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Quantitative Assessment of Potential Health Effects From the Use of Fire Retardant (FR) Chemicals in Mattresses

January 9, 2006



Mark Strobel
Note

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Inside are selected pages from this document. You will see in the highlighted lines: They excluded children under age five from the risk assessment; their table of chemicals used in flameproof mattresses; their assumptions of how much chemical we absorb through our skin appear very low; Ammonium Polyphosphate leaches from mattresses in significant quantities; there are uncertainties in the risk assessment and they have no data for how much Antimony we absorb through our skin; **they have clearly proven that toxic chemicals leach from the mattresses through our sheets and are absorbed by our bodies, and they say we will absorb .802 mg Antimony, .081 mg Boric Acid, .073 mg DBDPO, every day; the independent reviewer found they changed the rules of the child sucking test and did not even apply it to young children who the test was designed to protect, as they excluded young children from the risk assessment; the reviewer complained many times their assumptions of safe levels of toxin absorption do not agree with other agencies; there is a serious risk of cancer from the chemicals used; and they do not apply the Precautionary Principle to prove these chemicals are safe to sleep in.**

Table 1. Barrier ID and FRC Load			H3BO3 is Boric Acid	Sb2O3 is Antimony			
Barrier ID	Type/FRC content	Density (mg/cm ²)	FRC Percentage (%) Determined by CPSC				
			H ₃ BO ₃	Sb ₂ O ₃	DBDPO	Melamine	VC
1	Cotton Batting/ H ₃ BO ₃ , Sb ₂ O ₃	34.4	7.5	2.4			
2	Nonwoven modacrylic-visil/ Sb ₂ O ₃ , PVDC, Si	15.4		3.8			ND
3	Nonwoven visil/ Si, PVDC	21.4					ND
4	Nonwoven visil/ Si, PVDC	21.7					ND
5	Visil knit/ Si, PVDC	21.6					ND
6	Modacrylic knit/ Sb ₂ O ₃ , Si, PVDC	16.2		4.5			ND
7	Coated fiberglass/ DBDPO	17.4			7.5		
9	Coated Foam/ Melamine, H ₃ BO ₃ , Sb ₂ O ₃	61.5	4.1	4.1		4.9	
10	Coated Poly- Cotton Ticking/ Melamine, H ₃ BO ₃ , Sb ₂ O ₃	32.1	3.5	2.7		2.9	
11	Coated Poly- Cotton/ Melamine, H ₃ BO ₃ , Sb ₂ O ₃	21.7	4.0	3.1		4.1	
12	Coated Knit/ Melamine, H ₃ BO ₃ , Sb ₂ O ₃	28.1	4.0	4.4		6.6	
13	Melamine Resin					ND	
14	Melamine Resin					ND	
15	Melamine Resin					ND	
16	Melamine Resin					ND	
17	Melamine Resin					ND	
18	Melamine Resin					ND	
19	Melamine Resin					ND	

Note: ND – not detected. The limit of detection (LOD) for VC in the barrier samples is 30 ppm. The LOD for melamine in the barrier samples is 0.002%.

This is the table of chemicals used and percentages in flameproof mattresses from CPSC tab-h p. 17. H3BO3 is Boric Acid, Sb2O3 is Antimony. 5 of the systems contain Boric Acid and 7 contain Antimony. All the Boric Acid systems also contain Antimony. Melamine Resin systems are made from the reaction of Melamine and Formaldehyde, and contain free Formaldehyde. But they did not test for Formaldehyde content. Also there are other omissions of chemicals they did not test.

This 10-04 CPSC Document shows they knew Melamine Resin Flame Barriers contained Formaldehyde, and that Formaldehyde is a known carcinogen and sensitizer. They say data is needed for the release of Formaldehyde

This risk assessment is focused on the potential chronic health effects of the FR chemical monomer although the compound is used in the polymeric form in barriers. In this latter case, melamine is reacted with formaldehyde and other non-FR compounds to form fibers that are used to construct a barrier. Formaldehyde is a known sensitizer, and is also regarded as a carcinogen. If melamine-containing products release formaldehyde, sensitization (induction and elicitation of symptoms) may result in some susceptible individuals. Data are needed to determine the conditions for, and potential releases of, formaldehyde from barriers made with melamine/formaldehyde resin fibers. Although the ethylene urea formaldehyde melamine polymer (EUMF) has been shown to be a contact sensitizer, this is primarily through direct contact with EUMF treated fabrics. Staff believes that the mattress ticking should provide a barrier that reduces the potential for contact sensitization.

The 2006 CPSC Report makes no mention of Formaldehyde, and they did not test for it. The same authors wrote both the 2006 and 2004 report.

Formaldehyde concentrations of 10 to 15 parts per million have been found to cause nasal cancer in rats, and in June 2004 the International Agency for Research on Cancer reclassified formaldehyde as a known human carcinogen.

Millions of Americans will have their nose right next to these mattresses for 1/3 of their lives, 10 to 15 parts per million is a very small number, plus skin absorption.

Based on available data and staff judgment, the degree of concern for health effects for vinylidene chloride is moderate. Vinylidene chloride is used in a polymerized form in barriers, and is expected to have a low exposure potential. The overall potential risk for chronic health effects in the typical and worst-case scenarios is low.

SMOKE TOXICITY

As part of the upholstered furniture project, comments were raised by the public on the application of FR chemicals and the potential impact of irritant gases produced during combustion of these compounds. CPSC staff has previously reviewed the potential of irritant gases to impact egress in a home fire scenario (Thomas et al., 2003). Because of the dearth of data, very conservative estimates were used for application of FR chemicals to upholstered furniture and the resulting concentrations in air. It was estimated that FR chemicals would not significantly increase egress time for a normal healthy adult. These results can be qualitatively extrapolated to mattress fires to estimate the impact FR chemicals incorporated into mattresses may have on egress. If we assume an estimated 30 minute smoldering time from a mattress that meets the staff's draft proposed mattress flammability standard, staff does not expect that the combustion of FR chemicals that could be used in mattresses will significantly increase egress time during a typical fire

FORMALDEHYDE MSDS: "POISON! DANGER! SUSPECT CANCER HAZARD. MAY CAUSE CANCER. Risk of cancer depends on level and duration of exposure. VAPOR HARMFUL. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. STRONG SENSITIZER. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. CANNOT BE MADE NONPOISONOUS."

