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3-MCPD and glycidyl esters in infant formulas from the Brazilian market: Occurrence and risk assessment

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ABSTRACT

High concentrations of esters of 3-monochloropropane-1,2-diol (3-MCPDE) and glycidol (GE) have been reported in infant formulas due to the use of refined vegetable oils that may contain high levels of these contaminants. Commercial infant formulas available on the Brazilian market (n = 40) were analyzed for the first time for 3-MCPDE and GE using a gas chromatography-mass spectrometry method. For 3-MCPDE, the limits of detection (LOD) and quantitation (LOQ) were 0.08 mg/kg and 0.16 mg/kg, respectively. For GE, the LOD and LOQ were 0.10 mg/kg and 0.20 mg/kg, respectively. Mean recoveries varied from 93 to 108% for 3-MCPDE and from 82 to 97% for GE. Levels of 3-MCPDE in the products ranged from not detected to 0.60 mg/kg whereas concentrations of GE ranged from not detected to 0.75 mg/kg. A theoretical preliminary exposure assessment showed that 3-MCPDE and GE intakes were up to 5.81 and 10.46 μg/kg body weight/day, respectively, in a worst case scenario (95th percentile). According to the results obtained in this study, the levels of 3-MCPDE and GE in infant formulas marketed in Brazil may pose a potential risk to the health of the consumers of these products and need to be constantly monitored.

1. Introduction

Infant formulas are products for special dietary use only, as a complete or partial substitute for human milk. These products are recommended for children whose mothers cannot breastfeed or do not produce enough milk (FDA, 2015). Infant formulas are developed with ingredients aiming to mimic the composition of human milk and ensure the nutritional needs of children (Carroll, 2004). A mixture of vegetable oils is added to the product to obtain a fatty acid composition similar to the human milk. However, most of the vegetable oils present in these formulas are refined and may represent an important food safety concern due to the presence of high levels of chemical contaminants such as esters of 3-monochloropropane-1,2-diol (3-MCPDE) and glycidol (GE) (Franke, Strijowski, Fleck, & Pudel, 2009; Hrncirik & van Duijn, 2011; Pudel et al., 2011; Zelinková, Svejkovská, Velísek, & Dolezal, 2006). In palm oil and palm olein, which are usually employed in this kind of product, the levels of these compounds can reach up to 10 mg/kg (Arisseto, Marcolino, & Vicente, 2014; Karšulínová, Folprechtová, Doležal, Dostálová, & Velišek, 2007; Kuhlmann, 2011; MacMahon, Begley, & Diachenko, 2013; Weiβhaar, 2011).

3-MCPDE comprise a group of chemical contaminants derived from glycerol (1,2,3-propanetriol) which have been identified in various foods and food ingredients since 2004 (EFSA, 2016; Svejkovská et al., 2004; Zelinková et al., 2006). These compounds are formed from lipids and chlorides during the oil refining process, especially under the high temperatures employed in the deodorization step. GE is also formed under similar conditions in the refining process of vegetable oils, but through different precursors and mechanisms (Pudel et al., 2011).

The presence of 3-MCPDE and GE in the diet is a potential concern since these esters are effectively hydrolyzed by enzymes in the gastrointestinal tract, releasing their free forms, 3-MCPD and glycidol, which are potentially toxic (Abraham et al., 2013). 3-MCPD has already shown testicular and renal toxicity as well as potential to induce cancer in experimental animals while glycidol is considered a genotoxic carcinogen. According to the International

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Agency for Research on Cancer (IARC), 3-MCPD is classified as a possible human carcinogen (group 2B) and glycidol as a probable human carcinogen (group 2A) (IARC, 2000; IARC, 2012).

