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SUBECT; Dietary Risk Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) for Reregistration Eligibility Decision (RED) Process

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Executive Summary

Alkyl benzyl ammonium chloride (ADBAC) can be used as a disinfectant or sanitizer on counter tops, utensils, appliances, tables, refrigerators, on animal premises and/or farms, and in mushroom premises. The use of antimicrobial on food or feed contact surfaces, agricultural commodities, in animal premises and poultry premises including hatcheries and application to food-grade eggs may result in pesticide residues in human food. Residues from treated surfaces, such as food utensils, countertops, equipment, and appliances can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

In the absence of data for residues of ADBAC on treated food contact surfaces, the Agency estimated residue levels that may occur in food from the application rates on food contact surfaces. Dietary exposures from general agricultural premise use, poultry hatcheries, mushroom houses and hydroponic uses are expected to be much lower than the dietary exposures resulting from the surface disinfectant and sanitizing uses; therefore, these uses were not assessed.

To estimate the Estimated Daily Intake (EDI) to treated surfaces, an FDA (FDA, 2003) model was used in lieu of residue data. The maximum application rate for ADBAC in food handling establishments from the various labeled ready-to-use products is 0.0017 *a.i* pounds per gallon of treatment solution. The EDI calculations presented in this assessment assumes that food can contact 2,000 cm^2 or 4,000 cm^2 (50% and 100% of the FDA worst case scenario) of treated surfaces, and that 10% of the pesticide migrate to food, based on the Agency Residential SOPs. The use of the 10% transfer rate, instead of the use of a 100% transfer rate that is used in the FDA Sanitizer Solution Guidelines, requires the submission of confirmatory data to establish the reliability of the use of the10% transfer rate. These daily estimates were conservatively used to assess both acute and chronic dietary risks. None of the calculated % aPad or % cPad values exceeded 100%.

The maximum application rate for ADBAC for bottling/packing of food is 0.0103 lbs a.i per gallons of treatment solution. EDI values were calculated using an approach similar to that used for treated food-contact surfaces and food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged with treated material: milk, egg products, and beverages (alcoholic and non-alcoholic). None of the calculated % aPad or % cPad values exceeded 100%.

1. Dietary Toxicity

The acute or chronic Population Adjusted Dose (aPAD or cPAD) is presented in Table 1. The cPAD is 0.44 mg/kg/day (Antimicrobials ADTC (End Point Selection Committee)) Memo by Tim McMahon

Table 1: ADBAC Dietary Toxicity

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/ UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Chronic Dietary	**NOAEL** = 44 mg/kg/day (See Incidental Oral, Short-term dose and endpoint selection)	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Chronic Toxicity/Carcinogenicity - Rat MRID 41947501 **LOAEL** = 30 mg/kg/day based on *clinical sign* and decreased body weight gain
		cPAD = 0.44 mg/kg/day	

a. cPAD or aPAD= the RfD/FQPA SF (acute RFD and FQPA for aPAD and chronic RFD and FQPA SF for the cPAD)

2. Use Information

Twelve ADBAC products were identified that have uses that could lead to incidental ingestion. These uses/products are presented in Table 2. The labels with the maximum-listed application rate for each use are presented in bold.

Table 2: Use Site Categories and Application Rates

Use Site	Product Label (Registration No.)	Method of Application	Application Rates (lb a.i./gal)
Egg handling equipment and rooms: Incubator and hatchers	10324-108 10324-111 10324-117 10324-80 10324-81 **1839-155** 1839-173 **1839-81** **1839-86**	Fogger	0.0005-0.0938
Hatchery: hatchery, settlers, trays, racks, carts, sexing tables, delivery trucks, and other hard surfaces	10324-108 **10324-111** 10324-117 10324-140 10324-80 10324-81 1839-155 1839-173 1839-81 1839-86	Mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer	0.0009-0.0065
Egg packing plants: food grade eggs	**1839-86** 1839-173 **1839-155** 10324-81 10324-117 **10324-111**	Immersion, low pressure coarse sprayer, or swabs	0.0005-0.0016
Food handling establishments: utensils and equipment	**1839-81** 1839-173 10324-81 10324-117 10324-111	Immersion, low pressure coarse sprayer, or swabs	0.0013-0.0017
Food handling establishments: countertops, appliances, and tables	1839-86 1839-81 1839-155 10324-81 10324-140 10324-117 10324-108 1839-173 **10324-80** 10324-111	Mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer	0.0013-0.0071

