

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES



March 19, 2008

MEMORANDUM:

Subject: Occupational and Residential Exposure Chapter for Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT) for the Reregistration Eligibility Decision (RED) Document (Case 3074)

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DP Barcode: 346240

Chemical Name: Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT)

PC Code: 083301

CAS Registry No. 4719-04-4

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EXECUTIVE SUMMARY

The Antimicrobials Division (AD) prepared this occupational and residential exposure chapter for the inclusion in the Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT) Reregistration Eligibility Decision (RED) Document. It addresses the potential risks to humans that result from the use of this chemical in occupational and residential settings. The initial assessment was updated to reflect revisions made in the selection of cancer endpoints for formaldehyde.

Currently, HHT is an active ingredient used for materials preservation (Use Site Category VII) and industrial processes and water systems (Use Site Category VIII). Examples of the materials preserved using HHT include adhesives, metalworking fluids, coatings (e.g., stains, paints), construction compounds (e.g., caulks, spackling), and commercial and household I&I products (e.g., laundry detergent, dish detergent, all purpose cleaners, hard surface cleaners). Examples of industrial processes using HHT include oil field water systems, oil recovery, and oil drilling muds. The percentage of HHT in various products can range from 50.5% to 78.5%. Products containing HHT are formulated as liquid concentrates.

HHT hydrolyzes to form formaldehyde (HCOH). Therefore, exposures to HCOH resulting from the use of HHT products were also evaluated.

The routes and duration of exposure evaluated in this assessment include: short-term (ST) (1-30 days) and intermediate-term (IT) (1 - 6 months) dermal, inhalation, and incidental oral exposures. The following is a summary of the HHT NOAELs and Target MOEs:

- ST incidental oral NOAEL = 500 mg/kg/day with Target MOE = 1,000
- IT incidental oral NOAEL = 50 mg/kg/day with Target MOE = 100
- ST dermal systemic NOAEL = no endpoint identified
- IT and LT dermal systemic NOAEL = 250 mg/kg/day with Target MOE = 1,000
- ST, IT, and LT inhalation NOAEL = 50 mg/kg/day with Target MOE = 100; an MOE less than 1,000 may warrant an inhalation specific toxicity study to be conducted

The following is a summary of the HCOH endpoints:

- ST (peak) NOAEL = 0.1 ppm with a Target MOE = 1 for occupational scenarios and 10 for residential scenarios
- Cancer Unit Risk = $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$. The cancer risks were also estimated using the Tables 8 A and B from Conolly et al., 2004.

Based on examination of product labels describing uses for this antimicrobial, it has been determined that exposure to handlers can occur in a variety of occupational and residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by AD were evaluated using maximum application rates as stated on the product labels. To assess the handler and post-application exposures and risks, AD used standard assumptions, surrogate unit

exposure data (from the Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED)), *Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products* (HERA), and EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments*, EPA's Wall Paint Exposure Model (WPEM) and EPA's Consumer Exposure Module (CEM).

Handler Risk Summary

For the HHT residential handler exposure assessment, the ST inhalation MOEs for the application of paint and use of cleaners (mop, wipe, trigger pump products) were all above the target MOE of 1,000. IT durations were not assessed for residential handlers because it was assumed that these types of exposures occur on an intermittent basis.

For the HCOH residential handler exposure assessment, the following inhalation risks are of concern:

- The Do-it-Yourself (DIY) painter MOEs range from 0.3 to 1.0 depending on the amount of HCOH formation (target MOE = 10). Assuming 100% and 30% HCOH formation, the cancer risks using the IRIS unit risk is 2.2×10^{-5} and 6.8×10^{-6} , respectively, which exceed the Agency's level of concern of 1.0×10^{-6} . It should be noted that using the CIIT modeling approach, the cancer risks are well below the Agency's level of concern.
- The MOE for residential handlers of cleaning products is 0.41 (Target MOE = 10). Using the IRIS unit risk, the cancer risk is 2.5×10^{-5} which exceeds the Agency's level of concern of 1.0×10^{-6} . It should be noted that using the CIIT modeling approach, the cancer risk is well below the Agency's level of concern.
- The MOE for residential handlers of laundry detergent is 0.22 (Target MOE = 10). Using the IRIS unit risk, the cancer risk is 1.15×10^{-5} which exceeds the Agency's level of concern of 1.0×10^{-6} . It should be noted that using the CIIT modeling approach, the cancer risk is well below the Agency's level of concern.

For the HHT occupational handler dermal and inhalation risk assessment, the MOEs were above target MOEs of 1,000 (IT dermal and ST/IT inhalation) for all scenarios except the following:

- IT dermal MOE for mopping in medical facilities = 400 (Target MOE = 1,000)
- IT dermal MOE for metering pump in secondary recovery activities = 690 (Target MOE = 1,000)

For the HCOH occupational handler exposure assessment, the following inhalation risks are of concern:

- The painter MOEs range from 0.05 to 0.18 depending on the amount of HCOH formation (target MOE = 1). Using the IRIS unit risk, the cancer risks range from 2.9×10^{-3} to 8.7×10^{-4} which exceeds the Agency's level of concern of 1.0×10^{-4} . It should be noted that using the CIIT modeling approach, the cancer risk is well below the Agency's level of concern.

- AD can not consider using the metal working fluid exposure data provided by the registrants until the ethics review for the use of human subjects for this specific study has been completed

Post-application/Bystander Risk Summary

For the HHT residential post-application risk assessment, MOEs are above the respective target MOEs (1,000 for IT dermal and ST incidental ingestion exposures and 100 for IT incidental ingestion exposures) for all scenarios.

For the HCOH residential post-application risk assessment, the following inhalation risks are of concern:

- The MOEs range from 0.4 to 1.2 depending on the amount of HCOH formation (target MOE is 10) for the occupant of freshly painted homes/rooms. Assuming 100% and 30% HCOH formation, the cancer risks using the IRIS unit risk is 6.0×10^{-5} and 1.8×10^{-5} , respectively, which exceed the Agency's level of concern of 1.0×10^{-6} . It should be noted that using the CIIT modeling approach, the cancer risk is well below the Agency's level of concern.

HHT occupational post-application or bystander exposures are assumed to be minimal and therefore not quantitatively assessed.

For the HCOH occupational bystander assessment, exposures were not able to be assessed due to the lack of HCOH data. Inhalation exposure is the primary route of exposure for bystanders working in an industrial facility that utilizes HHT which releases HCOH. HCOH air concentration data are needed from an industrial facility such as paint manufacturing plant in order to make the safety finding.

Aggregate Risk Summary

For the HHT residential aggregate risk assessments, the MOEs were above target MOEs for all scenarios.

Based on use patterns, an aggregate assessment was not necessary to assess for HCOH residential exposures.

Data Limitations and Uncertainties:

There are a number of uncertainties associated with this assessment, including the following:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary CMA antimicrobial exposure study (US EPA 1999: DP Barcode D247642) or the Pesticide Handler Exposure Database (US EPA 1998). Most of the CMA data are of poor quality therefore, AD requests that confirmatory monitoring data be generated to support the values used in these assessments.

- The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (US EPA 1997a, 2001) and standard AD assumptions that can be further refined from input from registrants.
- The HCOH formation rate from HHT preserved products such as paint and metal working fluid is not well documented.
 - Currently, no exposure data are available to assess the bystanders' inhalation exposure to HCOH vapors resulting from HHT uses in industrial settings. Appropriate air monitoring data in the manufacturing setting are needed to support the preservative uses.
 - An air monitoring study in metal working facilities is needed to ascertain the extent of the *peak* and average HCOH exposure from the preserved material. Furthermore, AD can not consider using the metal working fluid exposure data provided by the registrants until the ethics review for the use of human subjects for this specific study has been completed.
- The Wall Paint Exposure Model is designed to estimate indoor-air concentrations and associated inhalation exposures for interior applications involving alkyd or latex primer/paint. The chamber tests on which the emission algorithms are based involve a limited set of chemicals with a correspondingly limited range of properties (molecular weight and vapor pressure). Further, the emission algorithms are valid only for chemicals that are formulated into alkyd/latex primers or paints. Actual monitoring data or a chamber study is needed to determine the amount of HCOH off-gassing from HHT treated paint and could be used to refine the occupational and residential scenarios pertaining to painting activities.
 - Without actual air monitoring data from painting activities, AD estimated HCOH formation based on assumptions and the results of the hydrolysis study. However, a study is needed to ascertain the actual amount of HCOH formation in the paint in order to estimate a more accurate exposure value.
- Without actual air monitoring data from cleaning and laundering activities, AD assumed 100% HCOH formation from HHT. However, a study is needed to ascertain the actual amount of HCOH formation in the cleaners and detergents in order to estimate more accurate exposure values.
- For each cancer assessment, it was conservatively assumed that every event utilized HHT treated products. If specific HHT treated product use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

1.0 INTRODUCTION

1.1 Purpose

This document presents the results of a review of the potential human health effects of occupational and residential exposure to hexahydro-1,3,5-tris(2-hydroxyethyl)-s-tirazine (HHT) and its formation product formaldehyde (HCOH). This information is for use in EPA's development of the HHT Reregistration Eligibility Decision (RED) Document.

1.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For HHT, both criteria are met.