In the last years, significant levels of 3-MCPDE and GE have been found in infant formula available on the market (Becalski, Zhao, Feng, & Lau, 2015; EFSA, 2016; Jędrkiewicz, Głowacz-Różyńska, Gromadzka, Kloskowski, & Namieśnik, 2016; Zelinková, Doležal, & Velíšek, 2009). According to data reported by EFSA (2016), the dietary exposure estimate to 3-MCPD of children fed exclusively with infant formula corresponds to 2.4 μg/kg body weight (bw) per day (mean occurrence) and 3.2 μg/kg bw per day (P95 occurrence). Considering the Tolerable Daily Intake (TDI) of 0.8 μg/kg bw established by EFSA (2016), potential risks to health could not be excluded. For glycidol, the dietary exposure values varied from 1.8 to 2.1 μg/kg bw per day (mean occurrence) and 4.9 μg/kg bw per day (P95 occurrence), which also suggest a concern.

Taking into account the potential health risks of 3-MCPDE and GE as well as the lack of occurrence and intake data in Brazil from this type of food, the objective of this study was to perform an in-house validation of a gas chromatography – mass spectrometry (GC-MS) method to analyze simultaneously 3-MCPDE and GE in infant formulas, determine the levels of these contaminants in samples available on the Brazilian market, perform a preliminary exposure assessment, and evaluate the potential risks associated with the consumption of infant formulas containing these compounds.

2. Materials and methods

2.1. Standards

3-MCPD-1,2-dipalmitoyl ester (PP-3-MCPD), 3-MCPD-1,2-dipalmitoyl-d5 ester (PP-3-MCPD-d5), glycidyl palmitate (P-Gly) and glycidyl palmitate-d5 (P-Gly-d5) with a purity >98% were purchased from Toronto Research Chemicals (North York, ON, Canada). Stock solutions of PP-3-MCPD and PP-3MCPD-d5 were prepared individually at 0.5 mg/mL in tetrahydrofuran (THF). Stock solutions of P-Gly and P-Gly-d5 were prepared at 1 and 0.2 mg/mL, respectively, in toluene. Stock solutions of PP-3-MCPD and P-Gly were combined and diluted to prepare calibration solutions at 55 μg/mL of PP-3-MCPD and 100 μg/mL of P-Gly, and at 5.5 μg/mL of PP-3-MCPD and 10 μg/mL of P-Gly, both in THF. Similarly, a combined solution of internal standards was prepared in THF at 40 μg/mL of PP-3-MCPD-d5 and 50 μg/mL of P-Gly-d5.

2.2. Solvents and reagents

Methanol (HPLC grade) was purchased from Tedia Company Inc. (Fairfield, OH, USA). Hexane, acetone, sulfuric acid, sodium hydrogencarbonate, and ammonium sulfate (analytical grade) were obtained from Labsynth (Diadema, SP, Brazil). Tetrahydrofuran (THF), toluene, methyl *tert*-butyl ether (MTBE) and sodium bromide (analytical grade), and phenylboronic acid (PBA) 97% purity, were supplied by Sigma-Aldrich (Sigma-Aldrich Corp., Steinheim, Germany). Ultrapure water was obtained from a Milli-Q Plus system (Millipore, Bedford, MA, USA).

2.3. Samples

Forty infant formula products from four different manufacturers were purchased from retail outlets in Campinas, São Paulo, Brazil, in 2015. Sampling was made considering the availability of the products in the market and included first infant and follow-on formula containing cow and soy milk as well as different ingredients such as prebiotics, nucleotides and essential fatty acids, among others. The analyses were carried out in the powdered product, non-reconstituted in water.

2.4. Determination of 3-MCPDE and GE

Sample preparation for the extraction of the compounds was performed according to Ermacora and Hrnčiřík (2014) with some modifications. For that, 350 mg of the sample were weighed into 50 mL centrifuge tubes and 50 μL of the combined solution of internal standards were added. Then, 3 mL of hexane:MTBE (1:2) solution and 2 mL of water were added into the tube followed by vigorous mixing (vortex, 20–30 s). The mixture was incubated at 60 °C for 10 min, homogenized (vortex, 10 s), sonicated during 10 min and centrifuged for 5 min (3000 rpm) at room temperature. The supernatant (organic layer) was transferred to a test tube and then evaporated to dryness under a nitrogen stream (at approximately 85–90 °C).

