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Office of Prevention, Pesticides
and Toxic Substances

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Eligibility Decision (TRED) for Boric Acid/Sodium Borate Salts

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Date _____

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I. Regulatory Determination

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires the Environmental Protection Agency (hereafter referred to as EPA or the Agency) to reassess all the tolerances for registered chemicals in effect on the day before enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. Existing tolerance exemptions associated with boric acid/sodium borate salts must be reassessed in accordance with FFDCA, as amended by FQPA.

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to boric acid, and boric acid does not produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment, EPA has not assumed that boric acid shares a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA's website at http://www.epa.gov/pesticides/cumulative/.

References to the terms "boric acid and sodium borate salts," and or "boric acid/sodium borate salts" in this document refer to boric acid and several borate salts including sodium tetraborate decahydrate, sodium tetraborate pentahydrate, sodium tetraborate anhydrous, disodium octaborate tetrahydrate, disodium octaborate anhydrous, and sodium metaborate. Risks summarized in this document are from boric acid and these sodium borate salts only.

Boric acid and sodium borate salts are used as acaricides, algaecides, fungicides, herbicides, and insecticides. Boric acid and sodium borate salts are frequently used for control of insects such as ants or roaches by application in non-agricultural food and feed areas. Boric acid and sodium borate salts have herbicide qualities causing desiccation, fungicidal properties by inhibiting the growth of fungi by preventing the production of conidia or asexual spores, and insecticidal properties by acting as a stomach poison against ants, cockroaches, silverfish, and termites. Use sites include animal housing, turf, wood products, forests, sewage systems, transportation and storage facilities, medical/veterinary

institutions, uncultivated agricultural/nonagricultural areas, refuse/solid waste sites, swimming pool (algae control), paved areas and aquatic structures. Boric acid and sodium borate salts are also used as inert ingredients in pesticide products as sequestrants.

The Agency's human health and residential risk findings for the pesticide boric acid and sodium borate salts are summarized in the following documents: *Boric Acid/Sodium Borate Salts: HED Chapter of the Tolerance Reassessment Eligibility Decision Document (TRED), Supplement to HED Chapter of the Tolerance Reassessment Eligibility Decision Document (TRED),* and *Boric Acid: Residential Exposure Assessment for the Tolerance Reregistration Eligibility Decision Document*. For further details, please refer to these risk assessments and other technical documents pertaining to the boric acid/sodium borate salts TRED, which are available on the internet at http://www.regulations.gov and in the public docket.

Ecological and occupational assessments were conducted when the reregistration eligibility decision (RED) was issued for boric acid/sodium borate salts in 1994. Therefore, no ecological or occupational assessments were conducted as part of this TRED for boric acid/sodium borate salts.

Although boric acid/sodium borate salts are registered for use on numerous food/feed crops, dietary risk assessments were not necessary since the pesticidal use on food items contributes negligible amounts of boron relative to the naturally occurring background of boron. The aggregate risk assessment for boric acid/sodium borate salts is based on the residential uses, including exposures from pesticides, inerts and consumer uses.

The Agency has evaluated the human health risks associated with all currently registered uses including inert ingredient uses of boric acid/sodium borate salts and has determined that there is a reasonable certainty that no harm will result from aggregate non-occupational exposure to the pesticide chemical risks for most of the scenarios assessed. The Agency used exposure studies submitted by the registrants in the public comment period to assess wood treatments and a risk assessment conducted by California Department of Pesticide Regulation for the carpet and the crack and crevice treatments. The risks associated with these scenarios are below the Agency's level of concern with this additional exposure information. Additional data will be required to confirm the exposure assumptions from the summaries. In addition, some of the residential postapplication scenarios for higher application rate uses in swimming pools and spas which were assessed in the risk assessment exceed the Agency's level of concern (LOC) for children's incidental ingestion during swimming activities. These scenarios are discussed later in the TRED and the Agency has identified risk mitigation measures that reduce the risks to below the Agency's LOC.