<http://www.jtbaker.com/msds/englishhtml/F5522.htm>

Si is Silicon, which was not tested for either. It also has health risks: "Silicon may cause chronic respiratory effects. ... Inhalation will cause irritation to the lungs and mucus membrane. Several epidemiological studies have reported statistically significant numbers of excess deaths or cases of immunologic disorders and autoimmune diseases in silica-exposed workers. These diseases and disorders include scleroderma, rheumatoid arthritis, systemic lupus erythematosus, and sarcoidosis. Recent epidemiological studies have reported statistically significant associations of occupational exposure to crystalline silica with renal diseases and subclinical renal changes. Crystalline silica may affect the immune system, leading to mycobacterial infections (tuberculous and nontuberculous) or fungal, especially in workers with silicosis Occupational exposure to breathable crystalline silica is associated with bronchitis, chronic obstructive pulmonary disease (COPD) and emphysema. ... **Lung cancer** is associated with occupational exposures to crystalline silica <http://www.lenntech.com/Periodic-chart-elements/Si-en.htm#Health%20effects%20of%20silicon>

Ammonium Polyphosphate is the only other chemical used to flameproof mattresses not listed above. Not as much is known of how toxic this chemical is to sleep in, but it is doubtful sleeping in and absorbing this fertilizer could be good for us. The CPSC has shown large amounts of this chemical leach from mattresses.

As you can see above 7 of the barriers contain Antimony and 5 contain Boric Acid. It is no wonder there are no labeling requirements for the FR chemicals used in mattresses. Which of the above systems would you choose to sleep in? We don't think any of these systems are safe, they all have risks.

Cotton Batting barriers contain 10 % poison, 7.5 % Boric Acid plus 2.4 % Antimony. Melamine Resin barriers contain Formaldehyde. Silicon and Formaldehyde were not studied.

We keep hearing about **inherently flame resistant fibers** from mattress manufacturers. These inherently flame resistant fibers have chemicals blended with the fiber as the fiber is made. Modacrylic fibers contain Antimony. Melamine resin fibers contain Formaldehyde. The only true inherently flame resistant fiber is fiberglass, and even that is blended with chemicals to make a barrier as you can see in the table above.

Antimony: Quote from College Chemistry Textbook: "**Antimony resembles Arsenic very closely;** the difference in its behavior being almost entirely accounted for by the fact that antimony is slightly more metallic." This helps explain why it is so poisonous. Quotes from ATSDR a division of the CDC on Antimony: "An increase in the number of spontaneous abortions, disturbances in menstruation, failure to conceive, May cause heart to beat irregularly or stop. ... Chronic Exposure: Prolonged or repeated exposure may damage the liver and the heart muscle." "In long-term studies, animals that breathed very low levels of antimony had eye irritation, hair loss, lung damage, and heart problems. Problems with fertility were also noted." "Two studies reported lung tumors in rats exposed to relatively low levels of antimony trioxide." Antimony tends to accumulate in the liver and gastrointestinal tract." The CDC cannot determine a safe level of Antimony exposure because: "At the lowest exposure levels tested, the adversity of the effects was considered to be serious." On cancer risks of Antimony even the CPSC admits: "**The cancer effects are cumulative. Every exposure contributes to the overall lifetime risk of developing cancer.**"

Boric Acid, also used as Roach Killer, is a known reproductive and developmental toxin, a known respiratory irritant, Demonstrated injury to the gonads and to the developing fetus. high prenatal mortality, Neonatal children are unusually susceptible. There are already 6,463 U.S. cases of Boric Acid poisoning each year. One human exposure study showed reduced sperm counts and reduced sexual activity in humans.

DBDPO, Deca, is in the family of PBDE's being found in women's breast milk, is known to bioaccumulate, is linked to cancer, and groups are trying to get it banned.

EPA Proves Flameproof Mattresses Toxic: The EPA says it is safe to absorb only .03 mg Antimony for the average adult. The CPSC says we will absorb .8 mg Antimony from flameproof mattresses every night, even with low skin absorption assumptions. Mattresses Toxic by 27 times safe level!

2. Cancer Endpoints

In the case of antimony trioxide, in which the cancer risk is based on the airborne concentration, the lifetime average daily exposure (LADE) by the inhalation route is calculated by:

$$LADE_I = \frac{ADE \cdot N_Y \cdot Y}{365.25 \cdot Y_E} \quad (1.10)$$

where: LADE_I, lifetime average daily exposure by inhalation, mg/m³; ADE, average daily exposure, mg/m³; N_Y, number of days per year that the product is used, d/y; Y, number of years of product exposure, y; 365.25, number of days per year, d/y; Y_E, average life expectancy, y.

Then, the lifetime individual excess cancer risk is:

$$R_I = Q_I \cdot LADE_I \quad (1.11)$$

where: R_I, lifetime individual excess cancer risk; Q_I, unit cancer risk, or cancer potency, by the inhalation route, (mg/m³)⁻¹; and LADE_I, lifetime average daily inhalation exposure, mg/m³.

D. Input Parameters

1. General Parameters

General parameters are those that are applicable to multiple exposure scenarios. The average lifetime of a mattress is estimated to be 10 years¹⁰ (Midgett, 2005). The average life expectancy of a person is 75 years (EPA, 1997a). Staff estimates a person is exposed to a FR-treated mattress for 70 years, which was derived by subtracting five years from the average life expectancy. This assumes children under the age of five sleep on mattresses protected with vinyl or plastic covers (Midgett, 2005), which would be expected to reduce FR chemical exposure to negligible levels during the first five years of life. The body weight for adults (45-54 years old) is 72.25 kg. For 5 year old children, the body weight is 19.2 kg. The body weight is the average of males and females in the 50th percentile for both adults and children (EPA, 1997a).