Use Site	Product Label (Registration No.)	Method of Application	Application Rates (lb a.i./gal)
Food processing plants: (poultry, meat, fish, tobacco etc.): hard surfaces and equipment, including utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage, display equipment, storage shelves, appliances, conveyers (fruits/vegetables or meat/poultry) etc.	10324-81 10324-117 10324-108 10324-140 10324-80 1839-173 1839-86 1839-155 1839-81 1839-51 10324-80 **10324-111**	Mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer	0.0013-0.0065
Food Bottling/Packaging: food contact surface sanitizer (i.e. bottle sanitizing, beer storage tanks, and beverage dispensing unit)	1839-173 10324-81 10324-117 10324-108 10324-80 1839-86 1839-155 10324-111 **1839-81** 10324-140	Fogger, mop, cloth, sponge, hand pump trigger sprayer, low pressure coarse sprayer, liquid pour – mechanical/automated systems, or circulation	0.0009-0.0103
Mushroom facilities	10324-81 10324-117 10324-108 1839-86 1839-155 **10324-80**	Mop, cloth, sponge, hand trigger sprayer, or coarse spray device	0.0015-0.0057
Farm (poultry, swine, dairy) premises and cows (utters, flanks, and teats)	1839-173 10324-81 10324-117 1839-86 1839-155 10324-111 **10324-140** 10324-108 10324-80 1839-81	Mop, cloth, sponge, hand pump trigger sprayer, low pressure coarse sprayer, or towels	0.0005-0.0063
Potato Storage: potato rinse and humidification	10324-117 1839-86 1839-155 **10324-111**	Mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer	0.0009-0.0065

3. Quantitative Dietary assessment

3.1 Egg handling equipment, Agricultural Premise Use, and Poultry Hatcheries

ADBAC products may be used on egg shells in both poultry hatcheries and food grade-eggs. Although it is possible that some of sanitizer/disinfectant chemicals may penetrate the egg shells, at this time the Agency believes that the amount of the chemical transferred into food is likely to be minimal. Dietary exposures from general agricultural premise use, poultry hatcheries, mushroom houses and hydroponic uses are expected to be much lower than the dietary exposures resulting from the surface disinfectant and sanitizing uses; therefore, these uses were not assessed.

3.2 Food Handling Establishments and Food Processing Plants

To calculate the EDI associated with use of an ADBAC product as a food utensil sanitizer in food handling establishments, a number of assumptions have been made based on the FDA guidelines (FDA, 2003).

1. When a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). The FDA recommended worst-case concentration for this quantity is 1 mg of solution per square centimeter of treated surface area. In the absence of any other data, this value has been used.

2. The FDA suggests that, as a worst-case scenario, all food that an individual consumes will come into contact with 4,000 cm^2 of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility.

3. It is assumed that 10% of the active material present on food contact surfaces will migrate.

4. The body weights used for this assessment are: adult man = 70 kg; adult woman = 60 kg, and 3-yr old toddler = 15 kg (USEPA, 1997).

For use of an ADBAC product as a counter top disinfectant in food handling establishments, the same assumptions as listed above were used, and one additional assumption was added:

1. The amount of counter top surface area that comes in contact with food should be much smaller than the amount of food utensil area that comes into contact with food. As a conservative estimate, it is assumed that 50% of the FDA value, or 2,000 cm^2 of treated counter top surface area, comes into contact with an individual's food per day.

The above assumptions and the following equations were used to calculate EDI and Dietary Daily Dose (DDD):

$$EDI\ (mg/p/day) = AR \times RS \times SA \times F \times 10^{-6} \qquad (1)$$

$$DDD\ (mg/kg/day) = AR \times RS \times SA \times F \times 10^{-6}/BW \qquad (2)$$

Where:

AR	=	Application rate (ppm)
RS	=	Residual solution (mg/cm^2)
SA	=	Surface area of the treated surface which comes into contact with food (cm^2)
F	=	Fraction of the pesticide transferred or migrated to food (unitless)
BW	=	Body weight (kg)

The input parameters listed in Table 4 and equations 1 and 2 were used to calculate the output parameters listed in Table 5.

