodorisation, where temperatures typically reach 240°C and above. Some oils appear more receptive to the formation of these esters, as

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was discussed by Weißhaar (2011). Even so, although palm oils have shown higher values in comparison to other refined vegetable oils, the history and source of oils have to be checked against the methodology used. Raznim *et al*. (2012) provided details of 3-MCPD esters in refined palm oil, olein and stearin where using the BfR 008 indirect method was used. The highest recorded value was 5.7 mg kg^{-1}. Currently, the palm oil industry in Malaysia is taking measures to reduce the formation of 3-MCPD esters based on research knowledge gained in recent years. The risk of exposure to 3-MCPD esters has not been fully evaluated, as potentially all vegetable oils in the presence of chlorides which are subjected to thermal treatments as in cooking, roasting, baking and frying, will have the probability of forming these components. Weißhaar (2011) calculated that an average German is estimated to be exposed to an average of 1.5 µg kg^{-1} of body weight (bw)/day of free 3-MCPD, assuming that the bound esters are fully hydrolysed in the gut. This works out to be the TDI value accepted by JEFCA.

TOXICOLOGY STUDIES

When it comes to toxicological risk of 3-MCPD-esters, there is still little data about the toxicological effects of 3-MCPD esters. In fact, in a 2008 statement from the European Food Safety Authority Panel in Contaminants in the Food Chain (EFSA CONTAM) concluded that: there was no comprehensive toxicological and bioavailability data on 3-MCPD esters available. Nevertheless, the German Federal Institute for Risk Assessment (BfR) based its recent risk assessment on toxicological data on free 3-MCPD, under the assumption that 100% of 3-MCPD are released from the esters. However, Seefelder and co-workers in 2007, using the intestinal model lipase studies have shown that the release of 3-MCPD from 3-MCPD diester was much slower than from the monoester. Furthermore, it was found that in vegetable oils, only 15% of the 3-MCPD are in mono-ester forms, while the majority are diesters.

Both SCF and JECFA used an uncertainty factor of 500 to account for three aspects: i) the default uncertainty factor of 100 for intra-and interspecies differences, ii) the fact that the TDI was derived from a Lowest Observed Adverse Effect Level (LOAEL) and not a NOAEL (No Observed Adverse Effect Level) for renal tubular hyperplasia, and iii) other limitations in the database (*e.g.* lack of reproduction/developmental toxicity studies). When using another approach to establish the TDI, the so called Bench Mark Dose (BMD) methodology with a BMDL10 value as point of departure instead of the LOAEL, part of this uncertainty factor of 500 would no longer be needed. This BMD approach derives a TDI-range for 3-MCPD of 6, 6-8, 7 µg kg^{-1} body weights per day, which is much higher than the TDI as established by SCF and JECFA. This TDI is no longer below the estimated current worst case intake levels of 3-MCPD, indicating that there is no need for concern.

Recently, a 90-day rat study was carried out by the University of Parma in response to the EFSA call to evaluate the toxicological profile of 3-chloropropane-1,2-diol (3-MCPD) esters (mono- and di-ester) compared to that of free (or unesterified) 3-MCPD. This study aimed to compare the toxicity of 3-MCPD dipalmitate and free 3-MCPD, performed on male and female rats (Barocelli *et al.,* 2011). Considering that only a small part (<15%) of the 3-MCPD bound in esters is in fact bound in monoesters (Seefelder *et al.,* 2008), the studies were performed using only di-ester form. Palmitic acid as fatty acid was proposed due to the fact that highest levels of 3-MCPD were found in palm oil and is the most commonly used di-ester to study the formation and the composition of 3-MCPD esters *in vitro*. This report covers the whole 90-day study with either 3-MCPD (respectively 29.5, 7.37, and 1.84 mg kg^{-1} of body weight day^{-1}) or 3-MCPD dipalmitate (respectively 156.75, 39.19, and 9.78 mg kg^{-1} day^{-1}). In male rats, BMD_{10} for severe renal and testicular damage induced by 3-MCPD dipalmitate were 41.1 and 64.4 mg kg^{-1} day^{-1}, respectively. The corresponding $BMDL_{10}$ were 17.4 and 44.3 mg kg^{-1} day^{-1}. The values for damage induced by the free 3-MCPD were much lower, indicating a higher toxicity level.

Research carried out by the MPOB on 3-MCPD esters in palm oil by looking at all stages of the refining process to identify the cause of its formation and conducting collaborative toxicological studies with other research institutions. An acute oral toxicity study was conducted on the effect of 3-MCPD palmitate-oleate using animal model. This study was undertaken to assess the health hazard potential of 3-MCPD esters by determining adverse effects following an oral administration in rats.