Mark Strobel
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They excluded children under age five from the risk assessment, by assuming all will sleep on vinyl sheets over their mattresses due to bed-wetting problems, and that this will protect them from the toxic chemicals in their beds. (Only 20% of young children have bed-wetting problems, and other research proves Antimony leaches through vinyl on beds.)

¹⁰ The ASTM F1566 (part 9) method, on which CPSC staff based their physical impact protocol, is assumed to approximate the typical use of a mattress during 10 years. Therefore, HS staff chose to use the conservative estimate of 10 years for the expected average lifetime of a mattress.

to calculate the unit cancer risk. Of the FR chemicals considered, only antimony trioxide is considered a probable carcinogen. Cancer estimates were only made for inhalation exposure to airborne antimony trioxide particles, which caused tumors only at the site of exposure (lung) in rats (reviewed in Hatlelid, 1999a). For calculating the cancer risk for antimony trioxide, the cancer risk for adults and children represents the risk from a cumulative exposure to a FR-treated mattress of 70 years (Table 4). Previously staff calculated an inhalation cancer potency for antimony trioxide of $0.51 \text{ (mg/m}^3\text{)}^{-1}$ (Babich and Thomas, 2001).

Table 8. Risk and Toxicological Parameters

Parameter			Antimony	Boric Acid (Boron)	DBDPO	Vinylidene Chloride
ADI	Acceptable daily intake	mg/kg-d	2.3	0.1	3.2	0.3
ADI _I	Inhalation ADI	mg/m ³	9×10^{-6}	NA	NA	NA
Q _I	Inhalation cancer potency	(mg/m ³) ⁻¹	0.51	NA	NA	NA
k _T	Percutaneous absorption rate	h ⁻¹	0.002	9×10^{-5}	0.01 or 0.001	NA

DBDPO = Decabromodiphenyl Oxide

NA = not applicable

6. Upper Bound

Upper bound, or worst-case, exposure to FR chemicals is based on maximum exposure to consumers for adults (45-54 years old) is 100 percent of the body weight. The body weight is the average of males and females in the 95th percentile. For estimating maximal dermal exposure, the estimated skin surface area is 2.19 m² (21,900 cm²) for adults and 0.33 m² (3,300 cm²) for 5 year old children. For both adults and children, this is an upper bound estimate (EPA, 1997a). To estimate the upper bound exposure (an intermittent exposure), the estimated skin surface area is 13 percent of the total skin surface area, 2,806.5 cm² (Midgett, 2005).

To estimate upper bound oral exposure to FR chemicals, staff applied an additional 5-fold factor to the 13 cm² mouthing area estimated for children increasing the mouthing area to 65 cm². For adults, the mouthing area was also increased by a 5-fold factor giving a total mouthing area of 30 cm² to estimate possible maximal oral exposure.

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Note

We know we use small patches to absorb medicines through our skin. Their assumptions for Percutaneous [skin] absorption are only 2/1,000 per hour for Antimony, and 9/100,000 per hour for Boric Acid, of the chemical that has leached to the surface of the mattress. This seems a very small number. They admit they have no skin absorption data and guessed. Other research has shown a single to six to eight skin applications of Antimony in a mixture to resemble sweat. Kills Rabbits.

the mini-mattress, but considerably lower than migration amounts observed in the beaker experiments.

Staff recently became aware of the use of ammonium polyphosphate barriers in mattresses. Therefore, CPSC laboratory staff also measured the migration of ammonium polyphosphate from a commercially available twin mattress containing an ammonium polyphosphate barrier, as described above. Although a substantial amount of ammonium polyphosphate was released from the barrier, ammonium polyphosphate is not expected to result in any health effects in consumers because it is not considered “toxic” under the FSHA.

In migration tests where samples are placed in beakers, chemical migration was higher compared to the full-scale tests. There was believed to be less moisture per unit area in the mini- and full-scale twin mattresses is believed to be less than what may be expected in a typical consumer sleep scenario. The excess moisture applied to the barrier samples does not represent what individuals will typically experience elevated sweat production, illness, sexual activity, perimenopause, and in high temperatures where cooling devices are not available.

**Mark Strobel
Note**

A substantial amount of ammonium polyphosphate is released from mattresses. Other agencies say it is not toxic. There are no chronic exposure studies. We doubt our children, even if they are chronically absorbing this fertilizer will grow any better.

When there was minimal migration of certain FR chemicals (antimony and DBDPO) in the aggressive tests, additional testing was not performed (Appendix 2). If more than minimal migration of an FR chemical was observed in the early tests, additional testing representing more realistic dermal exposure scenarios in mattresses was conducted. These results were then used in the risk models to estimate the potential health risk that may result from these dermal and oral FR chemical exposures.

Inhalation Tests

The inhalation of FR chemicals that are released to the surface of the mattresses could be a route of exposure in some scenarios. Consumer use scenarios including forceful play by children on the bed and other activities that occur prior to, or during actual sleep, may agitate the mattress, resulting in releases of FR chemical to the surface. In order to estimate the amount of FR chemicals released into the air, CPSC Directorate of Laboratory Sciences, Division of Mechanical Engineering staff developed a device that subjected mini-mattresses to physical abuse. The impaction device design was based, in part, on the impactor described in the ASTM F1566 (part 9) and is described in the laboratory memorandum by Cobb, 2005 and in an earlier section of this memo. The impaction device subjects the mini-mattress to approximately 3 psi of vertical pressure for 100,000 cycles. The ASTM F1566 method was interpreted by CPSC staff to suggest that this amount of physical impaction serves as a rough approximation of the amount of stress that would occur during 10 years of mattress use.

LSC staff used the impaction device to physically stress artificially aged and unaged mini-mattresses in an enclosed chamber. The 100,000 cycle impaction was completed in 28 hours. The total amount of respirable FR chemical released during the impaction

correction factor of 20 was also applied to the result to account for the non-respirable fraction.

