

Melamine Background: <1.0 ppm melamine in infant formula provides an adequate margin of safety.

<http://www.cfsan.fda.gov/~dms/melamra3.html>

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1. Melamine, in its chainlike “polymerized” form, has been used to manufacture dishes, plastic resins, and components of paper and paperboard that may come in contact with food.
2. Trichloro-melamine is approved for use as a sanitizing agent on food processing equipment and utensils, except for milk containers and equipment, and it readily decomposes to melamine during such uses.
3. FDA estimated that the cumulative dietary concentration from these approved food uses would be less than 15 µg/kg (0.015 ppm or 15 PPB). This is not intended as an estimate of the acceptable maximum level of melamine in an individual food.
4. Individual products may contain more or less melamine than 0.015 ppm of melamine as a result of approved uses. The levels would depend on the type of food and the conditions of the approved uses.
5. The October, 2008 safety/risk assessment used a TDI (Tolerable Daily Intake) of 0.63 mg/kg bw/d as its starting point.
6. For foods other than infant formula, the safety/risk assessment applied an additional 10-fold safety factor to compensate for the uncertainties regarding combined exposure to more than one of the melamine-related compounds (Melamine and its analogues – cyanuric acid, ammelide, and ammeline).
7. In applying this safety factor and using the TDI, the safety/risk assessment concluded that “levels of melamine and its analogues below 2.5 ppm in foods other than infant formula do not raise public health concerns.”
8. For infant formula, the safety/risk assessment determined that it could not, based on current information, apply such a safety factor to establish a level of melamine and its analogues in infant formula that would not raise public health concerns. This was based on several factors specific to infant formula contaminated with more than one melamine analogue:
 - a. such as the product represents the totality of caloric exposure for most infants,
 - b. exposure is chronic over months, and
 - c. the persons ingesting the products are infants and toddlers whose renal systems may not be fully developed
9. Therefore, if 100% of the diet of a 3 kg infant were contaminated at a level of 1.26 ppm of melamine in infant formula, an infant’s daily intake would equal 0.063 mg/kg bw/d. This value of 1.26 ppm is rounded down to 1.0 ppm melamine to provide an additional margin of safety.
10. The safety/risk assessment assumes the analogues to have equal effect. Thus, levels of melamine or one of its analogues alone below 1.0 ppm in infant formula do not raise public health concerns.