In this document, scenarios were assessed by using *unit exposure* data to estimate occupational and residential handlers' exposures. *Unit exposures* are estimates of the amount of exposure to an active ingredient a handler receives while performing various handler tasks and are expressed in terms of micrograms or milligrams (1mg = 1,000 µg) of active ingredient per pounds of active ingredient handled. A series of unit exposures have been developed that are unique for each scenario typically considered in assessments (i.e., there are different unit exposures for different types of application equipment, job functions, and levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization for Economic Cooperation and Development).

Using surrogate unit exposure data, maximum application rates from labels, and estimates of daily amount handled, exposures and risks to handlers were assessed. The exposure/risks were calculated using the following equations:

Daily Exposure: Daily dermal or inhalation handler exposures are estimated for each applicable handler task with the application rate, quantity treated/handled in a day, and the applicable dermal or inhalation unit exposure using the following formula:

$$\text{Daily Exposure:} \quad E = UE \times AR \times AT \quad (\text{Eq. 1})$$

Where:

- E = Amount (mg a.i./day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;
- UE = Unit exposure value (mg ai/lb ai) derived from August 1998 PHED data or from 1992 CMA data;
- AR = Maximum application rate based on a logical unit treatment, square feet (sq. ft.), gallons (gal), or cubic feet (cu. ft). Maximum values are generally used (lb a.i./sq ft, lb ai/gal, lb ai/cu ft); and

AT = Normalized application area based on a logical unit treatment such as square feet (sq ft/day), gallons (gal/day), or cubic feet (cu ft/day).

Daily Dose: The daily dermal or inhalation dose is calculated by normalizing the daily exposure by body weight and adjusting, if necessary, with an appropriate absorption factor. For HHT, a dermal endpoint was used for evaluation of dermal exposures therefore an absorption factor was not necessary to include. However, an oral endpoint was used to evaluate inhalation risks assuming 100% absorption. Daily dose was calculated using the following formula:

$$\text{Daily Dose: } ADD = \frac{E \times ABS}{BW} \quad (\text{Eq. 2})$$

Where:

ADD = Absorbed dose received from exposure to a chemical in a given scenario (mg active ingredient/kg body weight/day);
E = Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;
ABS = A measure of the amount of chemical that crosses a biological boundary such as lungs (% of the total available absorbed); and
BW = Body weight determined to represent the population of interest in a risk assessment (kg).

Margins of Exposure: Non-cancer inhalation and dermal risks for each applicable handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the daily dose to the toxicological endpoint of concern.

$$\text{Margins of Exposure: } MOE = \frac{NOAEL \text{ or } LOAEL}{ADD} \quad (\text{Eq. 3})$$

Where:

MOE = Margin of exposure, value used to represent risk or how close a chemical exposure is to being a concern (unitless);
NOAEL or LOAEL = Dose level in a toxicity study, where no observed adverse effects (NOAEL) or where the lowest observed adverse effects (LOAEL) occurred in the study; and
ADD = Average daily dose or the absorbed dose received from exposure to a chemical in a given scenario (mg ai/kg body weight/day).

In addition to the target MOEs from Table 3.2 that were used for the analysis, a series of assumptions and exposure factors served as the basis for completing the handler risk assessment. Each general assumption and factor for both residential and occupational assessments is detailed below. Assumptions specific to the use site category are listed in each separate section of this document. The general assumptions and factors include:

- HHT products are registered for various use patterns and use conditions too numerous to conduct a comprehensive assessment for this document. As such, this risk

assessment has been patterned on a series of scenarios that are believed to represent the vast majority of HHT uses.

- Average body weights of 70 kg for adults and 15 kg for children were used as appropriate to complete the non-cancer risk assessment.
- Exposure factors used to calculate daily exposures to handlers were based on applicable data, if available. When appropriate data were lacking, values from a scenario deemed similar were used.
- The maximum application rates allowed by labels were assumed.

1.3 Chemical Identification

The chemical under review is hexahydro-1,3,5-tris(2-hydroxyethyl)-s-tirazine (HHT) which hydrolyzes to form formaldehyde (HCOH). The Product Code for HHT chemical is 083301 and the CAS RN is 4719-04-4.

1.4 Physical/Chemical Properties

Table 1.2 shows physical/chemical characteristics that have been reported for HHT and HCOH.

	HHT	HCOH
Molecular Weight	219.28 g/mol	30 g/mol
Vapor Pressure	4.13×10^{-9} mmHg	1 mmHg (formalin)

2.0 USE INFORMATION

2.1 Formulation Types and Percent Active Ingredient

The products containing HHT as the active ingredient (a.i.) are formulated as soluble concentrates in end-use products. Concentrations of HHT in these products range from 50.5% to 78.5%.

2.2 Summary of Use Pattern and Formulations

HHT is a materials preservative and an industrial microbiocide that is an active ingredient in 16 registered products. AD determined potential occupational and residential exposure scenarios by reviewing currently registered labels. These scenarios are presented in Table 2.1. Examples of registered uses for HHT as a materials preservative (Use Site Category VII) include metalworking fluids, coatings, stains and paints, glues and adhesives, building materials, institutional and household cleaning products (i.e., laundry detergents, dish detergents, all purpose cleaners, hard surface cleaners, car care products, etc.). Examples of registered uses for HHT in industrial

processes (Use Site Category VIII) include oil field water systems, oil recovery, and oil drilling muds.

Table 2.1. Potential Use Scenarios Based on Product Labels for HHT		
Use Site Category	Example Use Sites	Scenarios
Use Site Category VII Material Preservatives	Used in the production of various household, institutional and industrial items	Addition to products during manufacture, including: <ul style="list-style-type: none"> • Paints, stains, and coatings • Metal working fluids • Institutional and household cleaning products (laundry detergents, dish detergents, fabric softeners, all purpose cleaners, hard surface cleaners, car care products) • Adhesives • Aqueous mineral slurries • Construction compounds (caulks, joint cements, spackling, grout, tapes, mortar) • Aqueous analytical and diagnostic reagents • Synthetic fiber lubricants (spin finishes) • Fuel systems (diesel oil, fuel oil, gasoline or kerosene systems)
Use Site Category VIII Industrial processes and water systems	Used on water supplies for commercial and industrial systems	<ul style="list-style-type: none"> • Oil field applications <ul style="list-style-type: none"> ○ Drilling muds ○ Workover/completion fluids ○ Oil recovery injection systems

From Table 2.1, representative exposure scenarios were selected for assessment in this document. These scenarios were selected to be representative of the vast majority of uses and are believed to provide high-end estimates of dermal, inhalation, or incidental ingestion exposure. The representative scenarios assessed in this document are shown in Table 4.1a (residential) and Table 6.1a (occupational).

As previously stated, HHT hydrolyzes to form formaldehyde (HCOH). Therefore, exposure to HCOH can also occur as a result of using or handling HHT. Thus, HCOH exposures resulting from the use of HHT were also evaluated in this document. Representative scenarios assessed for HCOH are presented in Tables 4.1b (residential) and Table 6.1b (occupational).

3.0 SUMMARY OF TOXICITY DATA

3.1 Acute Toxicity

Adequacy of database for Acute Toxicity: The acute toxicity data for HHT is summarized below in Table 3.1. The acute toxicity database for HHT is considered incomplete in the absence of acute inhalation exposure data. HHT has a moderate order of toxicity via the oral and dermal routes of exposure (Toxicity Category III) and is classified corrosive (Toxicity category I) by primary irritation studies. Dermal irritation studies classify HHT as a minimum irritant and the chemical is not a dermal sensitizer.

Table 3.1. Acute Toxicity data for HHT technical a.i.				
Guideline Number	Study Type/ Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral – Rat Purity 79.4% - HHT	41675206	LD ₅₀ =1250 mg/kg (males) LD ₅₀ =763 mg/kg (females)	III
870.1100 (§81-1)	Acute Oral – Mouse (Supplemental) Purity 78.5% - HHT	00155959	LD ₅₀ = 1.30 mL/kg	III
870.1200 (§81-2)	Acute Dermal – Rabbit Purity 79.96% - HHT	00155984	LD ₅₀ > 2000 mg/kg	III
870.1300 (§81-3)	Acute Inhalation – Rat	–	–	–
870.2400 (§81-4)	Primary Eye Irritation – Rabbit Purity 79.96% - HHT	00155985	Corrosive	I
870.2500 (§81-5)	Primary Dermal Irritation –Rabbit Purity 79.96% - HHT	00155986	Mild irritant	IV
870.2500 (§81-5)	Primary Dermal Irritation – Guinea pigs Purity 79.96% - HHT	00155987	Mild irritant	IV
870.2600 (§81-6)	Dermal Sensitization – Guinea pigs Purity 79.96% - HHT	00155987	Not a Sensitizer	NA

3.2 Summary of Toxicity Endpoints

The toxicological endpoints were selected for HHT and HCOH. Table 3.2 summarizes the toxicological endpoints for HHT used in the evaluation of exposures and MOEs. The reader is referred to the following memorandum for more details: *Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document, January 30, 2007.* Table 3.3 summarizes the toxicological endpoints for HCOH used in the evaluation of exposures and MOEs. The reader is referred to the following memorandum for more details: *Formaldehyde: Preliminary Risk Assessment for the Registration*

Eligibility Decision (RED), April 7, 2008.

