

# Baby Formula

## GOALS

The goals of this project were to:

- Check for chemical contaminants that have previously been reported in baby formula.
- Compare measured results of potassium against the reported values on nutrition labels.
- Compare the measured levels of the contaminants and potassium with available health-based guidelines or limits.

## TEST APPROACH AND METHODS

Forty-nine baby formulas (26 powdered, three concentrated, and 20 ready-to-feed) were tested. Three samples, representing one to three lots, were tested for potassium and all the contaminants, other than PFAS (per- and polyfluoroalkyl substances), at an accredited laboratory. PFAS analysis was performed on only one sample per model at another accredited laboratory.

The baby formulas were prepared and analyzed in accordance with the following methods:

- PFAS by LC-MS/MS. EPA 537 (Mod) - Per- and Polyfluoroalkyl Substances (PFAS) by LC/MS/MS.
- Acrylamide by LC-MS/MS. J. Agric. Food Chem. 54.19 (2006): 7001-7008 - Rapid Sample Preparation Method for LC-MS/MS or GC-MS Analysis of Acrylamide in Various Food Matrices.
- Bisphenol A, F, and S by LC-MS/MS. Adapted from J. Chromatogr. A 1306 (2013): 44-58 - Development of a liquid chromatography-tandem mass spectrometry procedure for determination of endocrine disrupting compounds in fish from Mediterranean rivers.
- AOAC 2015.01 Mod, Heavy Metals, Aluminum and Potassium in Food - Lab's Internal Methodology.
- Inorganic arsenic by IC-ICP-QQQ-MS - Lab's Internal Methodology.

We reviewed all the test results and quality control data provided by the contract labs for accuracy and clarity, and checked for errors.

## DATA ANALYSIS

We defined total PFAS as the sum of the concentrations of 33 PFAS compounds detected in each of the powdered baby

formulas tested. To estimate the average concentration of a contaminant (acrylamide, aluminum, bisphenols, or heavy metals) in a baby formula model, we applied a method used by many risk assessors,<sup>1</sup> including the Environmental Protection Agency.<sup>2</sup> If a contaminant was detected or measurable in any of the samples of the product, the samples that had test results below the method reporting limit, or MRL, were assumed to have a concentration of half the MRL for that contaminant. If the contaminant was not detected in any of the samples tested of the product, we assumed a concentration of zero for all the samples of that product for the contaminant. This approach to risk assessment appropriately considered important uncertainties about potential levels of undetected contaminants in samples that can influence risk estimates.

## RISK ASSESSMENT

We estimated a 3-month-old (6.1 kg or 13.4 pounds)<sup>3</sup> U.S. infant's intake of aluminum, acrylamide, inorganic arsenic, bisphenol A, cadmium, or lead from a daily serving (12 scoops of dry powder in 24 fluid ounces, 12 fluid ounces of concentrated, or 24 fluid ounces of ready-to-feed) of each infant formula model and, where appropriate and applicable, compared the intake estimates with the exposure limits in the table below.

**Health-Based Exposure Limits Selected for Risk Assessments for Acrylamide, Aluminum, Bisphenol A, and Heavy Metals**

Chemical	EPA RfD ug/kg bw/day	EFSA TDI/TWI ug/kg bw/day*	OEHHA MADL (NSRL) ug/day	FAO and WHO MPL ug/kg
Acrylamide	2 <sup>4</sup>	NA	140 (0.2) <sup>5</sup>	NA
Aluminum	NA	1,000 <sup>6</sup>	NA	400 <sup>7</sup>
Inorganic Arsenic	0.06 <sup>8</sup>	NA	NA	NA
Cadmium	NA	NA	4.1 <sup>9</sup>	NA
Lead	NA	NA	0.5 <sup>10</sup>	NA
Bisphenol A	NA	0.0002 <sup>11</sup>	3 <sup>12</sup>	NA

EFSA = European Food Safety Authority; EPA = U.S. Environmental Protection Agency; OEHHA = California's Office of Environmental Health Hazard Assessment; FAO = Food and Agriculture Organization; WHO = World Health Organization. MPL = maximum permissible limit. Ug/kg = micrograms per kilogram. \*Aluminum TWI in ug/kg bw/week; bisphenol A TDI in mg/kg bw/day.