B. Risk Assessment

1. Review of Models and Input Parameters

A previous section of this report summarizes the input parameters used to calculate the potential risk of health effects from the FR chemicals reviewed in this report. The models estimate the risks for a 72.25 kg adult and 19.2 kg child. Sleeping in a room with a breathing zone of 1.85 m³ for 8 and 11 hours per day, respectively, it is assumed that the adult and child sweat heavily and that this moisture penetrates through the sheets and ticking into the barrier. The dermal migration test results estimate the amount of FR chemical that migrates to the surface and comes in contact with the skin. The results have been conservatively extrapolated with the assumption that the entire surface area of the adult (18,200 cm²) and child (7,900 cm²) will be covered with the FR chemical in the amounts observed in the surrogate skin in the dermal migration tests.

For children about 5 years old, it is also assumed that additional FR chemical will migrate from the barrier as a result of urination, which is expected to occur for 2 days each month. If urination is more frequent, it was assumed that caretakers would use some type of barrier such as a plastic cover to prevent mattress soiling. This would also minimize FR chemical migration and contact with the skin. FR migration from urine is estimated to cover approximately 1,092 cm² (~13%) of a child's skin surface area.

The amount of FR chemical that is deposited on the skin may also be ingested orally. It is assumed that adults and children will mouth 6 cm² and 13 cm², respectively, of body and mattress (children only) surface, which includes the face and the hands, during the course of the night and during the early morning after the sleep episode before being washed (Midgett et al., 2005).

FR chemicals may also be inhaled. It is assumed that an adult and child will inhale 0.6 and 0.4 m³/h, respectively, while sleeping. For antimony and boric acid the amount of FR chemical released into the air and available for inhalation was estimated from the impaction of aged mini-mattresses and DBDPO of a new mini-mattress in an enclosed chamber. A certain portion of the airborne particles is assumed to be of respirable size. A correction factor (20) is applied to the final result to account for non-respirable particles entering the body. The particles are assumed to be released at a constant rate and they are expected to be uniform with respect to FR content. The particles are assumed to remain airborne in a confined breathing zone of 1.85 m³.

2. Estimation of Average Daily Dose

The models and assumptions used to estimate the average daily dose from each route of exposure, dermal absorption, inhalation, and ingestion are described in a previous section of this report. The average daily doses of these compounds are presented in Tables 16 and 17. The average daily dose from each route of exposure was summed to estimate the

total amount of each FR chemical that is expected to enter the body as a result of sleeping on a mattress containing the FR-treated barrier.

The average daily dose is then compared to the ADI. The acceptable daily dose is based on doses that enter through the oral route. However, the entire amount of FR chemical entering the body from all routes of exposure, is compared to the ADI due to the lack of exposure-specific ADIs for these compounds (Tables 16 and 17). If the quotient of the ADD/ADI (referred to as the hazard index (HI)) is greater than one, the product or exposure scenario under consideration is considered to present a hazard to consumers.

3. Inhalation Effects of Antimony

a) Chronic Inhalation Effects

An inhalation-specific ADI does exist for antimony and it was also the only compound that is believed to have any carcinogenic effects. These effects are observed only through inhalation of antimony. The effects are seen in the deep lung and are not cumulative, thus an exposure duration of 10 years was assumed for children and adults. The amount of antimony released during the 100,000 cycle chamber test was extrapolated over the 10 year mattress lifetime to estimate that average daily dose (ADD).

b) Carcinogenic Effects

In calculating cancer risks, which depend on cumulative exposure, the cancer risk in adults represents the risk from a lifetime of exposure, 75 years. The cancer risk in children represents the contribution to the lifetime risk from exposure during 70 years of product use. It was conservatively assumed that after the ten year lifespan of a mattress, the consumer would purchase another mattress containing an antimony-treated barrier, and this purchasing trend would continue for the duration of their lifetime. This conservative assumption of continuous use of a treated mattress throughout the 75 year consumer lifetime (70 years of product use; 75 - 5 years that a child sleeps on a mattress protected with fluid-resistant ticking or mattress covers due to bed wetting) is applied only to antimony since exposures are cumulative with regards to the increased risk of developing cancer later in life.

4. Results

a) Ammonium Polyphosphate

Ammonium polyphosphate is not considered to be “toxic” under the FHSA and, therefore, it is not considered “hazardous.” The National Academy of Sciences’ (NAS) National Research Council (NRC) also concluded that ammonium polyphosphates are probably not potent toxicants. Because ammonium polyphosphate is not classified as “toxic,” an exposure assessment was not needed to determine whether it may be hazardous. However, limited migration data were developed for this compound, where significant quantities were released from treated barriers. Regardless of the amount of exposure, ammonium polyphosphate is not expected to result in any health effects in consumers because it is not considered “toxic”.

assessment were based primarily on animal studies. Only chronic health effects were considered. The exposure assessment was accomplished by evaluating a series of dermal, oral, and inhalation exposure scenarios. Input data for the exposure assessment included migration (leaching) data, *in vivo* or *in vitro* percutaneous absorption data, and assumptions regarding consumer behavior. Due to the complexity of the exposure assessment, only point estimates of exposure were calculated. However, a variety of exposure scenarios were included. **As with any risk assessment, there are assumptions, limitations, and sources of uncertainty.** These are discussed below.

Risk assessment is an iterative process. Data on carcinogenicity, developmental and reproductive toxicity, or neurotoxicity were not available for all chemicals. **Furthermore, it should be noted that percutaneous absorption data were not available for antimony.** In these cases, percutaneous absorption rates were assumed based on data obtained with surrogate compounds with similar physico-chemical properties. 

The present risk assessment incorporates new data on inhalation exposure resulting from physical impact. These data were used to estimate dermal, oral, and inhalation exposure. Data gaps remain that can be addressed with additional data. Liquid-mediated migration data are available only for testing of full scale mattresses was completed for boric acid. Testing of full-scale mattresses for all chemicals may present an even more realistic estimation of possible consumer exposures.