The conversion of GE to 3-monobromopropanediol monoesters (3-MBPDE) was performed according to the American Oil Chemists Society Official Method Cd 29a-13 (AOCS, 2013). After the addition of 2 mL of anhydrous THF to the oil residue (approximately 100 mg) and vigorous mixing (vortex, 15 s), 30 μL of an acid aqueous solution of sodium bromide was added to the sample, which was incubated in water bath at 50 °C for 15 min. The reaction was stopped by adding 3 mL of a solution of sodium hydrogencarbonate 0.6%. Then, 2 mL of hexane were added to separate phases. The upper phase was transferred to another test tube and evaporated to dryness under a nitrogen stream for 15 min at 40 °C. The residue was diluted with 1 mL of anhydrous THF.

Transesterification and derivatization steps were performed according to Arisseto et al. (2014). Briefly, the procedure included acid transesterification (H_2SO_4 in methanol), neutralization with sodium hydrogencarbonate, salting-out of fatty acid methyl esters (FAMEs) using ammonium sulfate solution and hexane, and derivatization with PBA. Since an indirect analytical approach was used, individual esters could not be identified and quantified and, therefore, the total concentration of 3-MCPDE and GE was expressed as free 3-MCPD and 3-MBPD equivalents, respectively.

2.5. GC-MS analysis

GC-MS analyses were carried out on a HP 7890A gas chromatograph coupled to a MSD 5975C mass spectrometer (Agilent Technologies, Palo Alto, CA, USA). An aliquot of 1 μL of the extract was injected at 180 °C in splitless mode. The separation was carried out on a capillary column VF-1ms 30 m × 0.25 mm (0.25 μm) (Agilent Technologies). Helium was used as the carrier gas at a flow rate of 1.2 mL/min. The following temperature program was used in the oven: 60 °C (held for 1 min), 6 °C/min to 190 °C, 20 °C/min to 280 °C (held for 30 min). Detection was performed by selected ion monitoring (SIM) after positive electron impact ionization (70 eV). The following ions were monitored: *m/z* 147, 196 and 198 for 3-MCPD derivative, *m/z* 150, 201 and 203 for the internal standard 3-MCPD-d5 derivative, *m/z* 147 and 240 for 3-MBPD derivative, and *m/z* 150 and 245 for the internal standard 3-MBPD-d5 derivative.

2.6. Method validation

The method was in-house validated in terms of linearity, limit of detection (LOD), limit of quantitation (LOQ), accuracy (recovery), and precision (repeatability and within-laboratory reproducibility) according to the guidelines established by the Brazilian Institute of Metrology, Quality and Technology (INMETRO, 2011). Linearity was evaluated in the range 0–2.60 mg/kg for 3-MCPDE and 0–5.97 mg/kg for GE (nine calibration points for both solvent and matrix

calibration curves). LOD and LOQ were calculated as three- and six-fold standard deviation of six independent blank samples measured once each. Recovery, repeatability and within-laboratory reproducibility were evaluated by spiking a blank sample with PP-3-MCPD at 0.16, 0.60 and 2.03 mg/kg and P-Gly at 0.20, 1.31 and 4.66 mg/kg (six replicates for each concentration level).

2.7. Theoretical preliminary estimate of 3-MCPD and glycidol intake and risk assessment

The intakes of 3-MCPD and glycidol from their esters were estimated assuming that 100% of the esters are converted to their free forms (3-MCPD and glycidol) as suggested in other studies (EFSA, 2016). As occurrence data, it was considered both mean concentrations of 3-MCPDE and GE (for average consumers) as well as concentrations corresponding to the 95th percentile (P95) in order to represent a worst case scenario of exposure (high consumers). For the calculation of these levels, results below the LOQ were considered as half of the LOQ. The dilution factor used to convert the powdered product into ready-to-use liquid formula was 7.7, as recommended by EFSA (2016).