Table 3.2: Summary of Toxicological Doses and Endpoint Selection for HHT			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF ⁽¹⁾ and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessment			
Acute Dietary (All populations)	Oral NOAEL = 500 mg/kg/day UF = 1,000 (10X-Inter; 10X – Intra and 10X – database UF)	NA	Rat Developmental Toxicity (MRID 41161801), based on ulcerations, and scarring of the stomach mucosa.
Chronic Dietary (All populations)	Oral NOAEL = 50 mg/kg/day UF = 100 (10X-Intra; 10X - Inter)	NA	Rat 90-day Oral Study (MRID41483001), based on lymphocytic infiltration in females and erosion of gastric mucosa and prominence of limiting ridge of the stomach in males
Non-Dietary Risk Assessments			
Short-Term Incidental Oral (1-30 days)	Oral NOAEL = 500 mg/kg/day UF = 1,000 (10X-Inter; 10X – Intra and 10X – database UF)	N/A	Rat Developmental Toxicity (MRID 41161801), based on decreased body weight gain, ulcerations, and scarring of the stomach mucosa.
Intermediate-Term Oral (1-6 months)	Oral NOAEL = 50 mg/kg/day UF = 100 (10X-Intra; 10X - Inter)	N/A	Rat 90-day Oral Study (MRID41483001), based on lymphocytic infiltration in females and erosion of gastric mucosa and prominence of limiting ridge of the stomach in males
Dermal Ad. Factor	Note required (Dermal Study is used for Dermal End-points)		
Dermal (Systemic, Short-Term)	No risk assessment necessary. No effects observed in a 21-day dermal toxicity study up to 1000 mg/kg/day.		
Dermal (Inter-, and long-term)	Dermal NOAEL = 250 mg/kg/day UF = 1,000	N/A	Rat 90-day dermal Study (MRID41483002), based on systemic NOAEL was found to be greater than 250 mg/kg/day.

Table 3.2: Summary of Toxicological Doses and Endpoint Selection for HHT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF ⁽¹⁾ and Level of Concern for Risk Assessment	Study and Toxicological Effects
Inhalation short- and intermediate-term exposure)	Oral NOAEL = 50 mg/kg/day UF = 100 ((10X- Inter; 10X – Intra) Note: an additional 10X UF is applied for data gap and is used to require an inhalation specific toxicity study (UF = 1,000)	NA	Rat 90-day Oral Study (MRID41483001), based on lymphocytic infiltration in females and erosion of gastric mucosa and prominence of limiting ridge of the stomach in males
Cancer (oral, dermal, inhalation)			no cancer data available

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

NOTE:

(1). The Special FQPA Safety Factor recommended by the ADTC **assumes** that the exposure databases (dietary food, drinking water, and residential) are complete and that the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk for infants and children.

Table 3.3: Summary of Toxicological Doses and Endpoint Selection for HCOH

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF* for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (general population including infants and children)	An acute dietary assessment is not needed for the registered antimicrobial uses of formaldehyde.		
Chronic Dietary (all populations)	A chronic dietary assessment is not needed for the registered antimicrobial uses of formaldehyde.		
Non-Dietary Risk Assessments			
Incidental Oral	An incidental oral risk assessment is not required for the registered antimicrobial uses of formaldehyde.		
Dermal (all durations)	A dermal risk assessment is not required for the registered antimicrobial uses of formaldehyde.		
Inhalation (all durations)	NOAEL (human) = 0.1 ppm	UF = 1 (occupational) UF = 10 (residential)	ACGIH 2001 publication on formaldehyde Horvath, E.P. et al. (1986): JAMA 259(5): 701-707. Based on complaints of eye, nose, and throat irritation in particle board workers at concentrations of formaldehyde from 0.4 – 1.0 ppm. Redden, J. (2005): Section 18 Emergency Exemption for the use of Paraformaldehyde: U.S. Army Medical Research Institute of Infectious Diseases.
Cancer	Lifetime extra cancer unit risk estimate of 1.3×10^{-5} per $\mu\text{g}/\text{m}^3$ (US EPA IRIS http://www.epa.gov/ncea/iris/subst/0419.htm) And CIIT modeling: Tables 8A (for residential) and B (for professional). Hockey stick-shaped CRCP (nonsmoking) (Conolly, 2004)		

4.0 RESIDENTIAL EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Although no products containing HHT are labeled for residential uses, residents may be exposed to household items that have been treated with HHT through material preservation (e.g., paints and household cleaners). Table 2.1 presents a summary of exposure scenarios that may occur from the residential use site category based on examination of product labels. Table 4.1a identifies the representative HHT exposure scenarios assessed in this document. Since HHT hydrolyzes to form HCOH, HCOH exposures were also necessary to assess. Table 4.1b identifies the representative HCOH exposure scenarios assessed in this document.

Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated paints	Handler: ST inhalation (aerosol)	<ul style="list-style-type: none"> • brush/ roller • airless sprayer 	68868-1	0.24% a.i. by weight (78.5% a.i. x 0.3% product by weight of material)
Using treated household cleaners	Handler: ST inhalation (aerosol) Post-app child: ST and IT incidental ingestion and IT dermal	<ul style="list-style-type: none"> • mop • wipe • trigger pump/ aerosol 	68868-1	0.16% a.i. by weight (78.5% a.i. x 0.2% product by weight of material)
Using treated laundry detergents ¹	Post-app child: ST and IT incidental ingestion and IT dermal	NA	68868-1	0.16% a.i. by weight (78.5% a.i. x 0.2% product by weight of material)

¹ Note: Since the application rates are the same, the exposure for the handler of household cleaners is expected to be higher (and therefore representative) of the exposure of the detergent (laundry or dish) handler.

Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated paints	Handler: ST inhalation (vapor) and cancer	NA	68868-1	0.03% - 0.1% a.i. by weight ¹

Table 4.1b. Representative Uses Associated with HCOH Residential Exposure				
Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated household cleaners	Handler: ST inhalation (vapor) and cancer	NA	68868-1	0.07% a.i. by weight ²
Using treated laundry detergents	Handler: ST inhalation (vapor) and cancer	NA	68868-1	0.07% a.i. by weight ²

¹ HHT hydrolyzes to form formaldehyde (HCOH) (MRID 43181001). The rate of HHT degradation and formation of HCOH was fastest at pH 5 and declined with increasing pH. The hydrolysis half-lives of HHT were 3.2, 50, and 302 days for pH 5, 7, and 9, respectively. The maximum percentages of HCOH formation were about 100, 31, and 20, respectively.

At pH 5, HCOH formation reached 50% by 2 days, 85% by 7 days, and 97-100 % by 14-30 days. At pH 7, HCOH reached 19% by 1 day, 25% by 14 days, and 31% by 30 days. At pH 9, HCOH reached 17-21% by 1-30 days.

According to various sources, paint pH at the time of manufacture ranges from 8 to about 10. However, pH declines over time. Paint pH (water-based) must be at least 6.7 for proper application, and the acrylic polymer used to make paint becomes unstable at pH 7.5. At these pH values, HCOH is expected to reach between 20 and 30% of parent HHT within 30 days. If paints are stored longer than 30 days, the HCOH content is expected to be higher. Additionally, to estimate HCOH formation, these values must be adjusted based on the relative molecular weights of HHT and HCOH.

The molecular weights of HHT and HCOH are 219 and 30 grams per mole, respectively. The molecular weight of HCOH must be adjusted by a factor of three because each molecule of HHT generates three HCOH molecules. Based on the use of 0.24% HHT in paint, the resulting HCOH formation is approximately 0.03% HCOH. This estimate assumes that paint is not stored longer than 30 days. The equation for the conversion is:
 $0.24\% \text{ HHT} \times 30\% \text{ conversion} \times 30 \text{ g HCOH/mole} \times 3 \text{ HCOH/molecule HHT} \times 1 \text{ mole HHT}/219 \text{ g} = 0.03\% \text{ HCOH}$

As a worst-case assumption, assuming 100% of the HHT converts to HCOH, 0.1% HCOH is available for exposure. The equation for the conversion is:
 $0.24\% \text{ HHT} \times 100\% \text{ conversion} \times 30 \text{ g HCOH/mole} \times 3 \text{ HCOH/molecule HHT} \times 1 \text{ mole HHT}/219 \text{ g} = 0.1\% \text{ HCOH}$.

² As a worst-case assumption, assuming 100% of the HHT converts to HCOH, 0.07% HCOH is available for exposure. The equation for the conversion is:
 $0.16\% \text{ HHT} \times 100\% \text{ conversion} \times 30 \text{ g HCOH/mole} \times 3 \text{ HCOH/molecule HHT} \times 1 \text{ mole HHT}/219 \text{ g} = 0.1\% \text{ HCOH}$.

4.2 Dietary Exposure

Any risks pertinent to dietary exposures are discussed in the Preliminary Risk Assessment.

4.3 Drinking Water Exposure

Any risks pertinent to drinking water exposures are discussed in the Preliminary Risk Assessment.

4.4 Residential Exposures

4.4.1 Residential Handler Exposures

The types of products treated with HHT that are handled in a residential setting are treated paints, detergents, and similar products as described in Table 4.1a. The short-term inhalation residential cleaner and painter exposures were assessed and are considered to be representative of all other residential handler exposures. It should be reiterated that ST dermal exposures were not assessed because a toxicological endpoint was not selected due to the lack of effects observed in the dermal study. It should be further noted that due to HHT's low vapor pressure, inhalation exposure was only assessed for exposure to the aerosol not vapor phase of HHT.