**Mark Strobel
Note**

Uncertainty, any risk assessment is a best guess. Percutaneous [Skin] absorption data were not available for antimony. They are guessing! Limited

6. Conclusions and Recommendations

Extensive migration data were available for antimony trioxide (AT), boric acid, and DBDPO. Based on this risk assessment, the CPSC staff concludes that AT, boric acid, and DBDPO are not expected to pose any appreciable risk to consumers who sleep on treated mattresses. Detectable concentrations of vinylidene chloride were not found in initial rigorous extraction studies, thus it is considered highly unlikely that significant quantities of this compound will be released from mattress barriers. The estimated HI values for these compounds are all less than one under all exposure conditions indicating that the compounds are not likely to present a risk to consumers. Since ammonium polyphosphate and melamine do not satisfy the FHSA definition of “toxic”, these compounds also are not expected to pose any appreciable risk of health effects to consumers.

This risk assessment describes one approach that could be used to estimate exposure and risk from certain types of FR treatments. Based on the CPSC laboratory studies and assessments of exposure and risk for selected FR treatments described in this report, staff concludes that there are a number of FR treatments available including ammonium polyphosphate, antimony, boric acid, decabromodiphenyl oxide, melamine, and vinylidene chloride that are not expected to pose any appreciable risk of health effects to consumers who sleep on treated mattresses.

Table 15. Impaction Test Results – Unaged Mockups with DBDPO-Treated Barriers

Barrier ID	Mockup ID	Filter ID and (Type)	Time (hrs)	Air Volume (l)	DB µg	DB µg
7	2 Unaged	1 glass fiber	28	3360	0.4	0.4
		2 glass fiber	28	3360	<0.2	0.1 ¹
		3 glass fiber	28	3360	<0.2	0.1 ¹
		4 glass fiber	28	3360	<0.2	0.1 ¹
		Total sampled/100,000 Cycles				0.7

1 one-half detection limit used for samples

Table 16. Risk Assessment of FR Chemicals in Mattress Barriers - Conservative Best Estimate - Adults

Parameter	Antimony	Boric acid	DBDPO
ADD Sweat mediated dermal absorption (mg)	0.7862	0.056114	0.07280
ADD Oral Ingestion (mg)	0.016200	0.02460	0.00030
ADD Inhalation (mg)	0.0000161718	0.0006215661	0.0000435394
ADD Total (mg/d)	0.802	0.081	0.07314
ADD Total (mg/kg/d)	0.011	0.00113	0.00101
ADI mg/kg/d	2.3	0.10	3.20
Hazard Index, HI	0.005	0.01	0.0003
Hazard Index Inhalation, HI(i)	0.006	N/A	N/A
Cancer Risk	2.7E-08	N/A	N/A

This is the Average Daily Dose (ADD) of Poisons we will absorb every night based on small absorption assumptions, and no data for Antimony skin absorption. (Rabbits die from Antimony skin absorption)

Even the above .802 mg of Antimony is 28 times more than the EPA says is safe.

The CPSC ADI's (acceptable daily intake) do not agree with the EPA, 2.3 vs .0004 for Antimony (5,750 times more than EPA) and 3.2 vs .01 for DBDPO (320 times more than EPA)

In determining above skin absorption amount the CPSC assumed absorption rates of .002 for Antimony, .00009 for Boric Acid, and .001 for DBDPO. If we used a more reasonable absorption rate of only 2%, and use EPA ADI's in the above calculations, we would absorb 7.9 mg Antimony, 12.5 mg Boric Acid, and 1.4 mg DBDPO. The Hazard Index would be 280 for Antimony, 1.8 for Boric Acid, and 2.1 for DBDPO. This would have proven all these chemicals toxic and unsafe for use in mattresses.

Table 17. Risk Assessment of FR Chemicals in Mattress Barriers - Conservative Best Estimate - Children

Parameter	Antimony	Boric acid	DBDPO
ADD Sweat mediated dermal absorption (mg)	0.46926	0.033491	0.04345
ADD Urine mediated dermal exposure (mg)	0.00392	0.000290	0.00026
ADD Oral Ingestion, (mg)	0.03510	0.053300	0.00065
ADD Inhalation (mg)	0.000014824	0.000569769	0.000039911
ADD Total (mg/d)	0.50829	0.08765	0.04440
ADD Total (mg/kg/d)	0.026	0.005	0.002
ADI mg/kg/d	2.3	0.10	3.2
Hazard Index, HI	0.01	0.05	0.001
Hazard Index Inhalation, HI(i)	0.009	N/A	N/A
Cancer Risk	3.7E-08	N/A	N/A

Table 18. Effect of Parameter Uncertainty and Variability for Selected Parameters

FR Chemical	ADI 50 th percentile		ADI 95 th percentile	
	Children	Adults	Children	Adults
Antimony	0.01	0.005	0.01	0.004
Boric acid	0.05	0.01	0.20	0.03
DBDPO	0.001	0.0003	0.001	0.0003

Mark Strobel Note

This is the Average Daily Dose for 5 year old children, younger children were not considered. But crib mattresses must also be flameproof under the law.

Mark Strobel Note

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The CDC (Center for Disease Control) cannot determine a safe level of Antimony exposure because: "At the lowest exposure levels tested, the adversity of the effects was considered to be serious." Antimony accumulates in the body. "Chronic Exposure: Prolonged or repeated exposure may damage the liver and the heart muscle." "May cause heart to beat irregularly or stop." Antimony is a Heavy Metal almost identical to Arsenic. Cancer risk is cumulative. Boric Acid is Roach Killer and a reproductive and developmental toxin, targets developing fetus and testes. "Persons with pre-existing skin disorders or eye problems, or impaired liver, kidney or respiratory function may be more susceptible to the effects of the substance." There are 6,463 US cases of Boric Acid poisoning each year. DBDPO, Deca, is also simple poison and linked to cancer. It is in the family of PBDE's being found in women's bodies and breast milk in growing and alarming amounts, but scientists don't know how PBDE's enter the body. Some people say their new flameproof mattress made them sick.