For this preliminary exposure assessment, two age groups were considered: 0–5 months (fed exclusively with infant formula) and 6–11 months (fed with infant formula and other types of food). For the first age group, as recommended by the Dietary Guidelines for Infants and Toddlers established by the Brazilian Ministry of Health (MS), we considered a daily intake of 703 g of ready-to-use liquid formula which corresponds to 91.3 g of the powdered product per day. For the second age group, we considered a daily intake of 452 g of ready-to-use liquid formula which corresponds to 58.7 g of the powdered product per day (MS, 2005). These recommended values were used in the present assessment since there is no available data on the consumption of infant formula in Brazil.

The average body weight used was defined according to the World Health Organization (WHO) child growth standards. Values of 5.5 kg for children from 0 to 5 months and 8.4 kg for children between 6 and 11 months were used in calculations (WHO, 2006). The intake was estimated by using a deterministic approach.

For risk assessment purposes, the estimated intakes of 3-MCPD were compared to the Provisional Maximum Tolerable Daily Intake (PMTDI) of 4 μg/kg bw recently laid down by the Joint FAO/WHO Expert Committee on Food Additives - JECFA (FAO/WHO, 2016). The estimated intakes were also compared to the TDI of 0.8 μg/kg bw established by EFSA (2016). For glycidol, margins of exposure (MOEs) were calculated considering the estimated T25 of 10.2 mg/kg bw per day for peritoneal mesothelioma in rats (EFSA, 2016). T25 is the dose that represents an increase of 25% in the incidence of a particular tumor above the background level within the standard lifespan of the animal species investigated. According to EFSA (2016), MOEs higher than 25,000 may not represent a concern to human health. MOEs were also calculated using the lower 95% confidence limit on the benchmark dose for a 10% response ($BMDL_{10}$) of 2.4 mg/kg bw per day for mesotheliomas in the tunica vaginalis/peritoneum in male rats also recently established by the JECFA (FAO/WHO, 2016).

3. Results and discussion

3.1. Method validation

The results obtained during the in-house validation showed good linearity in the evaluated range for both solvent and matrix calibration curves ($r^2 > 0.995$). The superposition of these curves and the relationship between their angular coefficients showed that the matrix effect is not significant (less than 15%). For 3-MCPDE (expressed as free 3-MCPD equivalent), LOD and LOQ were 0.08 mg/kg and 0.16 mg/kg, respectively, while for GE (expressed as free 3-MBPD equivalent), a LOD of 0.10 mg/kg and a LOQ of 0.20 mg/kg were determined. Recovery and precision can be considered appropriate to ensure the reliability of the analytical procedure (Table 1).

3.2. Levels of 3-MCPDE and GE in infant formulas

Table 2 shows the mean levels of the contaminants found in the analyzed samples as well as details of each product regarding the type and amount (%) of vegetable oil used by each manufacturer.

The levels of 3-MCPDE in the samples of infant formula ranged from not detected (ND) to 0.60 mg/kg (mean = 0.15 mg/kg and P95 = 0.35 mg/kg). A total of 25 samples (63%) showed 3-MCPDE concentrations below the LOQ. Levels of GE ranged from ND to 0.75 mg/kg (mean = 0.22 mg/kg and P95 = 0.63 mg/kg). A total of 23 samples (58%) presented concentrations below the LOQ.

The lowest levels of 3-MCPDE were observed in formulas produced by manufacturer A, whose results did not exceed 0.17 mg/kg. On the other hand, the highest amount of 3-MCPDE (0.60 mg/kg) was found in a sample obtained from producer C. In relation to GE, manufacturer D presented the most variable results for GE, with concentrations varying from ND to 0.75 mg/kg, but large variations were also observed within samples of other producers.