The residential handler scenarios described in Table 4.1 were assessed to determine inhalation exposures. All of the HHT handler scenarios were assessed using CMA and PHED data and Equations 1-3 in Section 1.2, "Criteria for Conducting Risk Assessment." The assumptions and factors used for those scenarios in which CMA data were used include:

Unit Exposure Values: Unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the PHED data presented in HED's Residential SOPs (USEPA, 1997a).

- For the *mopping* scenario, the CMA inhalation unit exposure value for mopping was used (2.38 mg/lb a.i.). This value is based on data collected from six replicates mopping floors.
- For the *wiping* scenario, the CMA inhalation unit exposure value for wiping was used (67.3 mg/lb a.i.). This value is based on data collected from six replicates (dental technicians) who used a finger pump sprayer to apply the product and then wiped the surfaces with a paper towel.
- For *trigger pump* and *aerosol* scenarios, the PHED aerosol inhalation unit exposure value was used 2.4 mg/lb a.i. This value is based on homeowners applying an aerosol insecticide to baseboards in kitchens.
- For the *airless sprayer* scenario, PHED inhalation unit exposure value for a residential handler applying a pesticide using an airless sprayer was used. This unit exposure value (0.83 mg/lb a.i.) represents a handler painting a residential bathroom.
- For the *brush/roller* scenario, PHED inhalation unit exposure value for a residential handler applying a pesticide using a paint brush was used (0.28 mg/lb a.i.).

Quantity handled: The quantities handled were estimated based on HED's Residential SOPs (USEPA 1997a and 2001) and AD standard assumptions and are presented below. It should be noted that since HHT is used as a materials preservative in household cleaners and not a sanitizer or disinfectant, the labels did not provide use instructions (i.e., dilution rates). Therefore, it was assumed that the household cleaners were formulated as ready-to-use (RTU) products and were not further diluted.

- For the *mopping* scenarios, it is assumed that 1 gallon of diluted solution is used (Standard AD assumption). Assuming the solution has the density of water, 1 gallon of solution is equivalent to 8.34 lbs (8.34 lbs = 1 gal x 8.34 lbs/gal).
- For the *wiping and trigger pump spray* scenarios, it is assumed that 0.5 liter (0.13 gal) of diluted solution is used (Standard AD assumption). Assuming the solution has the density of water, 0.13 gallons of solution is equivalent to 1.1 lbs (1.1 lbs = 1 gal x 8.34 lbs/gal).
- For the *airless sprayer* in paint applications, it is assumed that 150 lbs (approximately 15 gallons where the density of the paint is 10 lbs/gal) of treated paint will be used. This is based on the coverage of 200 ft²/gallon and a house size of 40 x 30 x 20 ft (surface area of 2,800 ft²) (USEPA 1997a and 2001).
- For the *brush/roller* in paint applications, it is assumed that 20 lbs (approximately 2 gallons where the density of the paint is 10 lbs/gal) of treated paint will be used. This is based on the 90th percentile value of 8 gallons of latex paint used per year divided by the mean frequency of 4 painting events/year (USEPA 1997a and 2001).

Duration of Exposure: The duration of exposure for most homeowner applications of cleaning and paint products is believed to be best represented by the short-term duration (1 to 30 days). Only ST exposure durations (1 to 30 days) were estimated for the painter because it was assumed that a homeowner or do-it-yourself painter would typically paint on an intermittent basis (i.e., a few times per year). Furthermore, household cleaning exposure scenarios are assumed to be episodic, not daily. In addition, homeowners are also assumed to use different cleaning products with varying active ingredients, not exclusively HHT treated products.

Results: The resulting short-term exposures and MOEs for the representative residential handler scenarios are presented in Table 4.2. The calculated MOEs were above the target inhalation MOE of 100 for all scenarios. Furthermore, all short-term inhalation MOEs exceeded 1,000 therefore, a confirmatory inhalation toxicity study is **not** warranted based on the results of these exposure scenarios. It should be noted that the estimated HHT dose did not account for loss due to HCOH formation. Since the MOEs were well above the Target MOE, further refinement is not necessary.

Table 4.2 Short-Term HHT Residential Handlers Exposures and MOEs						
Exposure Scenario	Method of Application	Inhalation Unit Exposure (mg/lb ai)	Application Rate (% a.i.)	Quantity Handled per day	Inhalation Daily Dose (mg/kg/day) ^a	ST Inhalation MOE (Target = 100) ^b
Application to indoor hard surfaces	Mopping	2.38	0.16%	8.34 lbs	4.54E-04	110,000
	Wiping	67.3	0.16%	1.1 lbs	1.67E-03	30,000
	Aerosol	2.4	0.16%	1.1 lbs	5.95E-05	840,000
Painting	Brush/roller	0.28	0.24%	20 lbs	1.92E-04	260,000
	Airless sprayer	0.83	0.24%	150 lbs	4.27E-03	12,000

^a Inhalation Daily Dose (mg/kg/day) = Inhal UE (mg/lb ai) x app rate (%ai) x quantity handled (lbs/day) / body weight (70 kg).

^b Inhalation MOE = NOAEL (50 mg/kg/day) / Daily Dose (mg/kg/day). Target inhalation MOE = 100.

4.4.1.1 Residential HCOH Inhalation (vapor) Exposure

Residential Painter:

As previously stated, HHT hydrolyzes to form HCOH. Therefore, exposure to HCOH can also occur as a result of using or handling HHT treated products such as paint and household cleaners. Thus, it was necessary to evaluate HCOH exposures resulting from the use of HHT treated products. Since HCOH has such a high vapor pressure (1 mm Hg), the vapor inhalation exposure is the primary route of exposure. Inhalation exposure to the vapor is considered to be representative of exposure to the aerosol paint as well as vapor.

The painter inhalation exposure to HCOH vapor from the treated paint is assessed. AD utilized EPA's Wall Paint Exposure Model (WPEM) version 3.2 to estimate air concentrations resulting from the use of paint preserved with HHT. WPEM was developed under a contract by Geomet Technologies for EPA OPPT to provide estimates of potential air concentrations and consumer/worker exposures to chemicals emitted from wall paint which is applied using a roller or a brush. WPEM uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. The emission data can then be combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc.) to estimate exposure. Specific input parameters include: the type of paint (latex or alkyd) being assessed, density of the paint (default values available), and the chemical weight fraction, molecular weight, and vapor pressure. Detailed information and the executable model can be downloaded from <http://www.epa.gov/opptintr/exposure/docs/wpem.htm>.

For this exposure assessment, the WPEM default scenario for the homeowner painter (RESDIY) was used. This WPEM default scenario assumes that the homeowner is exposed to the chemical in paint when painting the bedroom of a house which takes 3 hours to complete. For a detailed description of the default RESDIY scenario, see the WPEM User's Guide. The following chemical-specific inputs were used in the model:

- HCOH's molecular weight (30 amu) and vapor pressure (1 mm Hg)
- The weight fraction of HCOH in paint (EPA Reg. 68868-1 contains 0.24% HHT which is equivalent to 0.03% - 0.1% HCOH by weight - see section 4.1 for details on the conversion of HHT to HCOH)

The model provides several dose measures (i.e., LADD, ADD), air concentration measures (i.e., peak, 15-min, 8hr, LADC), and a comma-separated (.csv) file as outputs. The comma-separated file contains details on time-varying concentrations within the modeled building as well as concentrations to which the individual is exposed. This file can be read directly into spreadsheet software (e.g., Excel) for calculating additional summary statistics. The air concentrations calculated by the model were used by AD to estimate inhalation exposures, MOEs, and cancer risks. The peak concentrations were used to estimate non-cancer risks while Lifetime Average Daily Concentrations (LADCs) were used to estimate cancer risks.

Since the actual amount of HCOH formation in the paint is not well documented, the inhalation exposures and risks were estimated assuming 100% HCOH formation and 30% HCOH formation. The 30% formation is the minimum amount of HCOH formation however, the HCOH formation could be even higher depending on the length of storage (see section 4.1). The model results and risk calculations are summarized in Table 4.3a and 4.3b for non-cancer and cancer, respectively.

At 100% HCOH formation the non-cancer inhalation (vapor) MOE is 0.3 and at 30% HCOH formation the MOE is 1.0 for the Do-it-Yourself (DIY) painter. Since the target MOE is 10 both exposure scenarios are of concern. A study is needed to ascertain the actual amount of HCOH formation in the paint in order to estimate a more accurate exposure value.

