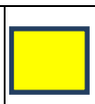
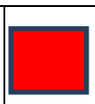
nampa NORTH AMERICAN METAL PACKAGING ALLIANCE, INC.
2200 Pennsylvania Avenue NW, Suite 100W • Washington, DC 20037-1701 • 866-522-0950 • www.metal-pack.org

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: Serial Free Bisphenol A and Bisphenol A Glucuronide Concentrations in Neonates

Authors: Rebecca M. Nachman, PhD, MPH, Stephen D. Fox, BS, W. Christopher Golden, MD, Erica Sibinga, MD, MHS, John D. Groopman, PhD, and Peter S. J. Lees, PhD

Journal: Journal of Pediatrics (2015)

CRITERIA	SCORE	COMMENTS
Analytical methodology sufficiently validated and reported		Method sufficiently detailed
Measurement of both the conjugated and unconjugated (aglycone or "free") forms of BPA		Both forms of BPA were measured
Preferred dosing with isotopically labeled BPA		Babies were not dosed, just compared formula fed and breast fed neonates
Quality of methods used, with the highest weight given to mass spectrometric methods, particularly liquid-chromatography–tandem mass spectrometry (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		Isotopically labelled BPA and BPAG were used as internal standards
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)		Quality control checks were performed to demonstrate no contamination
For determination of pharmacokinetic parameters, samples obtained from individual animals (and humans) were considered more powerful statistically than those derived from pooled/averaged determinations		

Note: Study shows that neonates of age 3-6 days and 7-27 days have sufficient capacity to fully metabolize BPA into the deactivated form of BPA-glucuronide. In all of the urine samples, BPA levels were below the level of detection, indicating ~100% conversion to the deactivated form of BPA.