The results obtained in the present study are in agreement with data reported by Zelinková et al. (2009), for which levels of 3-MCPDE in baby foods varied from 0.062 mg/kg to 0.588 mg/kg in the whole product. However, data reported in more recent studies seem to be slightly lower than the concentrations found in our work. Becalski et al. (2015) reported levels between <0.006 mg/kg and 0.089 mg/kg of 3-MCPDE in reconstituted infant formulas in three different forms (concentrate, ready-to-use and powder). For GE, this range was <0.010–0.070 mg/kg. According to Wöhrlin, Fry, Lahrssen-Wiederholt, and Preiß-Weigert (2015), levels of 3-MCPDE varied from 0.065 to 0.148 mg/kg and GE levels ranged from 0.032 to 0.213 mg/kg. EFSA (2016) reported mean levels of 3-MCPDE and GE in powder infant formulas of 0.108 and 0.087 mg/kg, respectively.

Differences observed in these studies could be due to variations in the formulation of infant formula, especially in relation to the composition and content of vegetable oils, since certain types of oils such as palm oil and palm olein tend to contain higher levels of these contaminants (Weißhaar, 2011).

In all samples evaluated here, manufacturers used three or more types of vegetable oils, and palm oil and derived products were added to 33 samples. No correlation was found between the oil content (%) and the concentration of the contaminants in the samples. This result differs from that reported by Zelinková et al.

Table 1
Recovery, repeatability and within-laboratory reproducibility.

Compound	Spike level (mg/kg)	R (%)	CV_r (%)	CV_R (%)
PP-3-MCPD	0.16	104.6	8.8	8.2
	0.60	92.8	14.3	15.5
	2.03	108.0	6.6	13.5
P-Gly	0.20	82.0	12.0	10.5
	1.31	89.4	7.5	10.7
	4.66	97.0	7.4	10.8

R = recovery (mean); CV_r = coefficient of variation under repeatability conditions (same day); CV_R = coefficient of variation under within-laboratory reproducibility conditions (different days). PP-3-MCPD: 3-MCPD-1,2-dipalmitoyl ester; P-Gly: glycidyl palmitate.

Table 2
Mean levels (±standard deviation estimate) of 3-MCPDE and GE (expressed as free 3-MCPD and 3-MBPD equivalents, respectively) in samples of infant formula and composition of vegetable oils used in these products.