Appendix 5: Uncertainty and Variability of Selected Risk Assessment Model Parameters

Many of the values used in the parameters in the risk models are based on experimental results, published literature, or expert judgment. Although these values may be used to estimate the risk for a significant portion of the population, it may not represent the full range of possible values for the entire population. In general, the staff's analysis applied conservative assumptions in areas of scientific uncertainty, that is, assumptions that may overestimate, rather than underestimate exposure and risk. The laboratory experiments for the liquid-mediated release of FR chemicals from treated mattresses were conservative in nature, and are believed to be higher than would be experienced during most consumer use scenarios. These results were used to estimate the amount of FR chemical that would migrate to the mattress and skin surface and be either dermally absorbed, or ingested as a result of mouthing the skin or mattress surface. Estimates of body surface area and mouthing areas were determined using a combination of published literature and expert judgement. In the risk assessment calculations, values for body surface and mouthing area were selected to represent the typical consumer or "50th percentile". In the uncertainty analysis, values were selected to represent a consumer that would have much higher than average or 95th percentile values.

Mouthing Area

The suggested mouthing rate and area (1 hour daily, 50 cm²) originated with the NAS's NRC study of flame-retardant chemicals (2000) for use in upholstered furniture. That estimate assumed exposures of a 1-year old child to furniture designed for day-time use. The CPSC's mattress exposure estimate requires consideration of furniture designed for night-time use when children are primarily asleep, and therefore interacting less vigorously with their environment. Furthermore, CPSC staff has chosen to examine older children (5 year olds) because younger children's mattresses are more likely to be waterproofed due to their higher likelihood of bed wetting. This waterproofing, either with fluid-resistant ticking or mattress covers, could provide more containment of FR particles, and so would be inappropriate for an estimate of exposures at the high end of the range of possibility. Also, mouthing of non-body-part objects decreases across the lifespan, and notably after the age of 3 years. However, staff acknowledges that some mouthing of sheets and covers may occur in 5 to 15 year old children, but believes this event would be infrequent and slight. The NRC scientists state that the actual oral exposures that they used are "hard to imagine" and could be "100-fold less" (page 51) than their mouthing parameter (50 cm²). Because mattresses have a different use pattern, and the CPSC estimates focus on an older child, it seems reasonable to include the NRC's estimate in a modified form. Assuming that the 50 cm² was 100-fold less than actual exposures, then the actual exposures would be about 0.5 cm². If this actual estimate were increased 10 times to be conservative, this would yield an oral exposure of 5 cm² a day. This estimate of actual mouthing of the mattress has been added to the current hand-to-mouth estimates for a total of 13 cm² of mattress and body surfaces that would be mouthed by children. An additional 5-fold factor was applied to the 13 cm² mouthing area to estimate the 95th percentile mouthing area. The increased mouthing area of 65



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: January 9, 2006

TO : Margaret Neily, Project Manager for Mattresses and Bedding
Directorate for Engineering Sciences

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director for Health Sciences *Mad*
Lori E. Saltzman, M.S., Director, Division of Health Sciences *LS*

FROM *PT* Treye A. Thomas, Ph.D., Toxicologist, Division of Health Sciences *PT*
AB Patricia A. Brundage, Ph.D., Pharmacologist, Division of Health Sciences

SUBJECT : Response to TERA Comments on Mattresses—Toxicity of Flame Retardant Chemicals

This memorandum provides the Directorate for Health Sciences staff responses to comments made to the U.S. Consumer Product Safety Commission (CPSC) staff on the CPSC staff risk assessment of selected flame retardant (FR) chemicals that may be used to meet a flammability standard for mattresses (CPSC 2004). In September 2005, CPSC contracted with Toxicology Excellence in Risk Assessment (TERA) to review the CPSC staff risk assessment and provide written comments. Included are written comments received from TERA.

General Comments

Comment 1. All calculations and algorithm details should be checked.

Answer. The authors have checked all calculations and spreadsheets. A Health Sciences staff person not associated with this risk assessment, but with expertise in using models in spreadsheets has checked all models and calculations.

Comment 2. A table of contents should be added. The risk assessment sections could be re-organized.

Answer. A table of contents has been added. CPSC staff is comfortable with the organization of the paper.

Comment 3. The worst case scenarios should be included (95th percentile).

Answer. The worst case scenario has been addressed in the uncertainty analysis section of this report where the 95th percentile and other potential factors were incorporated into the calculations. This is in addition to the already conservative nature of the exposure assessment.

Comment 4. Inhalation dose calculation for antimony versus boric acid should be re-calculated.

Answer. The calculations have been adjusted by the CPSC staff.

Comment 5. Data on the inhalation exposure to DBDPO should be included, or more explanation on the lack of experimental inhalation data.

Answer. DBDPO releases into the air from the impaction experiments have been quantified. The results have been included in the risk models for DBDPO.

Comment 6. Differences between PVC5 and accurately presented.

Answer. CPSC staff has made the appropriate filters.

Comment 7. The total mass of airborne particles rather than the respirable fraction. In the absence of data, a 20-fold correction should be made.

Answer. The staff has adjusted the estimate of the particle exposure by applying a 20-fold correction factor. The 20-fold factor was agreed upon during a telephone discussion with the expert reviewers.

Mark Strobel
Note

They changed the rules of the child sucking test. Young children might suck more on their mattresses than upholstered furniture. Then they did not even apply the test to young children who the test was designed to protect, they excluded them from the risk assessment. Our analysis shows Boric Acid mattresses would fail this test, and this was previously sent to the CPSC.

Comment 8. The volume of air that will contain particles should be reduced.

Answer. The volume of air that contains the particles has been reduced to a considerably smaller volume that largely encompasses the breathing zone. 

Comment 9. Mouthing area should be increased to include 50 cm² of direct mouthing of sheets.