II. Tolerance Reassessment

A. Toxicity Categories

The available toxicity data on boric acid/sodium borate salts are adequate to assess boric acid/sodium borate salts hazard potential. Table 1 below presents the acute toxicity profile for boric acid and Table 2 presents the acute toxicity profile for sodium tetraborate decahydrate (borax). These represent the acute toxicity information for the boric acid/sodium borate salts.

Table 1. Acute Toxicity Profile on Boric Acid

Guideline	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral toxicity / rat	00006719	LD_{50} males= 3,450 mg/kg LD_{50} females= 4080 mg/kg	III
870.1100	Acute oral toxicity/ beagle dog	00064208	LD_{50}>631 mg/kg	III
870.1200	Acute dermal toxicity/ rabbit	00106011	LD_{50} > 2 g/kg	III
870.1300	Acute inhalation toxicity / rat	00005592	LC_{50} > 0.16 mg/L	II
870.2400	Acute eye irritation / rabbit	000064209	Conjunctival irritation clearing by Day 4	III
870.2500	Acute dermal irritation / rabbit	00106011	Irritant	III

Table 2. Acute Toxicity Profile on Sodium Tetraborate Decahydrate (Borax)

Guideline	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral toxicity / rat	40692303	LD_{50} males= 4,550 mg/kg LD_{50} females= 4,980 mg/kg	III
870.1100	Acute oral toxicity/ dog	40692304	LD_{50}>974 mg/kg	III
870.1200	Acute dermal toxicity/ rabbit	43553201	LD_{50} > 2000 mg/kg	III
870.2400	Acute eye irritation / rabbit	43553203	Corrosive	I
870.2500	Acute dermal irritation / rabbit	43553202	Non-irritating	IV

B. Toxicity Endpoints

(For a complete discussion, see Section 4 of the *Boric Acid/Sodium Borate Salts: HED Chapter of the Tolerance Reassessment Eligibility Decision Document by L. Hansen and J.*

Evans dated 6/26/06 (D320894).)

In general, the toxicological database for boric acid/sodium borate salts is adequate for hazard characterization and sufficient data are available to assess potential susceptibility to the young. The toxicological data and findings are presented fully in the document, *Boric Acid/Sodium Borate Salts HED Risk Assessment for Tolerance Reassessment Eligibility Decision (TRED) Document.*

Boric acid and sodium borate salts exist as undissociated boric acid in aqueous solution at physiological pH. For this reason, they are considered together as a group for purposes of hazard and risk characterization and individual toxicology studies on each active ingredient are not required. The moiety of toxicological concern is boron. Dose comparisons are normalized by conversion to boron equivalents, allowing comparison of studies on boric acid or borax. Boric acid/sodium borate salts are well absorbed via the gastrointestinal tract and via inhalation, but not via the dermal route through intact skin. Boric acid/sodium borate salts distribute evenly across the body and do not accumulate in the soft tissue. A limited amount of literature exists on the mechanism of action on the testes and skeletal abnormalities and growth retardation. However, the exact mechanism of action is unknown.

Boron is a ubiquitous element that occurs naturally in plants and water. Humans ingest naturally occurring boron in the diet, and there is some data to suggest that trace levels are required in the human diet. At higher exposure levels, boron causes toxicity. Based on animal studies, it appears that males are most sensitive to boric acid/boric salts. A major target organ of boric acid/boric salts is the testes (signs of toxicity include seminiferous tubule degeneration, atrophy, reduction in sperm count, and reduced testicular weight). Neurotoxicity is also reported in rat studies. However evidence of clinical signs of neurotoxicity occurs only at high dose levels that are above the exposure levels causing other signs of toxicity. Developmental effects on the brain (enlarged lateral ventricles) were observed in the rat at doses above those causing the most sensitive effect (skeletal variation and malformations). Since developmental and neurotoxicity effects occur at doses well above the regulatory endpoint, a developmental neurotoxicity (DNT) study is not required and an additional database uncertainty factor is not necessary for the lack of a DNT study.

