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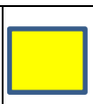
BPA Study Report Card – Pharmacokinetic Criteria

The criteria identified in this Report Card have been established by the U.S. Food and Drug Administration in critical aspects of Pharmacokinetics studies for evaluation of BPA studies as it relates to human exposures.*
http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/UCM424071.pdf

 Study Meets Criteria	 Study Criteria Unknown or not applicable	 Study fails criteria

Study: 24-hour human urine and serum profiles of bisphenol A: Evidence against sublingual absorption following ingestion in soup

Authors: Justin G. Teeguarden, Nathan Twaddle, Mona I. Churchwell , Xiaoxia Yang, Jeffrey W. Fisher, Liesel M. Seryak, Daniel R. Doerge

Journal: Toxicology and Applied Pharmacology (2015)

CRITERIA	SCORE	COMMENTS
Analytical methodology sufficiently validated and reported		Detailed explanation of methods
Measurement of both the conjugated and unconjugated (aglycone or "free") forms of BPA		Measured both metabolized and “free-BPA”
Preferred dosing with isotopically labeled BPA		Used isotopically labeled BPA
Quality of methods used, with the highest weight given to mass spectrometric methods, particularly liquid-chromatography–tandem mass spectrometry (LC/MS/MS), as it provides best signal/noise performance and requires minimal sample preparation		All measurements of BPA done with LC/MS/MS
Use of isotope dilution quantification (i.e., use of isotopically-labeled internal standards) of at least 3 atomic mass units is preferred because of higher performance		Internal standards used.
Adequate demonstration of quality control in sample preparation and analysis (i.e., laboratory reagent and sample collection blanks, matrix spikes at relevant concentrations, authentic standards)		Proper Quality Control reported and documented
For determination of pharmacokinetic parameters, samples obtained from individual animals (and humans) were considered more powerful statistically than those derived from pooled/averaged determinations		Samples obtained from 10 random human volunteers

Note: Excellent demonstration of controlled human experiment that determined that BPA is not bio-accumulating and quickly metabolized. Using a human model showed that absorption of ingested BPA through non-metabolizing tissues of oral cavity is negligible.