HCOH Formation	Peak Air Conc. (mg/m³)^a	Peak Air Conc. (ppm)^b	Inhal. MOE^c Target MOE= 10
100%	0.42	0.34	0.3
30%	0.13	0.10	1.0

^a The WPEM peak air concentration during 3 hours of exposure (during the painting activities only)

^b HCOH air conc (ppm) = HCOH air conc (mg/m³) x 24.45 / HCOH MW (30 g/mol)

^c Inhalation MOE = Inhalation NOAEL (0.1 ppm based on 15-min exposure) / Peak Air Conc. where Target MOE = 10

For the cancer exposure calculations, all of WPEMs default assumptions were used except for the following which were changed to standard AD assumptions:

- EF = Exposure Frequency (number of DIY painting events per year): 4 days/year (USEPA 1997b)
- ED = Exposure Duration: 35 years

To assess cancer risks the lifetime average daily air concentration ($\mu\text{g}/\text{m}^3$) is multiplied times the unit risk of $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$. Cancer risks that are less than 1.0×10^{-6} are generally not of concern for residential populations. Cancer risks were calculated using the following equation:

$$\text{Cancer Risk} = \text{LADC} (\mu\text{g}/\text{m}^3) \times \text{Unit Risk} (\mu\text{g}/\text{m}^3)^{-1}$$

Cancer risks were also estimated using the CIIT modeling presented in Table 8A (hockey stick-shaped CRCP; nonsmoking) of Conolly 2004.

Table 4.3b. Inhalation (vapor) Exposure and Cancer Risks for Residential Painters				
HCOH Formation	Days Exposed per Year	Years Exposed per Lifetime	Life Time Average Daily Concentration^a	Cancer Risk^{b,c}
IRIS Unit Risk				
100%	4	35	1.7 ($\mu\text{g}/\text{m}^3$)	2.2×10^{-5}
30%	4	35	0.52 ($\mu\text{g}/\text{m}^3$)	6.8×10^{-6}
CIIT Modeling				
100%	4	35	0.0014 ppm ^c	$<2.94 \times 10^{-9}$
30%	4	35	0.00042 ppm ^c	$<2.94 \times 10^{-9}$

^a LADC = WPEM output

^b IRIS Cancer Risk = LADC ($\mu\text{g}/\text{m}^3$) x Unit Risk $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$

^c CIIT Cancer Risks are presented in Table 8A (hockey stick-shaped CRCP; nonsmoking) of Conolly et al., 2004

At 100% and 30% HCOH formation, the cancer risks using the IRIS unit risk values are 2.2×10^{-5} and 6.8×10^{-6} which exceed the Agency's level of concern of 1.0×10^{-6} . However, using the CIIT modeling the risks at 100% or 30% HCOH formation are below 2.94×10^{-9} all of which do not exceed the Agency's level of concern of 1.0×10^{-6} . It should be noted that it was conservatively assumed that every painting event utilized HHT treated paint. If specific HHT treated paint use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

Residential All Purpose Household Cleaner Handler:

The EPA's Consumer Exposure Module (CEM) was used to estimate HCOH air concentrations resulting from the use of all purpose cleaners preserved with HHT. Detailed information and the executable model can be downloaded from <http://www.epa.gov/opptintr/exposure>. The default scenario for the general purpose cleaner was used for this exposure assessment. This scenario assumes that the homeowner uses the general purpose cleaner in the kitchen of a house.

The following general inputs were used in the model:

- The molecular weight of HCOH is 30 amu.

- The vapor pressure is 1.0 mmHg for HCOH (as a liquid in formalin).
- The weight fraction of 0.0007 is based upon the maximum product application rate of HHT and 100% HCOH formation (see Table 4.1b).
- The air exchange rate is 0.45 air exchanges per hour.

To assess non-cancer risks, the following inputs were used to calculate a peak concentration:

- The amount of general purpose cleaner used is 123 grams which is the default high end value.
- The duration of exposure is 1.42 hours which is the default high end value from CEM.

To assess cancer risks, the following inputs were used to calculate a lifetime average daily concentration:

- The frequency of use was set to 52 events per year which is based on professional judgment (assuming cleaning once per week).
- The exposure duration was set to 57 years which is the default value in CEM.
- The amount of product used per event was set to 61.5 grams which is a central tendency value.
- The event duration was set to 0.667 hours which is a central tendency value.

The CEM model results and risk calculations are summarized in Tables 4.4a and 4.4b for non-cancer and cancer, respectively. The MOE for non-cancer risk is 0.41, which is below the target MOE of 10, and is of concern. The cancer risk using the IRIS unit risk is 2.5×10^{-5} and is also of concern because it exceeds the Agency's level of concern of 1.0×10^{-6} . However, the cancer risk using the CIIT modeling is $< 2.94 \times 10^{-9}$ which does not exceed the Agency's level of concern for cancer. It should be noted that in the cancer assessment it was conservatively assumed that every cleaning event utilized HHT treated cleaning products. If specific HHT treated product use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

Table 4.4a. Inhalation (vapor) Exposure and MOE for Residential Handlers of Cleaning Products			
HCOH Formation	Peak Air Conc. (mg/m³)^a	Peak Air Conc. (ppm)^b	Inhal. MOE^c Target MOE = 10
100%	0.301	0.25	0.41

^a The CEM peak air concentration

^b HCOH air conc 0.25 ppm = HCOH air conc 0.301 mg/m³ x 24.45 / HCOH MW (30 g/mol)

^c Inhalation MOE = Inhalation NOAEL (0.1 ppm based on 15-min exposure) / Peak Air Conc. where Target MOE = 10

Table 4.4b. Inhalation (vapor) Exposure and Cancer Risk for Residential Handlers of Cleaning Products		
HCOH Formation	LADC	Cancer Risk^{b,d}
IRIS		
100%	$1.96 \times 10^{-3} \text{ mg/m}^3$ ^a	2.5×10^{-5}
CIIT		
100%	$1.60 \times 10^{-3} \text{ ppm}$ ^c	$< 2.94 \times 10^{-9}$

^a The CEM LADC concentration

^b IRIS Cancer Risk = LADC (mg/m^3) x 1000 $\mu\text{g/mg}$ x Unit Risk ($1.3 \times 10^{-5} \mu\text{g/m}^3$)⁻¹

^c LADC (ppm) = CEM LADC (mg/m^3) x 24.45 / HCOH MW (30 g/mol)

^d CIIT Cancer Risks are presented in Table 8A (hockey stick-shaped CRCP; nonsmoking) of Conolly et al., 2004

Residential Laundry Detergent Handler:

The EPA CEM model was used to estimate HCOH air concentrations resulting from the use of laundry detergents treated with HHT. The default CEM laundry detergent scenario, which assumes that the homeowner is exposed to the chemical in laundry detergent when using the laundry detergent in the utility room of a house, was used for this assessment.

The following general inputs were used in CEM:

- The molecular weight of HCOH is 30 amu.
- The vapor pressure is 1.0 mmHg for HCOH (as a liquid in formalin).
- The weight fraction of 0.0007 is based upon the maximum product application rate of HHT and 100% HCOH formation (see Table 4.1b).
- The air exchange rate is 0.45 air exchanges per hour.

To assess non-cancer risks, the following inputs were used to calculate a peak concentration:

- The amount of laundry detergent used per day is 400 grams which is the default high end value in CEM.
- The duration of exposure is 0.667 hours which is the default high end value in CEM.

To assess cancer risks, the following inputs were used to calculate a lifetime average daily concentration:

- The frequency of use was set to 104 events per year (assuming 2 wash loads per week per year) which is based on professional judgment.
- The exposure duration was set to 57 years which is the default value in CEM.
- The amount of product used per event was set to 200 grams which is a central tendency value in CEM.
- The event duration was set to 0.333 hours which is a central tendency value in CEM.

The CEM model results and risk calculations are summarized in Table 4.5a and 4.5b for non-cancer and cancer, respectively. The MOE for non-cancer risk is 0.22,

which is below the target MOE of 10, and is of concern. The cancer risk using the IRIS unit risk is 1.5×10^{-5} and is also of concern because it exceeds the Agency's level of concern of 1.0×10^{-6} . However, the cancer risk using the CIIT modeling is $< 2.94 \times 10^{-9}$ which does not exceed the Agency's level of concern for cancer. It should be noted that in the cancer assessment it was conservatively assumed that every laundering event utilized HHT treated products. If specific HHT treated product use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

Table 4.5a. Inhalation (vapor) Exposure and MOE for Residential Handlers of Laundry Detergent Products			
HCOH Formation	Peak Air Conc. (mg/m³)^a	Peak Air Conc. (ppm)^b	Inhal. MOE^c Target MOE = 10
100%	0.55	0.45	0.22

^aThe CEM peak air concentration

^bHCOH air conc 0.55 ppm = HCOH air conc 0.45 mg/m³ x 24.45 / HCOH MW (30 g/mol)

^cInhalation MOE = Inhalation NOAEL (0.1 ppm based on 15-min exposure) / Peak Air Conc. where Target MOE = 10

Table 4.5b. Inhalation (vapor) Exposure and Cancer Risk for Residential Handlers of Laundry Detergent Products		
HCOH Formation	LADC	Cancer Risk^b
IRIS		
100%	1.15×10^{-3} mg/m ³ ^a	1.5×10^{-5}
CIIT		
100%	9.37×10^{-4} ppm ^c	$< 2.94 \times 10^{-9}$

^aThe CEM LADC concentration

^bIRIS Cancer Risk = LADC (mg/m³) x 1000 µg/mg x Unit Risk (1.3×10^{-5} µg/m³)⁻¹

^cLADC (ppm) = CEM LADC (mg/m³) x 24.45 / HCOH MW (30 g/mol)

^dCIIT Cancer Risks are presented in Table 8A (hockey stick-shaped CRCP; nonsmoking) of Conolly et al., 2004

4.4.2 Residential Post-application Exposures

For the purposes of this screening level assessment, post-application scenarios have been developed that encompass multiple products, but still represent a high end exposure scenario for all products represented. As shown in Table 4.1, representative HHT post-application scenarios assessed include contacting hard surfaces/floors cleaned with treated products (dermal and incidental oral exposure to children) and wearing clothing washed with treated detergents (dermal exposure to adults and children, and incidental oral exposure to children). Additionally, HCOH post-application/bystander vapor inhalation exposures were assessed for use of the paints (vapor exposure to adults and children).