Manufacturer	Product	Vegetable oil composition[a]	Fat (%)[a]	3-MCPDE (mg/kg)[b]	GE (mg/kg)[b]
A	1	Sunflower, coconut, soybean, corn	18	ND	ND
	2	Sunflower, coconut, soybean	28	<LOQ	ND
	3	Sunflower, coconut, soybean	28	<LOQ	ND
	4	Sunflower, coconut, soybean	28	0.17 (±0.01)	0.72 (±0.06)
B	1	Palm, canola, coconut, sunflower	27	ND	<LOQ
	2	Palm, canola, coconut, sunflower	21	<LOQ	<LOQ
	3	Palm, canola, coconut, sunflower	26	<LOQ	0.24 (±0.06)
	4	Palm, canola, coconut, sunflower	27	0.21 (±0.01)	0.23 (±0.08)
	5	Palm, canola, coconut, sunflower	22	<LOQ	0.28 (±0.07)
	6	Palm, sunflower, rapeseed	23	<LOQ	0.38 (±0.01)
	7	Palm, sunflower, rapeseed	23	0.20 (±0.04)	0.63 (±0.07)
	8	Palm, canola, coconut, sunflower	25	0.18 (±0.07)	ND
	9	Palm, canola, coconut, sunflower	22	0.23 (±0.08)	0.27 (±0.03)
	10	Palm, canola, coconut, sunflower	26	<LOQ	<LOQ
	11	Palm, rapeseed, coconut, sunflower	21.3	ND	<LOQ
	12	Palm, canola, coconut, sunflower	27	0.23 (±0.01)	0.38 (±0.04)
	13	Palm, canola, coconut, sunflower	26	0.18 (±0.01)	ND
	14	Palm, canola, coconut, sunflower	23	0.34 (±0.03)	<LOQ
	15	Palm, canola, coconut, sunflower	21	<LOQ	ND
C	1	Palm, coconut, soybean, high oleic sunflower	29	0.34 (±0.04)	0.33 (±0.01)
	2	Palm, coconut, soybean, high oleic sunflower	22	0.25 (±0.06)	0.20 (±0.00)
	3	Palm, coconut, soybean, high oleic sunflower	26	<LOQ	ND
	4	Palm, coconut, soybean, high oleic sunflower	26	0.17 (±0.05)	ND
	5	Palm, coconut, soybean, high oleic sunflower	27	<LOQ	<LOQ
	6	Palm, coconut, soybean, high oleic sunflower	26	0.27 (±0.06)	0.27 (±0.04)
	7	Palm, coconut, soybean, high oleic sunflower	27	0.60 (±0.11)	0.47 (±0.01)
D	1	Canola, palm kernel, corn	28	ND	0.35 (±0.07)
	2	Sunflower, high oleic sunflower, canola, coconut	26	ND	ND
	3	Palm olein, canola, palm kernel, corn	26	ND	ND
	4	Palm, palm kernel, canola	21	ND	ND
	5	Palm, palm kernel, canola, corn	26	ND	0.20 (±0.00)
	6	Palm olein, canola, sunflower	21	ND	<LOQ
	7	Palm olein, palm kernel, canola, corn	27	0.26 (±0.01)	0.45 (±0.03)
	8	Palm olein, palm, canola, corn	21	ND	ND
	9	Palm olein, palm kernel, canola, corn	27	ND	<LOQ
	10	Palm, palm kernel, canola, corn	22	ND	0.75 (±0.10)
	11	Palm, canola, sunflower	19.29	<LOQ	ND
	12	Palm olein, low erucic acid canola, coconut, sunflower	26	0.51 (±0.06)	0.26 (±0.08)
	13	Sunflower, canola, corn	18	<LOQ	<LOQ
	14	Sunflower, canola	18	ND	<LOQ

ND = not detected (below the limit of detection (LOD): 0.08 mg/kg for 3-MCPDE and 0.10 mg/kg for GE). <LOQ = below the limit of quantitation: 0.16 mg/kg for 3-MCPDE and 0.20 mg/kg for GE).
[a] According to the label.
[b] The analyses were carried out in duplicate.

(2009) whose findings showed a certain correlation between the levels of 3-MCPDE and the fat content of the samples. Therefore, the contamination of infant formula by 3-MCPDE and GE will also depend on the mitigation strategies applied during oil refining, which may vary between different producers of these ingredients.

Since the first reports on the occurrence of 3-MCPDE and GE in refined vegetable oils by Zelinková et al. (2006) and Weißhaar (2008), some approaches to mitigate these contaminants have been proposed in many studies. These strategies include reduction of precursors in the raw material prior to processing, optimization of some parameters and conditions used during oil extraction and refining, and reduction of 3-MCPDE and GE in the refined oil by applying suitable absorbent materials or enzymatic treatment (Matthäus & Pudel, 2014). The high levels still found in the Brazilian samples suggest that mitigation strategies for these compounds have not yet been fully adopted by national oil producers, especially for GE, for which the mechanism and key precursors/conditions of formation have already been better defined.

3.3. Exposure and risk assessment

In this preliminary assessment of dietary exposure to 3-MCPD and glycidol from their esters, different scenarios were considered. For each age group (0–5 months and 6–11 months), the daily intake was estimated using the mean values and the P95 concentrations of the contaminants in order to represent average and high consumers, respectively. Fig. 1 shows the estimated intake for both 3-MCPD and glycidol for two age groups considering the two scenarios of exposure.