<sup>1</sup> Xue, J.; Zartarian, V.; Wang, S.; et al., "Probabilistic Modeling of Dietary Arsenic Exposure and Dose and Evaluation with 2003-2004 NHANES Data," *Environmental Health Perspectives* 118, no. 3 (2009): 345-350. <sup>2</sup> "Regional Guidance on Handling Chemical Concentration Data Near the Detection Limit in Risk Assessments," *Environmental Protection Agency*, <https://www.epa.gov/risk/regional-guidance-handling-chemical-concentration-data-near-detection-limit-risk-assessments>. <sup>3</sup> <https://www.medicalnewstoday.com/articles/325630#by-age>. <sup>4</sup> [https://iris.epa.gov/ChemicalLanding/&substance\\_nmbr=286](https://iris.epa.gov/ChemicalLanding/&substance_nmbr=286). <sup>5</sup> MADL and NSRL for acrylamide at <https://oehha.ca.gov/proposition-65/chemicals/acrylamide>. <sup>6</sup> [https://www.efsa.europa.eu/en/news/efsa-advises-safety-aluminium-food#:~:text=In%202008%2C%20the%20European%20Food%20Safety%20Authority,of%20aluminum%20per%20kilogram%20of%20body%20weight](https://www.efsa.europa.eu/en/news/efsa-advises-safety-aluminium-food#:~:text=In%202008%2C%20the%20European%20Food%20Safety%20Authority,of%20aluminum%20per%20kilogram%20of%20body%20weight.). <sup>7</sup> [https://pmc.ncbi.nlm.nih.gov/articles/PMC9407326/#:~:text=%20Maximal%20acceptable%20limit%2C%20\(MPL,by%20the%20FAO%20and%20WHO](https://pmc.ncbi.nlm.nih.gov/articles/PMC9407326/#:~:text=%20Maximal%20acceptable%20limit%2C%20(MPL,by%20the%20FAO%20and%20WHO.). <sup>8</sup> [https://iris.epa.gov/static/pdfs/0278\\_summary.pdf](https://iris.epa.gov/static/pdfs/0278_summary.pdf). <sup>9</sup> <https://oehha.ca.gov/proposition-65/chemicals/cadmium>. <sup>10</sup> <https://oehha.ca.gov/proposition-65/chemicals/lead>. <sup>11</sup> <https://www.efsa.europa.eu/en/topics/topic/bisphenol>. <sup>12</sup> <https://oehha.ca.gov/proposition-65/chemicals/bisphenol-bpa>.

## Baby Formula

We compared our estimated daily intakes with health-based limits in the above table using the following equation:

- $\% \text{ CR Level of Concern} = (\text{Estimated Daily Intake} / \text{Exposure Limit}) \times 100$

This equation derives from the public health concept of hazard quotient and the following equation: Hazard Quotient (HQ) = Estimated Daily Intake / Exposure Limit.

A % CR Level of Concern greater than 100 indicates a comparatively higher health risk at this consumption level.

We used the California Office of Environmental Health Hazard Assessment (OEHHA) Maximum Allowable Dose Levels (MADL) as our benchmarks for CR's levels of concern for acrylamide, cadmium, and lead. MADLs are levels established through California's Proposition 65 law. CR uses these values because the standards are the most

protective of health. A measured level greater than 100% of CR level of concern indicates that consumption of that serving amount per day would pose a comparatively higher health risk.

However, while we use the MADLs involved in Prop 65, we approach our exposure assessment differently from what's outlined in Prop 65. Prop 65 takes into consideration consumers' average exposure over time and dietary frequency to calculate whether a product exceeds the MADL and requires a warning label. By contrast, Consumer Reports assumes the label recommended daily serving of the product in its risk assessment calculations. This difference in methodology means no Prop 65 judgments can be made based on CR's findings. Our results are meant to provide guidance on which products have comparatively higher levels of lead, not to identify the point at which lead exposure will have measurable harmful health effects, or to assess compliance with California law.