Answer. TERA's suggested mouthing rate and area (1 hour daily, 50 cm²) originated with the National Academy of Sciences' (NAS) National Research Council (NRC) study of flame-retardant chemicals (2000) for use in upholstered furniture. That estimate assumed exposures of a 1-year old child to furniture designed for day-time use. However, CPSC staff's mattress exposure estimate requires consideration of furniture designed for night-time use when children are primarily asleep, and therefore interacting less vigorously with their environment. Additionally, CPSC staff has chosen to examine older children (5 year olds) because younger children's mattresses are more likely to be waterproofed due to their higher likelihood of bedwetting. This waterproofing, either with fluid-resistant ticking or mattress covers, is expected to reduce contact with FR chemicals, and so would be inappropriate for an estimate of exposures at the high end of the range of possibility. Also, mouthing of non-body-part objects decreases across the lifespan, and notably after the age of 3 years. Staff acknowledges that some mouthing of sheets and covers may occur in 5 to 15 year old

children, but believes this event would be infrequent and the actual oral exposures that they used are “hard to imagine” (page 51) than their mouthing parameter (50 cm²).

Mark Strobel

Note: The NRC scientists state that

Independent reviewer complained many times that CPSC assumptions of safe levels of toxin absorption do not agree with other agencies. (ADI is Acceptable Daily Intake) Indeed the EPA safe level for Antimony is 5,750 times lower than the CPSC assumption. The EPA number would prove mattresses toxic by 27.5 times if used in CPSC safety calculations.

Because mattresses have a different use pattern than upholstered furniture, CPSC staff estimates focus on an older child, CPSC staff used a modified form. Assuming that the 50 cm² was 100-fold actual exposures would be about 0.5 cm². If this estimate is a conservative estimate, this would yield an oral exposure that is 100-fold lower than the current hand-to-mouth estimates. The increased mouthing area of 50 cm² has been incorporated into the uncertainty analysis where more conservative assumptions and 95th percentile factors have been used in the models.

Comment 10. The rationale for extrapolating the aging results to a 10 year mattress lifetime should be substantiated or presented as indeterminate aging.

Answer. The mattresses that have been subjected to the aging process are classified as “aged” without regard to any specific time period.



Comment 11. CPSC staff should consider harmonizing methods of calculating ADI's with other organizations.

Answer. CPSC staff is obligated to assess the potential hazards of chemicals using the methodology outlined in the Federal Hazardous Substances Act (FHSA) and the supporting Chronic Hazard Guidelines (CPSC, 1992). While there are several methods for calculating an ADI¹, in many cases, the use of different methods does not ultimately result in substantial differences in risk. Pros and cons exist for the use of different methods. The method that the CPSC staff uses to calculate ADIs for the flame retardant chemicals that may be used with mattresses versus use of another methodology (e.g., benchmark dose methodology) does not result in substantial differences in risk as compared to that used by other organizations.

A difference of 320 times for DBDPO and 5,750 times for Antimony is Substantial.

Comment 12. Comments on specific chemical assessments

Comment 12a. Derivation of the ADI for decabromodiphenyl oxide (DBDPO) should consider new studies.

CPSC assumption of safe level is 320 times more than EPA. Reasonable assumptions of 2% skin absorption with EPA ADI would prove DBDPO toxic in mattresses.

Answer. CPSC staff reviewed the new studies on DBDPO. The new studies did not alter the DBDPO ADI.

Comment 12b. The possible carcinogenicity of DBDPO should be discussed.

Answer. CPSC staff previously determined that DBDPO is a possible carcinogen. Staff reviewed and discussed the evidence on the carcinogenicity of DBDPO and maintains

¹ The acceptable daily intake (ADI) is the amount of a compound that one may be exposed to on a daily basis without posing a significant risk of health effects.

that DBDPO is a possible carcinogen in humans according to the CPSC's Chronic Hazard Guidelines based on the minimal evidence of carcinogenicity in animals, along with the lack of genotoxicity. This means that DBDPO is not considered "toxic" by virtue of its carcinogenicity under the FHSA.

Comment 12c. Chemical specific adjustment factors could be applied to the ADI derivation for boric acid.

Answer. In accordance with the CPSC's Chronic Hazard Guidelines, chemical specific adjustment factors (i.e., safety factors) are not applied. For the derivation of the ADI for boric acid, CPSC staff followed the Chronic Hazard Guidelines and applied a 100-fold safety factor to account for possible differences between animals and humans, and for differences in the sensitivity among individuals.

Comment 12d. An inhalation ADI for boric acid should be calculated.



Answer. An inhalation ADI for boric acid was not calculated by CPSC staff. ADIs are calculated when a given chemical is considered "toxic" due to its chronic effects and sufficient toxicity information is available. In accordance with the guidance provided in the CPSC's Chronic Hazard Guidelines on how to evaluate toxicity studies, the CPSC staff determined that there is not sufficient evidence of systemic toxicity in humans caused by chronic inhalation exposure. Thus, staff only developed an oral ADI for which there was sufficient evidence of developmental toxicity due to oral exposure.

Comment 12e. Slow clearance of antimony from the lung could be considered, but it is unlikely to have a major impact on systemic exposure.

Answer. The impact of the slow clearance of antimony from the lung was considered by CPSC staff in its assessment of the health effects of antimony trioxide.

Comment 12f. The derivation of the vinylidene chloride ADI should be reconsidered.

Answer. No adjustments to the vinylidene chloride ADI were made. CPSC staff based its ADI on a study conducted by National Toxicology Program (NTP) (1982). Staff did not use the Quast et al. study (1983) chosen by other organizations. However, recalculation of the ADI using the Quast et al. study would not change the risk characterization as no vinylidene chloride was detected in the aggressive mice. Both inhalation and oral exposures are considered equally toxic. One Boric Acid human chronic inhalation study showed reduced sperm counts and reduced sexual activity.

Comment 12g. An inhalation ADI for vinylidene chloride compound is volatile.

Answer. Inhalation exposure to vinylidene chloride is expected to be negligible and staff concludes that it would not be sufficient to result in an unreasonable risk of health effects.

Mark Strobel Note

Both inhalation and oral exposures are considered equally toxic. One Boric Acid human chronic inhalation study showed reduced sperm counts and reduced sexual activity.

is expected to be negligible and staff concludes that it would not be sufficient to result in an unreasonable risk of health effects.

Comment 13. An expanded risk calculation including an uncertainty analysis would be useful.

Answer. An uncertainty analysis section has been added to the risk assessment. Values that represent the 95th percentile were used in the calculations in addition to the already conservative estimates of exposure.