Typically, most products used in a residential setting result in exposures occurring over a short-term time duration (1 to 30 days). Homeowners are assumed to use different cleaning products with varying active ingredients, not exclusively HHT treated products.

If the products are used on a routine basis (i.e., once a week) and the active ingredient has a long indoor half-life, exposures may occur over an intermediate-term time duration (30 days – 6 months). At this time, AD does not have residue dissipation data or reliable use pattern data, including the frequency and duration of use of antimicrobial products in the residential setting. AD does not believe that the use patterns of many residential products result in intermediate-term exposure. However, AD does believe that intermediate-term exposure to children may occur in day care centers where disinfecting/cleaning products are used more frequently. Additionally, AD also believes that exposures will occur on a routine basis for adults and children wearing laundered clothing where one container of laundry detergent lasts for 25 uses. Therefore, short- and intermediate-term exposures were necessary to assess for the post-application laundry detergent scenario.

4.4.2.1. Hard Surface/Floor Cleaners

Dermal Exposure to Children from Treated Floors

Exposure Calculations

There is the potential for HHT dermal exposure to toddlers crawling on hard floors after mopping with HHT treated products. Intermediate-term exposures and MOEs were calculated for children contacting treated hard surface floors in commercial daycare centers (intermediate-term exposure). Since a ST dermal endpoint was not selected due to lack of effects observed in the dermal toxicity, ST dermal exposures in a residential setting were not assessed. To determine toddler exposure to HHT floor residues (mopping), the following equation was used:

$$PDD = \frac{AR \times DTF \times DRF \times CF1 \times CF2 \times SA}{BW}$$

where,

PDD	=	Potential daily dose (mg/kg/day);
AR	=	Application Rate (lb ai/ft ²);
DTF	=	Dermal transfer factor (%);
DRF	=	Disinfectant remaining on floor (%);
CF1	=	Conversion factor (4.54x10 ⁵ mg/lb);
CF2	=	Conversion factor (10.8 ft ² /m ²);
SA	=	Surface area of the body which is in contact with floor (m ² /day);
BW	=	Body weight (kg)

Assumptions

- Toddlers (3 years old) were used to represent the 1 to 6 year old age group. A total body surface area of 0.657 m² and a body weight of 15 kg was been assumed, which are the median values for 3 year olds (USEPA, 1997).
- The labels did not provide information on the volume of disinfectant/cleaner to be used for cleaning surfaces such as floors. It was assumed that the

treatment solution is applied at a rate of 1 gallon per 1,000 sq. ft. The maximum use rate on the EPA Label 68868-1 is 0.16% ai for application to hard surfaces (see Table 4.1a). Therefore, the application rates used in the post-application scenarios were $1.33\text{E-}05 \text{ lb ai/ft}^2$ ($1.33\text{E-}05 \text{ lb ai/ft}^2 = 1 \text{ gal/1000ft}^2 \times 0.16\% \text{ ai} \times 8.34 \text{ lb/gal}$; where 8.34 lb/gal is the density of water).

- No transferable residue data were available that could be used to estimate the transfer HHT residues from the floor to skin. Therefore, it is assumed that 10% of the deposition rate is available for dermal transfer (USEPA, 1997 and 2001).
- No data could be found regarding the quantity of solution residue left on the floor after treatment. As a conservative measure, it has been assumed that 25% of the cleaner remains after the final mopping.
- It was assumed that the exposed toddler plays regularly on the treated floor. Although not conducted, in a residential home, a short-term exposure duration is most likely to occur since homeowners are expected to clean the floor only intermittently. In a commercial daycare center, intermediate-term exposure duration is likely to occur since it is expected that the floors are cleaned on a routine basis.

Results

The calculations of the intermediate-term dermal dose and MOE are shown in Table 4.6. The dermal MOE for the institutional settings (intermediate-term MOE) is above the target MOE of 1,000. It should be noted that the estimated HHT dose did not account for loss due to HCOH formation. Since the MOE was well above the Target MOE, further refinement is not necessary.

Table 4.6. Intermediate-term Post-application Dermal Exposures and MOEs for Children Contacting Treated Floors

Exposure Scenario	Application Rate (lb ai/sq ft)	Product remaining after mopping	Percent Trans. Residue	Body Area in contact with floor (m²)	Potential daily dose^a (mg/kg/day)	Dermal MOE^b (Target MOE = 1,000)
Hard surfaces - daycare center	1.33×10^{-5}	25%	10%	0.657	0.072	3,500 (IT)

a Potential Daily Dose (mg/kg/day) = [(Application rate, lb ai/ft²) x (conversion factor, 4.54 x 10⁵ mg/lb) x (conversion factor, 10.8 ft²/ m²) x (product remaining after mopping, 25%) x (dermal transfer factor, 10%) x (body surface area in contact with floor, 0.657 m²)] / (body weight, 15 kg)

b Dermal MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day) [Where IT dermal NOAEL = 250 mg/kg/day]. Target MOE = 1,000.

Child Incidental Ingestion Exposure to Treated Floors

Exposure Calculations

In addition to dermal exposure, toddlers crawling on treated hard floors will also be exposed to HHT residues via incidental oral exposure through hand-to-mouth activity. To calculate incidental ingestion exposure to these chemicals due to hand-to-mouth transfer, the methodologies established in the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* (USEPA 1997a and 2001) were used. These use assumptions that are similar to those used in calculating dermal exposures for toddlers crawling on treated hard floors. Exposures were calculated for children contacting treated floors in residential homes and in commercial day care centers using the following equations for hand-to-mouth transfer of pesticide residues to toddlers:

$$PDD = \frac{AR \times DTF \times DRF \times SA \times FQ \times SE \times ET \times SE \times CF1}{BW}$$

where:

PDD	=	Potential daily dose (mg/kg/day);
AR	=	Application Rate (lb ai/ft ²);
DTF	=	Dermal transfer factor (%);
DRF	=	Disinfectant remaining on floor (%);
SA	=	Surface area of the hands that contact both the treated area, and the individuals mouth (cm ² /event);
FQ	=	Frequency of hand-to-mouth events (events/hr);
SE	=	Saliva extraction efficiency (%);
ET	=	Exposure Time (hrs/day);
CF1	=	Conversion factor (4.54x10 ⁵ mg/lb);
CF2	=	Unit conversion factor (1.08x10 ⁻³ ft ² /cm ²)
BW	=	Body weight (kg)

Assumptions

- Toddlers (3 years old) were used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers (USEPA, 1997a and 2001).
- Based on HED's Residential SOP, it was assumed that the surface area used for each hand-to-mouth event is 20 cm². For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time was 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency was 50% (USEPA, 2000 and 2001).
- The labels did not provide information on the volume of disinfectant/cleaner to be used for cleaning surfaces such as floors. It was assumed that the treatment solution is applied at a rate of 1 gallon per 1,000 sq. ft. The maximum use rate on the EPA Label 68868-1 is 0.16%ai for application to hard surfaces (see Table

4.1a). Therefore, the application rates used in the post-application scenarios were $1.33\text{E-}05 \text{ lb ai/ft}^2$ ($1.33\text{E-}05 \text{ lb ai/ft}^2 = 1 \text{ gal/1000ft}^2 \times 0.16\% \text{ ai} \times 8.34 \text{ lb/gal}$; where 8.34 lb/gal is the density of water).

- No data could be found regarding the quantity of solution residue left on the floor after treatment. As a conservative measure, it was assumed that 25% of the cleaner remains after the final mopping.
- No transferable residue data were available that could be used to estimate the transfer of HHT from the floor to skin. Therefore, it was assumed that 10% of the deposition rate is available for dermal transfer (USEPA, 1997 and 2001).

Results

The calculation of the short- and intermediate-term oral doses and the oral MOEs are shown in Table 4.7. The oral MOEs are above the target MOE of 1000 (ST) or 100 (IT) for residential settings and institutional settings. It should be noted that the estimated HHT dose did not account for loss due to HCOH formation. Since the MOE was well above the Target MOE, further refinement is not necessary.