Table *3*: Input Parameters for Food Handling Establishments and Food Processing Plants Hard Surface Sanitizer

Parameter	Value		Rationale
	Food Utensil	Countertop	
Residual Solution on Surface	1 mg/cm^2		FDA worst-case assumption
Area of Treated Surface	4,000 cm^2	2,000 cm^2	100% and 50% of FDA worst-case assumption for food utensils
ADBAC concentration in diluted Solution[a]	0.0017 lb a.i./gal or *200* ppm	0.0071 lb a.i./gal or 850 ppm	Diluted Solution concentration, based on maximum concentration.
Fraction Transferred	10%		EPA Assumption
Body Weight (kg) Adult man = Adult woman = Child =	 70 60 15		EPA, 1997

a. Maximum application rates for food utensils were from product label 1839-81for Utensils and product label 10324-80 for counter-tops.

Table *4*: Calculated EDIs, aPAD, and cPAD for Utensils and Countertops

Exposure Group	Utensils				Countertops				Aggregate			
	EDI (mg/p/d)	DDD (mg/kg/d)		% cPAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)		% cPAD[a]	EDI (mg/p/d)	DDD (mg/kg/d)		% cPAD[a]
Adult males	0.0815	0.00116		0.265	0.170	0.00243		0.552	0.252	0.00359		0.817
Adult females	0.0815	0.00136		0.309	0.170	0.00284		0.645	0.252	0.00419		0.953
Children	0.0815	0.00543		1.23	0.170	0.0113		2.58	0.252	0.0168		3.81

a. % PAD = exposure (DDD) /(aPAD or cPAD) x 100.

For ADBAC treatments of food processing plants, the application rates are similar to food handling establishments presented above, and hence the exposure, EDIs, DDDs, and % aPAD and cPADs are also similar.

3.4. Food Bottling/Packaging

ADBAC may also be used as a sanitizer or disinfectant in processing equipments, utensils in dairies, breweries, canning operations, meat and vegetable processing plants. In assessing this use, the following assumptions were made, based on USEPA (2005):

1. The ADBAC concentration in the treatment solution is 0.0103 lb a.i./gal, or 123 ppm (0.000123 wt/wt)

2. When a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). The FDA recommended worst-case concentration for this quantity is 1 mg of solution per square centimeter of treated surface area. In the absence of any other data, this value has been used.

3. For the fraction of pesticide that migrates from the residue to the food (*F* in equations 3 and 4), a transfer rate of 100% was used instead of 10% because the food is in contact with the treated surfaces for potentially very long periods of time.

4. For a given person, the grams of food per surface area of container were as follows (g/cm^2):
    a. Milk (dairy): 6.6
    b. Egg/mayonnaise: 64.0
    c. Beer, beverages: 150

5. The daily intake rates for an adult (g/person/day) were as follows:

    a. Beverages, alcoholic/beer: 182
    b. Beverages, non-alcoholic: 240
    c. Egg products: 9.0

d. Milk: 124

6. A child will consume a smaller quantity of calories in a given day. To account for differences between intake values among children and adults a calorie intake modification factor of 0.64 was applied to the EDI for a child. Recommended energy allowances measured in kilocalories per body weight for different age groups and genders were taken from the National Research Council's Recommended Energy Allowances. The values are based on the resting energy expenditure and the energy required for light to moderate levels of activity, as determined by the World Health Organization (USAID, 2005). The calculation of the factor is presented in Table 6 below.