In this study, a single dose of acute oral toxicity was performed using Sprague Dawley rats by oral gastric intubation (*Figure 1*). It was demonstrated that there were no ill effects nor did any death occurred in any of the groups of male and female rats fed with the 3-MCPD palmitate-oleate at 50, 200 or 400 mg kg^{-1} of body weight. The 3-MCPD ester, which is known to be the most abundant 3-MCPD esters found in palm oil, showed no pattern and unlikely toxicity at every dose tested in terms of body weight changes and pathology.

Generally, body weight is a simple and sensitive index of toxicity after exposure to toxic substance. A decrease in body weight would be an indicator of adverse effects. In this study, all rats at each dosage group continued to gain weight throughout the course of 14 days observations with no significant percentage of weight change. Percentages of weight changes of male and female rats fed with 3-MCPD palmitate-oleate were given in *Figure 2a* and *b*. Furthermore, gross pathology observations conducted during the necropsy examinations revealed no sign of abnormality seen especially on the animal vital organs such as brain, heart, liver, kidneys, spleen, lungs and stomach.

CONCLUSION

Based on the observations and data generated, no death or remarkable loss of body weight and no adverse effects were noted in rats treated with 50 to 400 mg kg^{-1} BW of 3-MCPD palmitate-oleate. These findings suggest that this 3-MCPD diester tested was considered non-toxic. Nevertheless, other less

Figure 1. Oral gavage of 3-MCPD esters using Sprague dawley.

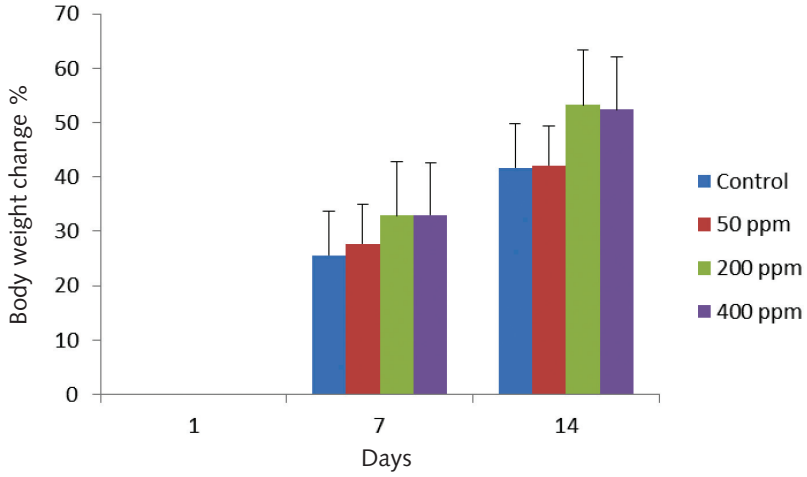

Figure 2b. Percentage of body weight changes for female rats orally administrated 3-MCPD palmitate-oleate at doses of 50, 200 and 400 mg kg^{-1} of body weight (BW) during acute toxicity study. Results are means ± SE of three replicates and the results are expressed as percent of control values.

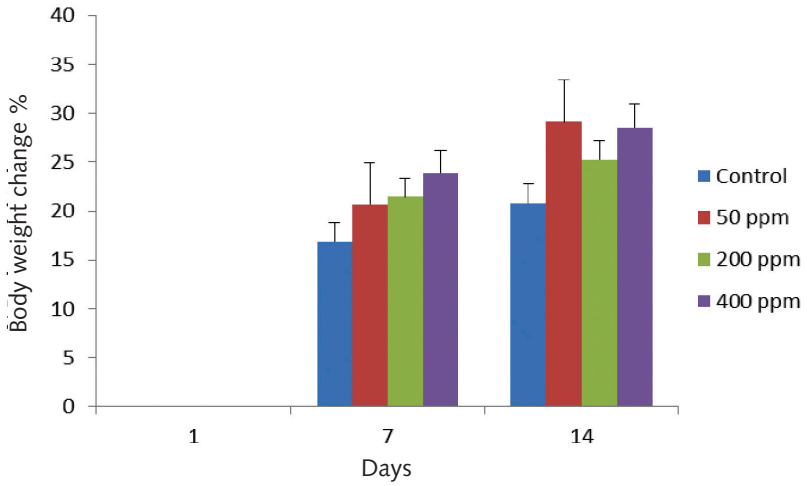

Figure 2a. Percentage of body weight changes for male rats orally administrated 3-MCPD palmitate-oleate at doses of 50, 200 and 400 mg kg^{-1} of body weight (BW) during acute toxicity study. Results are means ± SE of three replicates and the results are expressed as percent of control values.

known information regarding overall exposure to different foodstuffs, food preparation methods, bioavailability, metabolism, are in fact warranted before overall dietary exposure can be fully determined.

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