Table 4.7. Short- and Intermediate-term Incidental Oral Post-application Exposures and MOEs for Children Contacting Treated Floors									
Exposure Scenario	Appl. Rate (lb ai/ ft²)	Product remaining after mopping	Percent transfer	SA mouthed (cm²/event)	EF (events/hr)	SE (%)	Exp. Time (hrs/day)	Potential Daily Dose^a (mg/kg/day)	Oral MOE^b
									ST Target MOE = 1000 IT Target MOE=100
Hard surfaces - residential setting	1.33×10^{-5}	25%	10%	20	20	50%	4	8.72E-03	57,000 (ST)
Hard surfaces - daycare center	1.33×10^{-5}	25%	10%	20	9.5	50%	4	4.14E-03	12,000 (IT)

a Potential Daily Dose (mg/kg/day) = [(AR, lb ai/ft²)*(%Disinfectant remaining on floor, 25%)*(conversion factor, 4.54E+05 mg/lb)*(conversion factor, 1.08E-03 ft²/cm²) (% transfer, 10%)*(exposure time, 4 hrs/day)*(surface area of hands, 20 cm²/event)*(frequency of hand-to-mouth activity, 20 events/hr or 9.5 event/hr)*(extraction by saliva, 50%)]/(body weight, 15 kg)

b MOE = NOAEL (mg/kg/day) / potential daily dose(mg/kg/day) [Where ST NOAEL = 500 mg/kg/day and IT NOAEL = 50 mg/kg/day]. ST Target MOE = 1000 and IT Target MOE = 100.

4.4.2.2. Laundry Detergents

HHT labels include several household cleaning uses such as laundry detergents and softeners. Since no short-term dermal endpoint was identified, the laundry applicator scenarios were not necessary to assess. Post-application exposure to the laundry detergent use was selected to represent all post-application laundry cleaning scenarios (i.e., pre-soak, spot, softeners). To evaluate post-application dermal (IT) and incidental

oral (ST and IT) exposure to treated clothing via the laundry detergent use, the guidance provided in Human and Environmental Risk Assessment (HERA) Guidance Document (2003) was used for *indirect skin contact from wearing clothes* and *oral exposure from mouthing or sucking on treated fabric*. HERA (2003) provides the following basic equations.

Dermal Exposure

$$\text{Dermal Exposure (mg/kg/day)} = [F1 \times (M \times F' \times FD)/WI] \times S_{\text{der}} \times F2 \times F3/BW$$

where

F1	=	weight fraction of ai (EPA Reg 68868-1, 0.16% ai)
M	=	amount of product used (150g, HERA 2003)
F'	=	percentage of substance deposited on fabric (5%) (HERA 2003)
FD	=	fabric density for mixed cotton and synthetics (10 mg/cm ²) (HERA 2003),
WI	=	total weight of all fabric being laundered (1E+6 mg) (HERA 2003),
S _{der}	=	Surface area of the body which is in contact with clothing (child = 5670 cm ² /day and adult = 16,900 cm ² /day),
F2	=	weight fraction transferred from clothing to skin (100%),
F3	=	weight fraction remaining on skin (100%) (HERA 2003),
BW	=	Body weight (70 kg adult; 15 kg child)

Ingestion/Mouthing

$$\text{Oral Exposure (mg/kg/day)} = [F1 \times (M \times F' \times FD)/WI] \times F_m \times SE/BW$$

where

F1	=	weight fraction of ai (EPA Reg 68868-1, 0.16% ai)
M	=	amount of product used (150g, HERA 2003)
F'	=	percentage of substance deposited on fabric (5%) (HERA 2003)
FD	=	fabric density for mixed cotton and synthetics (10 mg/cm ²) (HERA 2003),
WI	=	total weight of fabric estimate (1E+6 mg) (HERA 2003),
F _m	=	fabric area mouthed (100 cm ² /day) (AD standard assumption),
SE	=	saliva extraction efficiency (50%) (HED Residential SOPs), and
BW	=	Body weight (15 kg)

Data on which these calculations could be based were generally unavailable; therefore, a number of conservative assumptions have been made:

- Toddlers (3 years old) are used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers. The median surface area for a 3 year old, minus the head, is 0.567 m². Median values for body weights and surface areas for adults have been used (70 kg and 1.69 m², not including head surface area).

- No leaching data were available that could be used to estimate a transfer rate of the chemical from clothing to skin. Therefore, a conservative assumption of 100% transfer was used.
- No dissipation data were available, therefore, the amount of HHT remaining on the skin is assumed to be 100 percent.

Results

The calculation of the intermediate-term dermal and short- and intermediate-term oral doses and MOEs are presented in Table 4.8. All of the MOEs are well above the Target MOEs and are not of concern. It should be noted that the estimated HHT doses did not account for loss due to HCOH formation. Since the MOEs were well above the Target MOEs, further refinement is not necessary.

Table 4.8 Short- and Intermediate-term Risks Associated with Post-application Exposure to Laundered Clothing			
Parameter	Toddler	Adult	Rationale
Body Weight	15 kg	70 kg	Median body weight
Surface area, minus head	5,670 cm ²	16,900 cm ²	Median surface area
Surface area of cloth mouthed	100 cm ²	NA	AD standard assumption
Concentration on clothing	0.00012 mg/cm ²		(150,000 mg product x 0.16% ai x 5% clothing deposition x 10 mg/cm ² cloth density)/1E+6 mg weight of fabric.
Dermal Dose	0.029 mg/kg/day	0.045 mg/kg/day	(concentration on clothing mg/cm ² x surface area cm ² /day x transfer efficiency 100% to skin) / Body Weight
Incidental Oral Ingestion Dose (mouthing)	4.0e-4 mg/kg/day	NA	(concentration on clothing mg/cm ² x surface area mouthed cm ² x saliva extraction 50%) / Body Weight
IT Dermal NOAEL	250 mg/kg/day		Dermal endpoint selected
ST Oral NOAEL	500 mg/kg/day		Oral endpoint selected
IT Oral NOAEL	50 mg/kg/day		Oral endpoint selected
IT Dermal MOE	8,600	5,500	(NOAEL) / (Dose) IT Target MOE = 1,000
ST Incidental Oral MOE (mouthing)	1,250,00	NA	(NOAEL) / (Dose) Short-term Target MOE = 1,000
IT Incidental Oral MOE (mouthing)	125,000	NA	(NOAEL) / (Dose) Inter-term Target MOE = 100

4.4.2.3. Paint

Due to the low vapor pressure of HHT, no significant post-application HHT exposures are expected to occur from the painting scenario. However, AD utilized WPEM to estimate HCOH air concentrations resulting from the use of paint preserved with HHT. For this exposure assessment, the RESADULT WPEM default scenario was used to evaluate HCOH exposure to occupants of a newly painted home/room. In this scenario, occupants are located in a non-painted part of the house while a bedroom is

being painted by a professional painter. For a detailed description of the RESADULT scenario, see the WPEM User's Guide. The following chemical-specific inputs were used in the model:

- HCOH's molecular weight (30 amu) and vapor pressure (1 mm Hg)
- The weight fraction of HCOH in paint (EPA Reg. 68868-1 contains 0.24% HHT which is equivalent to 0.03% - 0.1% HCOH by weight - see section 4.1 for details on the conversion of HHT to HCOH)

The model provides several dose measures (i.e., LADD, ADD), air concentration measures (i.e., peak, 15-min, 8hr), and a comma-separated (.csv) file as outputs. The comma-separated file contains details on time-varying concentrations within the modeled building as well as concentrations to which the individual is exposed. This file can be read directly into spreadsheet software (e.g., Excel) for calculating additional summary statistics. The air concentrations calculated by the model were used by AD to estimate inhalation exposures, MOEs, and cancer risks. The peak air concentration was used to estimate non-cancer risks (MOEs) while a LADC was used to estimate cancer risks. It should be noted that the WPEM model moves the occupant throughout the home (i.e., zone 1 = painted room, zone 2 = non-painted room, and outdoors) based on predefined activity schedules.

Since the actual amount of HCOH formation in the paint is not well documented, the inhalation exposures and risks were estimated assuming 100% HCOH formation and 30% HCOH formation. The 30% formation is the minimum amount of HCOH formation however, the HCOH formation could be even higher depending on the length of storage (see section 4.1). The model results and risk calculations are summarized in Table 4.9a and 4.9b for non-cancer and cancer, respectively

At 100% HCOH formation post-application inhalation (vapor) MOE is 0.4 and at 30% HCOH formation the MOE is 1.2 for the occupant of freshly painted homes/rooms. Since the target MOE is 10 both exposure scenarios are of concern. A study is needed to ascertain the actual amount of HCOH formation in the paint in order to estimate a more accurate exposure value.

Table 4.9a. Post-Application Inhalation (vapor) Exposures and MOEs for Residential Occupants of Painted Homes			
HCOH Formation	Peak Air Conc. (mg/m³)^a	Peak Air Conc. (ppm)^b	Inhal. MOE^c Target MOE = 10
100%	0.35	0.28	0.4
30%	0.104	0.085	1.2

^a The peak air concentration

^b HCOH air conc 0.24 ppm = HCOH air conc 0.30 mg/m³ x 24.45 / HCOH MW (30 g/mol)

^c Inhalation MOE = Inhalation NOAEL (0.1 ppm based on 15-min exposure) / Peak Air Conc. where Target MOE = 10

For the cancer exposure calculations, all of WPEMs default assumptions were used except for the following which were changed to standard AD assumptions:

- ED = Exposure Duration: 35 years

To assess cancer risks the lifetime average daily air concentration ($\mu\text{g}/\text{m}^3$) is multiplied times the unit risk of $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$. Cancer risks that are less than 1.0×10^{-6} are generally not of concern for residential populations. Cancer risks were calculated using the following equation:

$$\text{Cancer Risk} = \text{LADC } (\mu\text{g}/\text{m}^3) \times \text{Unit Risk } (\mu\text{g}/\text{m}^3)^{-1}$$

Cancer risks were also estimated using the CIIT modeling presented in Table 8A (hockey stick-shaped; nonsmoking) of Conolly 2004.