The above assumptions and the following equations were used to calculate EDI and Dietary Daily Dose (DDD):

$$EDI\ (mg/p/day) = AR \times RS \times DIR \times MSA^{-1} \times F \times 10^{-6} \times CMF \quad (3)$$

$$DDD\ (mg/kg/day) = AR \times RS \times DIR \times MSA^{-1} \times F \times 10^{-6} \times CMF/BW \quad (4)$$

Where:

AR	=	Application rate (ppm)
RS	=	Residual solution (mg/cm^2)
MSA	=	Mass-surface area ratio (the treated surface that comes into contact with food) (g/cm^2)
DIR	=	Daily intake rate of food in a given day (g/p/day)
F	=	Fraction of the pesticide transferred or migrated to food (unitless)
BW	=	Body weight (kg)
CMF	=	Calorie intake modification factor (100% adults; 64.4% Children)

Assumptions 1-4, inputs from Table 6 and 7, and equations 3 and 4 were used to calculate the dietary rates and doses presented in Table 8.

Table *5*: Toddler (3-yr old) and Adult Calorie Intake Comparison

Group (Age)	Body Weight (kg)	Kilocalories per kg[a]	Kilocalories[b]
Child (1-3)	15.0	102	1,530
Female (25-50)	60.0	36.0	2,160
Male (25-50)	70.0	37.0	2,590
Output			
Child Modification Factor (CMF)[c]			0.644

a. USAID, 2005
b. Kilocalories = Kcal/Kg x BW
c. CMF = Kcal-child ÷ [(Kcal-female + Kcal-male)/2]

Table *6*: Input Parameters for Food Bottling/Packaging Hard Surface Sanitizer

Parameter	Input		Rational
Food mass/surface (g/cm^2)	Milk	6.6	USEPA, 2005
	Egg/Mayonnaise	64	
	Beer, beverages	150	
Intake rates (g/p/d)	Milk	124	USEPA, 2005
	Egg products	9	
	Beer, beverages	182	
	Beverages/ nonalcoholic	240	
Fraction Transferred	100%		FDA worst case assumption
Residual Solution on Surface	1 mg/cm^2		FDA worst case assumption
Quantity ADBAC	0.0103 lb ai or 1234 ppm		Diluted solution concentration, based on maximum concentration.
Body Weight (kg) Adult man = Adult woman = Child =	 70 60 15		USEPA, 1997

a. Maximum application rates for food utensils were from product labels 1839-173, 10324-81, and 10324-117.

Table *7*: Calculated EDIs, aPAD, and cPAD for Representative Dairy and Beverage Consumption

Food Type	Exposure Group	EDI (mg/p/d)	DDD (mg/kg/d)	% cPAD
Milk	Adult Male	0.0232	$3.31x10^{-4}$	0.0753
	Adult Female		$3.86x10^{-4}$	0.0878
	Child[a]	0.0149	$9.96x10^{-4}$	0.226
Egg product	Adult Male	$2.14x10^{-7}$	$3.06x10^{-9}$	$7.00x10^{-7}$
	Adult Female		$3.57x10^{-9}$	$8.00x10^{-7}$
	Child[a]	$1.38x10^{-7}$	$9.20x10^{-9}$	$2.00x10^{-6}$
Beverages, non-alcoholic	Adult Male	0.118	0.00169	0.385
	Adult Female		0.00197	0.449
	Child[a]	0.0763	0.00509	1.16
Beverages, alcoholic, beer	Adult Male	0.00150	$2.14x10^{-5}$	0.00490
	Adult Female		$2.50x10^{-5}$	0.00570

a. Child EDI values are multiplied by a modification factor of 0.64

4.0 References

FDA. 2003. "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions." http://www.cfsan.fda.gov/~dms/opa-cg3a.html. Last accessed June 9, 2003.

USAID. 2005. "ANNEX III: Recommended Energy Allowance Tables." November 2005. http://www.usaid.gov/our_work/humanitarian_assistance/ffp/crg/annex-3.htm. Last viewed January 23, 2006.

USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa. August 1997.

USEPA. 2005. Dietary Assessment of Chlorine Dioxide, Sodium Chlorite From Their Use As Indirect Food Contact Sanitizers/Disinfectants (Hard Surface Sanitizers). Memorandum from Najm Shamim, USEPA to Melba Morrow and Jennifer Slotnick, USEPA. Dates August 15, 2005.

Versar. 2006. ADBAC Occupational and Residential Exposure Assessment. Memorandum from Adria Diaz/Karie Riley/Kelly McAloon, Versar, Inc., to Laura Bailey, USEPA dated January 16, 2006.