3-MCPD intakes were 2.49 and 1.05 μg/kg bw/day for average consumers from 0 to 5 months and 6–11 months, respectively, while high consumers presented intakes of 5.81 and 2.45 μg/kg bw/day for the respective age groups. The exposure estimated values for 3-MCPD in children from 0 to 5 months found in this study are not substantially different from the exposure estimated values reported by EFSA (2016) which found 2.4 and 3.2 μg/kg bw at the mean and P95 occurrence values, respectively, for children from 1 to 4 months old.

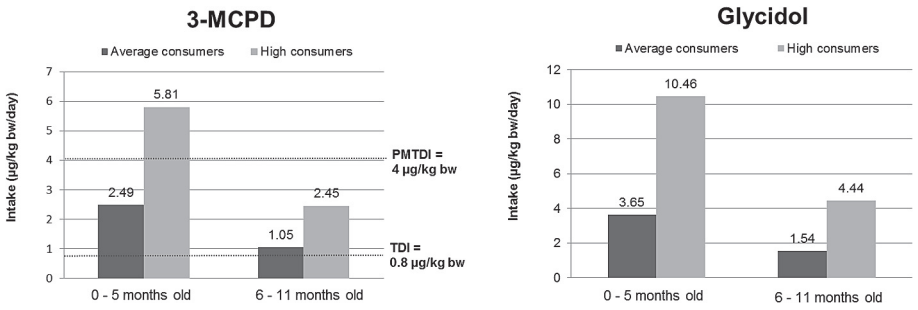

Fig. 1. Estimated intakes for 3-MCPD and glycidol from their esters in infant formula. Description: PMDTI = Provisional maximum tolerable daily intake (FAO/WHO, 2016); TDI = Tolerable Daily Intake (EFSA, 2016); bw = body weight.

Glycidol intakes were 3.65 and 1.54 µg/kg bw/day for average consumers from 0 to 5 months and 6 to 11 months, respectively, while high consumers presented intakes of 10.46 and 4.44 µg/kg bw/day for the respective age groups. These results are approximately 2-fold higher than those reported by EFSA (2016) for children from 1 to 4 months old, *i.e.* 1.9 and 4.9 µg/kg bw/day at the mean and P95 occurrence values, respectively. For both contaminants, children from 0 to 5 months old showed the highest level of exposure, which can be attributed to their low body weight and the exclusive diet based on infant formula as milk substitute.

When the estimated intakes of 3-MCPD were compared to the TDI of 0.8 µg/kg bw established by EFSA (2016), average and high consumers of both age groups exceeded the limited set as safe, suggesting a potential concern. When the results were compared to the PMTDI value of 4 µg/kg bw recently established by JECFA (FAO/WHO, 2016), only high consumers aged from 0 to 5 months old exceeded the safe value.

Considering the T25 of 10.2 mg/kg bw per day (EFSA, 2016), the MOEs for GE were 2793 and 975 for the mean and P95 occurrence levels in the population 0–5 months old, respectively, while consumers aged 6–11 months old presented MOEs of 6635 and 2317 for the respective occurrence levels. Since all values of MOE are below 25,000, these results are considered of high health concern. Similarly, taking into account the $BMDL_{10}$ of 2.4 mg/kg bw (FAO/WHO, 2016), MOEs ranged from 1561 (average consumers 6–11 months old) to 229 (high consumers 0–5 months old), which is comparable to those obtained by JECFA and may also indicate a human health concern.

4. Conclusions

This study is the first report on the occurrence of 3-MCPD and glycidyl esters in infant formulas in Brazil. The contamination of these products with 3-MCPDE and GE may be expected due to the use of refined oils in their formulation, especially palm oil and palm olein, because of their fatty acid composition which is similar to breast milk. The levels of 3-MCPDE and GE found in infant formula available on the Brazilian market and the exposure of children to these contaminants may raise a potential health concern for this age group. Results reported in this study will contribute to data accumulation for global health risk assessment. It is pivotal establishing means to mitigate the formation of these contaminants during the refining process of oils that will be used as ingredients of these products.

Conflict of interest

The authors declare that there are no conflicts of interest.

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