The toxicological endpoints for boric acid/sodium borate salts are summarized in Table 3. For the residential exposure assessment, EPA used a weight of evidence approach from three dog reproductive studies to set the NOAEL and LOAEL. The oral NOAEL of 8.8 mg/kg/day boron equivalents came from a two year dog dietary study (MRID 40692310). The NOAEL from this study was reported from the highest dose tested, thus no LOAEL was reported. The Agency used a weight of evidence approach from two other dog studies to confirm the NOAEL reported in the 2-year study. Evidence of testicular atrophy and slight anemia at the LOAEL of 32 mg/kg/day boron equivalents was seen in a 90-day dog study (MRID 40692307). In a separate study, testicular atrophy was reported at a LOAEL of 40 mg/kg from a 38-week dog study (MRID 40692308). Although the exact onset of the testicular effects is not known from the three studies, testicular effects are clearly evident by 90 days.

The NOAEL was selected for the short-term (<1 month) incidental oral endpoint as well as the intermediate-term (1-6 month) incidental oral endpoint. For inhalation exposures, 100% absorption of the oral dose was conservatively assumed.

Boric acid and sodium borate salts are classified under the current carcinogen assessment guidelines as "not likely to be carcinogenic to humans." Available genotoxicity studies do not indicate mutagenic potential. A two-year dietary study in the rat and a mouse carcinogenicity study did not show clear evidence of increased cancer incidence.

Table 3. Summary of Toxicological Endpoints Boric Acid/Sodium Borate Salts

Exposure Scenario	Factor Used in Risk Assessment	Study and Endpoint of Risk Assessment
Dietary Risk Assessment		
Dietary (Acute and Chronic)- all populations	NA	The contribution of boron residues from food/feed crop application of boric acid/sodium borate salts to the total naturally occurring background dietary boron intake from food and water is not considered to be significant. Endpoints for acute and chronic dietary exposure were not selected for this risk assessment because it was determined that a dietary risk assessment (food plus drinking water exposure) was not necessary at this time.
Residential Risk Assessment (Adults and Toddlers)		
Acute Oral Exposure (Toddlers) Acute, Short-term and Intermediate-term	Level of Concern MOE= 100	**MRID no: 40692310** **Chronic (2-year) toxicity (dogs)** NOAEL = 8.8 mg/kg/day LOAEL was not determined **MRID no: 40692308** **Chronic (38-week) toxicity (dogs)** NOAEL was not determined LOAEL= 40 mg/kg/day males and 46 mg/kg/day females Based on decreased body weight gain in males and females and testicular atrophy in males. **MRID no 40692307** **Subchronic (90-day) toxicity (dogs)** NOAEL= 4.1 mg/kg/day, males LOAEL= 32 mg/kg/day, males based on testicular atrophy, anemia in subchronic study.

Table 3. Summary of Toxicological Endpoints Boric Acid/Sodium Borate Salts		
Exposure Scenario	**Factor Used in Risk Assessment**	**Study and Endpoint of Risk Assessment**
Inhalation Short-term and Intermediate-term	Level of Concern MOE= 100 (Assumes inhalation absorption = oral absorption	**MRID no: 40692310** **Chronic toxicity (dogs)** NOAEL = 8.8 mg/kg/day
Dermal	NA	No evidence of absorption across intact skin.
Cancer	Not likely to be carcinogenic to humans	

MOE = margin of exposure
LOAEL=lowest observed adverse effect level
NOAEL= no observed adverse effect level

C. FQPA Safety Factor Considerations

The FFDCA, as amended by the FQPA, directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure. For boric acid, the FQPA safety factor can be reduced to 1X because there are no residual uncertainties with regard to pre- and/or postnatal toxicity. Also there were no effects on male reproductive function in the rat and mouse reproductive toxicity studies at doses greater than the endpoint used for this risk assessment suggesting that there is no increased developmental sensitivity. And thirdly the residential risk assessment and the background assumptions regarding dietary exposures are not expected to underestimate boric acid exposures. For all exposure scenarios, uncertainty factors of 10X for interspecies and 10X for interspecies variation (total UF of 100x) were used.