Comment 14. Exposures from other sources (e.g., upholstered furniture) and their potential impact on risk should be mentioned.

Answer. CPSC staff estimates the potential risks resulting from the exposure from a specific consumer product. Aggregate exposures resulting from the use of other products that may contain the same FR chemical are not considered.

Comment 15. Please explain the statement (P. 33, in the context of the inhalation-specific ADI and related risk) that the effects of antimony (trioxide) inhalation are “not cumulative,” particularly in light of the long half-life described above. This appears to be a non-conservative assumption.

Answer. There was a misinterpretation of the text by the reviewers which was addressed in a telephone discussion with the reviewers.

The inhalation effects of antimony are assessed by CPSC staff based on daily exposures. An inhalation average daily exposure (ADE) is calculated, and exposures are estimated to determine whether they would exceed the acceptable daily exposure. The cancer effects are cumulative. Every exposure contributes to the overall lifetime risk of developing cancer.

 **Comment 16.** Information on the ADE for antimony and comparison to ADI and cancer risk should be included in the summary tables.

Answer. This information has been added to the tables.

Comment 17. the volatility of vinylidene chloride is not clear. While and dermal exposure, one might expect the volatility of vinylidene chloride to be sufficient to result in an unreasonable risk of health effects, particularly for a new mattress.

Answer. The volatile phase of this compound is not detectable and therefore was not measured. However, CPSC staff believes that inhalation exposure to vinylidene chloride would be negligible based on the other data collected on vinylidene chloride. CPSC staff does not consider the potential exposure to be sufficient enough to result in an unreasonable risk of health effects.

Comment

Some individuals commented that the “precautionary principle” should be applied to FR chemicals, that is, they should not be used until proven safe (7, 26, 44, 47, and 51).

Response

All of the statutes that provide regulatory authority to the CPSC explicitly require risk-based decision making, thus precluding application of the “precautionary principle.”

Comment

Several commenters recommended including in the standard a requirement that mattresses provide a label listing FR chemicals used or a statement warning of health risks (37, 38, 52, 92, 112, 130, 145, 312, 477, 504, 530, S. Baldwin). These comments included: “it will allow the consumer to make a decision regarding whether the potential hazard is a factor to be considered when purchasing these products,” mattresses should be treated similar to food items, where ingredients are required to be listed, and “It is the consumer’s right to have a warning label of health risks on a mattress. . . . deserves as much attention as the tobacco industry.”

Response

The staff has found that numerous FR materials are available that will enable mattresses to meet the draft standard without posing any appreciable risks of health effects to consumers. Moreover, the FHSA itself would require a hazard warning label if a mattress were a “hazardous substance”, as that term is defined in the FHSA. The potential health hazard associated with any chemical depends on both toxicity and exposure. A label stating the names of any FR chemicals used in the mattress would not likely provide useful information to the consumer because the mere presence of an FR chemical is not an indication that the mattress containing that chemical poses any health risk.

Mark Strobel
Note

4/24/2006 8:31:55 PM

We don't think it is safe to absorb any amount of poisons from our beds, especially for children or impaired people. Our chronic exposure in mattresses for the rest of our and our children's lives seems very risky. We already know these chemicals are acutely toxic, and may also find it is ones we now think are low toxicity, that later prove harmful from chronic absorption. Young children were excluded from the risk assessment. Crib mattresses must also be flameproof. **They have clearly proven that toxic chemicals leach from the mattresses through our sheets and are absorbed by our bodies, and they say we will absorb .802 mg Antimony, .081 mg Boric Acid, .073 mg DBDPO, every day;** The independent reviewer found many problems that were not answered. Their assumptions of how much poison we absorb seem very low, and their assumptions of how much poison is safe to absorb seem very high. If you use the EPA safe number in CPSC calculations it proves new mattresses toxic by 27.5 times. They changed the rules of the child sucking test, and did not even apply it to young children. There is a serious risk of cancer from the chemicals used. Manufacturers are free to use any chemical they find cheapest to flameproof beds, without any safety testing. There are no labeling requirements of the chemicals in beds. They do not apply the Precautionary Principle to prove it is safe to sleep in these chemicals. We don't think this short risk assessment is sufficient justification for every American to sleep in toxins. For a one in one million mattress fire risk, we think the toxic risk outweighs the benefit, and many Doctors agree.

This page is not a CPSC document, but the CPSC probably knew about this study.

ingentaconnect

Antimony leaching from cot mattresses and sudden infant death syndrome (SIDS)

Authors: Jenkins R.O.¹; Craig P.J.¹; Goessler W.²; Irgolic K.J.²

Source: [Human & Experimental Toxicology](#), Volume 17, Number 3, 1998, pp. 138-139(0)

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Our “National Academies of Science” in their study, “Toxicological Risks of Selected Flame-Retardant Chemicals (2000)” cited this European study that proves Antimony leaches through vinyl on crib mattresses, and linked it to SIDS.

The National Academies of Science gave strong warnings, including cancer risks, about using Antimony as a flame retardant in upholstered furniture and basically recommended not to use it.

Antimony is now the most widely used chemical to flameproof mattresses, including crib, in the US.

Abstract:

1 Polyvinyl chloride (PVC) cot mattress covers from SIDS cases were investigated as potential sources of soluble (potentially ingestable) antimony in the cot environment. 2 Body fluids (urine, saliva) and proprietary domestic detergents/sterilizing fluids markedly enhanced leaching of antimony from PVC. Release of antimony was also enhanced at both low and high pH and by elevated temperature. The extent of antimony leaching did not correlate well with PVC content of this element. 3 These data do not support the assumption that postmortem analysis of antimony content proves exposure to gaseous antimony trihydride from mattress PVC. 4 Ingestion of antimony released from PVC could account for the high variability associated with reported detectable levels of antimony in liver from both SIDS and other infants. It could also explain suspected additional postnatal exposure to this element, which gives rise to elevated levels of Sb in the hair of some healthy infants.

Keywords: [antimony](#); [SIDS](#); [infant death](#); [cot mattress](#); [PVC](#)

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