D. Dietary Risks from Food and Drinking Water

(For a complete discussion, see Section 6 of the *Boric Acid/Sodium Borate Salts: HED Chapter of the Tolerance Reassessment Eligibility Decision Document by L. Hansen and J. Evans* dated 6/26/06 (D320894).)

Use of boric acid/sodium borate salts on agricultural crops to control disease and insect infestations has historically been a minor use and as of this assessment there are few agricultural uses. The “screening level” usage data for boric acid/sodium borate salts available for California indicates very low usage. Only broccoli (4,000 lb ai/yr) and grapes (2,000 lb ai/yr) had usage higher than 500 lb ai/yr. Based on a review of the currently registered products, which currently have low application rates and low concentrations and

percent considering the use of these chemicals as inert ingredients in pesticide products, EPA has no reason to believe that the residue from current agricultural practices will significantly contribute to the total dietary boron intake in humans.

An assessment of dietary (food and water) exposure was not conducted. Boron is a naturally occurring component of food and water and may be a necessary nutrient at trace levels, although no minimum daily requirement has been established. Background food and drinking water exposures were not included in this risk assessment based on the assumption that there is also background exposure from dietary and drinking water to the laboratory animals used in toxicology studies on boric acid/sodium borate salts. As active and inert ingredients, boric acid and sodium borate salts are exempt from tolerances and therefore residue data were not submitted for the food/feed uses.

EPA has recently received registration applications for new agricultural crop uses. EPA has requested that the registrants submitting the registration applications for these uses also submit magnitude of residue data on some agricultural crops to ascertain the amount of residue found on the plant. In the future, EPA will use these data to determine if boron tolerances are necessary for any expansion of use.

E. Residential Risks

For a complete discussion, see the following document:

- Section 6 of the *Boric Acid/Sodium Borate Salts: HED Chapter of the Tolerance Reassessment Eligibility Decision Document by L. Hansen and J. Evans* dated 6/26/06 (D320894).

Boric acid/sodium borate salts are used as active and inert ingredients in pesticide formulations. Residential use products are most commonly applied indoor as a broadcast spray (e.g., decks and carpets) and crack and crevice treatments. Boric acid/sodium borate salts are applied in wood preservatives through pressure treatment and deck spray, and are added to suppress algae growth in swimming pools and as a buffer and chlorine extender. There is a variety of use patterns and formulations (e.g., liquids, dusts, and granulars) for boric acid/sodium borate salts.

For boric acid/sodium borate salts, EPA assessed short-term (<1 month) and intermediate-term (1 to 6 month) residential risks. Long-term exposures were not considered to be realistic based on the use patterns. Since dermal absorption is negligible, a dermal exposure assessment was not necessary. However, EPA did assess inhalation exposure to residential applicators.

EPA evaluated non-cancer risks by calculating the margin of exposure (MOE) which is the ratio of the estimated exposure to the NOAEL. Estimated MOEs are compared to a level of concern (LOC) which reflects the dose selected for risk assessment and uncertainty factors

(UFs) applied to that dose. The UF for boric acid/sodium borate salts is 100x, which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences between laboratory animals and humans). EPA determined that the available data support the removal of the 10X FQPA safety factor. Thus, scenarios that yield MOEs less than 100 may trigger concern.

No inhalation exposure scenarios resulted in exceedances of the LOC. Calculated handler (e.g, applicator) inhalation MOEs ranged from a low of 800 for mixing, loading, applying dusts containing boric acid via a shaker can to a high of 5,600,000 for the application of pour-on ready-to-use formulations containing sodium teraborate pentahydrate. The scenarios assessed included applying with aerosol cans, shaker cans, applying by trigger-pump and hand-wand sprayers, and making a granular bait application.

EPA's preliminary risk assessment, which used screening-level assumptions in lieu of actual data, indicated post-application risks of concern to children resulting from incidental ingestion of residues from wood products, crack and crevices, and carpets. During and after the public comment period, the registrant and the California Department of Pesticide Regulation (CDPR) provided additional information on potential exposures and risks which allowed the Agency to refine the initial assessment. The registrant submitted wood residue information (Lake and McIntyre (2006)) and dislodgeable transfer assumptions (J.D. Lloyd, 1996) to support treated wood uses. Additionally, EPA received a CDPR memorandum (CDPR, 1996) which presented boron surface residue measurements to refine the carpet and crack and crevice use. Using this information, EPA recalculated the post-application risks for these scenarios resulting in significantly higher MOEs which do not exceed the LOC and are not of concern. The Agency is requiring the boric acid/sodium borate salts registrants to provide complete studies that confirm the exposure assumptions made based on these summaries. The residential uses for which confirmatory data are required are listed below in Table 4 with the MOEs calculated with the summary information.

Table 4: Summary of Representative Post-Application Exposures for Young Children Based on Hand-to-Mouth Transfer from the Treated Surface				
Exposure Scenario	Application Rate	Dislodgeable Surface Residue ($\mu g/cm^2$) Boron	Average Daily Dose (mg/kg-day	MOE
Dust/Carpet	0.02 lb ai/ sq ft	0.498	0.05	170
Crack and Crevice Dust Carpet	0.02 lb ai /sq ft	0.249	0.03	330
Pressure Treated Wood	10,340 µg boron/sq ft	1.1	0.015	590
Deck Spray (in situ)	462,470 µg boron/sq ft	3.73	0.05	180

For the scenarios presented in Table 4, the carpet assessment is based on exposure information from a CDPR Memorandum (HSM-96004); from T. Formoli, Worker Health and Safety Branch to Karen Fletcher, Pesticide Registration Branch; Re: Evaluation of Human Exposure Potential to eco-fresh Carpet Treatment for Fleas (CDPR, 1996). The assessment for crack and crevice treatments is based on considering the carpet dislodgeable residue measurement in carpets. It is assumed that half the carpet residues are available for crack and crevice exposure scenarios. The Agency will require confirmatory data for all residential uses, including confirmatory data based on surface wipe/press samples representing the various boron containing compounds (in dry, bait and sprayable formulations).

The wood preservative assessment has boron concentration measurements based on summary data presented in a MeadWestvaco Memorandum dated April 21, 2006 (Lake and McIntyre, 2006). For pressure treated wood, the dislodgeable surface residue was calculated by assuming a 10% dislodgeable factor (J.D. Lloyd, 1996). For the deck spray, the dislodgeable surface residue was calculated by assuming a 1% dislodgeable factor (J.D., Lloyd, 1996). Confirmatory data supporting the boron wood measurements presented in Lake and McIntyre (2006) and dislodgeable data factors of J.D. Lloyd (1996) will be required.

Post-application incidental oral exposure to adults and children may be anticipated from swallowing swimming pool water containing sodium tetraborate pentahydrate from products which may be applied to both swimming pools and spas. A range of maximum application rates were reported from the product labels. The rates reported were 4.5 lb ai per 1,000 gallons (540 mg/L pool water concentration), 4 lb ai per 1,000 gallons (480 mg/L pool water concentration),

and 2 lb ai per 1,000 gallons (240 mg/L). These products are all designed to reduce algae growth in swimming pool water. Also boric acid use as an inert ingredient resulted in spa/pool water maximum pool water concentrations of 5.4 mg/L. Exposure to adult and older child swimmers did not result in risks which exceed the LOC; however, the higher boron concentrations in pool and spa water resulted in risks for children 7 to 10 years of age which do exceed the LOC. The values are listed in Table 5.

Table 5. Post-application Exposures to Non-Competitive Child (7 to 10 year old) Swimmers

Scenario	Chemical concentration in water (mg/L)	Adjusted ADD (mg/kg/day)	MOE
Incidental oral exposure while swimming.	540	0.134	65
	480	0.119	74
	240	0.059	150
	5.4	0.0016	5,600

For inert uses, such as laundry detergent and general purpose cleaners, the residential exposures were calculated and the risks were not of concern for children (e.g., MOE $\geq$ 16,000). The use of other products containing boric acid and its sodium salts as inert ingredients were also examined; however, many of the scenarios were identical to that of the active ingredient. Thus, those active scenarios which were not a risk concern for the actives were also determined not to be a risk concern for the inerts because the concentration was much less.

F. Incident Reports

For a complete discussion, see the following documents:

- Section 5 of the *Boric Acid/Sodium Borate Salts: HED Chapter of the Tolerance Reassessment Eligibility Decision Document by L. Hansen and J. Evans* dated 6/26/06.
- *Review of Boric Acid Incident Reports* (DP320914) dated 9/22/05.

EPA reviewed the available incident data from the OPP Incident Data System (IDS), Poison Control Centers (PCCs), California Department of Pesticide Regulation, National Pesticide Information Center (NPIC), and NIOSH. In summary, from 1984-1991, NPIC reports that boric acid ranked 25th on the list of the top 200 chemicals which NPIC received calls. OPP has tracked PCC data from 1993 to 2003. The PCC has reported that the largest number of incidents were related to children, with children under six years of age comprising over 80% of the incidents reported. The most common symptoms included vomiting, eye irritation, coughing, difficulty breathing nausea, and oral irritation. Several incidents were the

result of improper applications of carpet and crack and crevice uses. Inadvertent exposure of infants and small children to boric acid seldom produces a moderate or severe risk and life-threatening incidents are rare; however, ingestions of substantial amounts pose serious risks.

G. Aggregate Risk

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. A risk assessment was not conducted for boric acid/sodium borate salts to characterize the risk from dietary intake (food and drinking water). An aggregate assessment was not considered necessary for the different residential uses since the Agency believes it is unlikely that indoor and outdoor uses will co-occur. The carpet treatment is for fleas, the crack and crevice treatments are for ants and cockroaches and the in situ deck treatments are for termites. A homeowner is not likely to treat for three different pests at the same time. In addition, the swimming pool exposures were assessed for a different age group (7 years to adult) than for the incidental oral exposure from hand-to-mouth intake (toddler) and would therefore not be combined.

III. Regulatory Decision

A. FQPA Assessment Supporting Tolerance Reassessment Decision

The Agency has reassessed the current exemptions from the requirement for tolerances from boric acid/sodium borate salts (see Table 6 for tolerance exemptions). As a result of this assessment, the Agency determined that the active tolerances exemptions should be maintained and are considered reassessed as safe under section 408(q) of the FFDCA. It should be noted however that the higher application rates for the swimming pool uses resulted in residential post-application scenarios which exceed the Agency's LOC. The high rates for these pool and spa uses must be deleted from the end-use product labels. Registrants have agreed to amend their labels by removing the higher application rates to Agency acceptable levels.

Taking into consideration the available information on all uses; including the inert ingredient uses, of boric acid, sodium metaborate, and sodium tetraborate, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure when considering dietary exposure and all other remaining non-occupational sources of pesticide exposure for which there is reliable information. Therefore, the three exemptions from the requirement of a tolerance established for residues of boric acid, sodium metraborate, and sodium tetraborate in/on raw agricultural commodities under 40 CFR §180.920 and the exemptions for tolerances established for the boric acid/sodium borate salts under 40 CFR §180.1121 are considered reassessed as safe under section 408(q) of the FFDCA.

The Agency has conducted risk assessments to ensure that the boric acid/sodium borate salts meet the safety standards established by FFDCA, as amended by FQPA. These recent risk assessments for boric acid/sodium borate salts include evaluation of potential susceptibility to infants and children to aggregate risk from residential uses.

Table 6: Tolerance Exemptions for Boric Acid/Sodium Borate Salts

Chemical Name and CAS Nos.	PC Code	Use Pattern
Under 40 CFR 180.1121		
Boric Acid: 10043-35-3 11113-50-1 41685-84-1	011001	Acaricide, algaecide, fungicide, herbicide, insecticide
Sodium tetraborate decahydrate: 1303-96-4 12447-40-4	011102	Fungicide, insecticide, herbicide
Sodium tetraborate pentahydrate: 11130-12-04 12178-04-3	011110	Algaecide, herbicide, insecticide
Sodium tetraborate: 1330-43-4 12007-42-0	011112	Acaricide, herbicide, insecticide
Disodium octaborate tetrahydrate: 12008-41-2 12280-03-4	011103	Fungicide, insecticide
Disodium octaborate: 12008-41-2 12280-03-4	011107	Fungicide
Sodium metaborate: 15293-77-3 7775-19-1	011104	Herbicide
Under 40 CFR 180.920		
Boric Acid: 10043-35-3 11113-50-1	011001	Sequestrant
Sodium tetraborate: 1330-43-4	011102	Buffering Agent; corrosion inhibitor
Sodium metaborate: 7775-19-1	011104	Sequestrant

In reaching this determination, the Agency has considered the available information on the potential sensitivity of infants and children. Although boric acid/sodium borate salts are registered for use on food/feed crops, dietary or drinking water risk assessments were not necessary. For residential uses, the Agency conducted handler and postapplication assessments. Handler risks were below the Agency's LOC. Post-application exposures were

above the LOC for swimming pool treatments at rates above 240 mg/L. The higher swimming pool application rates must be deleted from the end-use product labels. Therefore, the Agency has made a safety finding for the boric acid tolerance exemptions.

B. Cumulative Risk

FQPA requires that EPA consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency considers other substances because low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the substances individually. Risks summarized in this document are those that result only from the use of boric acid/sodium borate salts. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to boric acid/sodium borate salts and any other substances. In addition, boric acid/sodium borate salts does not produce a toxic metabolite produced by other substances which have tolerances in the U.S. Therefore, for the purposes of tolerance reassessment, EPA has not assumed that boric acid/sodium borate salts shares a common mechanism of toxicity with other compounds.

C. Endocrine Disruptor Effects

EPA is required under the FFDCA as amended by FQPA, to develop a screening program to determine whether certain substances "may have an effect in humans that is similar to endocrine effects." The potential for disruption of the endocrine system by boric acid/sodium borate salts is not known at this time. Boric acid and sodium borate salts are known to inhibit spermiation in multiple species. Studies indicate that at high dose levels, boric acid causes a mild reduction in basal serum testosterone levels in male rats and that this effect may be CNS-mediated, based on lack of apparent effects on steroidogenic function on isolated Leydig cells. Fail, *et al*(1998) have noted that boron is unlikely to act as an endocrine disruptor because the hormonal changes appear to be secondary to testicular cytotoxicity. However, the mechanism by which inhibition of spermiation, as well as effects on the ovary, occur *in vivo* have not been fully characterized. The NOAEL of 8.8 mg/kg/day chosen for the current risk assessment based on the effect of testicular atrophy is considered to be protective of effects caused by endocrine disruption. When additional appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruption Screening Program (EDSP) have been developed, boric acid/sodium borate salts may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

D. Risk Mitigation

A risk assessment was conducted for exposures to boric acid/sodium borate salts resulting from inert and pesticidal exposures of boric acid and borate salts, and the Agency has determined that the human health risks from these combined exposures are within acceptable levels for most uses.

Sodium borate applications to swimming pools and spas resulted in unacceptable risks for some of the higher boron concentrations in pool water (e.g., concentration in water of 480 mg/L and 540 mg/L); however, the lower concentration of 240 mg/L did not result in risks of concern. Therefore, the end-use product labels for swimming pool products must be revised to delete application rates above 240 mg/L. Registrants have agreed to amend their labels by removing the higher application rates to Agency acceptable levels.

E. Data Needs

Additional exposure data in accordance with Series 875.2100 guidelines for dislodgeable surface residues in carpet, crack and crevice, and wood treatments are required to confirm our safety finding for these uses. The Agency will be issuing a DCI for these data.

IV. References

Lake, M.A. and McIntyre, M.A. (2006) Formosan Termite Response to Weathered Borate-Treated Wood: Paper given at the Forest Products Society Meeting in New Orleans, LA on March 2006.

Lloyd, J.D. (1996) Indicative Study of the Post In Situ Treatment Pick-Up of Disodium Octaborate Tetrahdrate..

California Department of Pesticide Regulation (CDPR) (1996). Memorandum from T. Formoli, Worker Health and Safety Branch, to Karen Fletcher. HSM-96004