Table 4.9b. Inhalation (vapor) Exposure and Cancer Risks for Residential Occupants of Painted Homes				
HCOH Formation	Days Exposed per Year	Years Exposed per Lifetime	Life Time Average Daily Concentration ^a	Cancer Risk ^{b,c}
IRIS				
100%	4	35	4.6 ($\mu\text{g}/\text{m}^3$)	6.0×10^{-5}
30%	4	35	1.38 ($\mu\text{g}/\text{m}^3$)	1.8×10^{-5}
CIIT				
100%	4	35	0.0013 ppm	$<2.94 \times 10^{-9}$
30%	4	35	0.0004 ppm	$<2.94 \times 10^{-9}$

^a LADC from WPEM output

^b IRIS Cancer Risk = LADC ($\mu\text{g}/\text{m}^3$) x Unit Risk $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$

^c CIIT Cancer Risks are presented in Table 8A (hockey stick-shaped CRCP; nonsmoking) of Conolly et al., 2004

At 100% and 30% HCOH formation, the cancer risks using the IRIS unit risk are 2.1×10^{-6} and 6.4×10^{-6} which exceed the Agency's level of concern of 1.0×10^{-6} . However, at 100% or 30% HCOH formation, the cancer risks using the CIIT modeling are $<2.94 \times 10^{-9}$ none of which exceed the Agency's level of concern of 1.0×10^{-6} . It should be noted that it was conservatively assumed that every painting event utilized HHT treated paint. If specific HHT treated paint use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

4.4.3 Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the residential handler and post-application exposure assessments which include the following:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix A for summaries of these data sources). Most of the CMA data are of poor quality therefore, AD requests that confirmatory monitoring data be generated to support the values used in these assessments.

- The quantities handled were estimated based on information from various sources, including HED’s Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 1997 and 2001) and standard AD assumptions. In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios could be further refined from input from registrants.
- The Wall Paint Exposure Model is designed to estimate indoor-air concentrations and associated inhalation exposures for interior applications involving alkyd or latex primer/paint. The chamber tests on which the emission algorithms are based involve a limited set of chemicals with a correspondingly limited range of properties (molecular weight and vapor pressure). Further, the emission algorithms are valid only for chemicals that are formulated into alkyd/latex primers or paints. Actual HCOH monitoring data or a chamber study could be used to refine the exposures and risks estimated in this assessment.
 - Without actual monitoring data from painting activities, AD estimated HCOH formation based on assumptions and the results of the hydrolysis study. However, a study is needed to ascertain the actual amount of HCOH formation in the paint in order to estimate a more accurate exposure value.
- Without actual air monitoring data from cleaning and laundering activities, AD assumed 100% HCOH formation from HHT. However, a study is needed to ascertain the actual amount of HCOH formation in the cleaners and detergents in order to estimate more accurate exposure values.
- For each cancer assessment, it was conservatively assumed that every event utilized HHT treated products. If specific HHT treated product use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

5.0 RESIDENTIAL AGGREGATE RISK ASSESSMENT AND CHARACTERIZATION

5.1 Acute and Chronic Dietary Aggregate Risk

Acute and chronic dietary aggregate risks are discussed in the risk assessment document for HHT.

5.2 Short and Intermediate Term Aggregate Risk

In order for a pesticide registration to continue, it must be shown “that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.” Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). However, this assessment only addresses non-dietary residential aggregate exposures and risks. The PRA of the RED will address

the complete aggregate assessment including both dietary and non-dietary residential exposures and risks.

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>). Steps for deciding whether to perform aggregate exposure and risk assessments are listed, which include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk

Short- and Intermediate-Term Aggregate Exposures and Risks

Short- and intermediate-term aggregate exposures and risks were assessed for adults and children that could be exposed to HHT residues from the use of products in non-occupational environments. The following lists summarize all of the non-dietary, non-occupation potential sources of HHT exposures for adults and children:

Adult HHT exposures sources:

- Cleaning indoor hard surfaces via mopping, wiping, or spraying
- Wearing clothing laundered with treated detergents
- Applying HHT preserved paint

Child HHT exposures sources:

- Post-application exposures to residues from cleaning products used on hard surfaces (i.e., floors)
- Wearing clothing laundered with treated detergents

The use patterns of the products and probability of co-occurrence must be considered when selecting scenarios for incorporation in the aggregate assessment. In the case of HHT, homeowner painting activities occur intermittently. Therefore the probability of co-occurrence and the potential for exposure to residues from painting as well as exposure to other HHT products on the same day is highly unlikely. However, it is likely that someone could clean the kitchen via mopping, wiping and spraying applications using a cleaning product containing HHT during the same day.

Cleaning activities in a residential setting occur on a short-term basis. However, the HHT-containing cleaning products are can also be used in institutional settings such as day care facilities where cleaning activities can occur on an routine or intermediate-

term basis. Therefore, children could have exposure to cleaning product residues on a more continuous basis in a day care facility thus, these post-application scenarios were included in the intermediate-term aggregate assessment. Table 5.1 summarizes the scenarios included in the short- and intermediate-term aggregate assessments. It should be noted that based on the use patterns and probability of co-occurrence, an aggregate assessment was not necessary to conduct for HCOH residues resulting from the use of HHT treated products.

Table 5.1: Summary of Exposure Scenarios Included in the HHT Short- and Intermediate-Term Aggregate Assessments		
	Short-term Aggregate	Intermediate-Term Aggregate
Adults	Inhalation: <ul style="list-style-type: none"> • Mopping applicator • Wiping applicator • Trigger pump applicator 	Dermal or Oral or Inhalation: <ul style="list-style-type: none"> • No applicable exposures
Children	Oral: <ul style="list-style-type: none"> • Post-app exposure to floor cleaner residues • Post-app exposure to laundry detergent residues 	Oral: <ul style="list-style-type: none"> • Post-app exposure to floor cleaner residues • Post-app exposure to laundry detergent residues
		Dermal: <ul style="list-style-type: none"> • Post-app exposure to floor cleaner residues • Post-app exposure to laundry detergent residues

Since the oral and dermal endpoints were based on route specific studies and different effects, the dermal and oral exposures were aggregated in separate analyses. The Total MOE method outlined in OPP guidance for aggregate risk assessment (September 1, 2000, Standard Operating Procedure (SOP) for Incorporating Screening Level Estimates of Drinking Water Exposure into Aggregate Risk Assessments) was utilized in the assessment. This method was used because the assessment was route specific where each scenario has the same uncertainty factors or target MOEs. The target MOE for ST oral exposure is 1,000, while the target MOE of ST inhalation and IT oral and IT dermal exposure is 100. The general equation used to estimate total or aggregate MOEs is:

$$\text{Aggregate MOE} = 1 / ((1/\text{MOE}_{\text{route 1, scenario 1}}) + (1/\text{MOE}_{\text{route 1, scenario 2}}) + (1/\text{MOE}_{\text{route 1, scenario n}}))$$

Where, route represents oral, dermal, or inhalation exposures, and scenario represents handler or post-app wiping, mopping, etc.

Tables 5.2 and 5.3 present the HHT adult and children aggregate assessments, respectively. All of the short- and intermediate-term aggregate MOEs for residential scenarios were above the target MOEs of 100 or 1000 and therefore not a concern.

Furthermore, since the adult inhalation Total MOE is greater than 1,000, an inhalation specific toxicity study is not warranted to support the uses included in this scenario.

Table 5.2 ST Aggregate MOEs for Adult Residential Handlers of HHT Products				
	Mopping MOE	Wiping MOE	Spraying MOE	Total MOE ^a (Target MOE = 100)
ST inhalation	110,000	30,000	840,000	23,000

a Total MOE = 1/((1/MOE_{mop}) + (1/MOE_{wipe}) + (1/MOE_{spray}))

Table 5.3 ST and IT Aggregate MOEs for Children Exposed to Residues of HHT Products				
	Floor Cleaner MOE	Laundry Detergent MOE	Total MOE ^a	Target MOE
ST oral	57,000	1,250,000	55,000	1,000
IT oral	12,000	125,000	11,000	100
IT dermal	3,500	5,500	2,100	1,000

a Total MOE = 1/((1/MOE_{floor cleaner}) + (1/MOE_{laundry detergent}))

6.0 OCCUPATIONAL EXPOSURE ASSESSMENT

Potential HHT occupational handler exposure can occur in various use sites, which include: commercial/institutional/industrial premises and medical premises, metal working facilities and oil fields. Additionally, HHT occupational exposure can occur during the preservation of materials such as household and commercial cleaners, paints/coatings, construction compounds, and metal working fluids. The “preservation of materials” refers to the scenario of a worker adding the preservative to the material being treated (metalworking fluid, paint, etc.) through either liquid pour or liquid pump methods. Liquid pour refers to transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow.

As previously discussed, HHT hydrolyzes to form HCOH. Therefore, exposure to HCOH can also occur as a result of using or handling HHT treated products such a paint and metal working fluids. Thus, it was necessary to evaluate HCOH exposures resulting from the use of HHT treated products.

The HHT and HCOH occupational exposure scenarios assessed in this document for the representative uses selected by AD are shown in Table 6.1a and Table 6.1b, respectively. The tables also show the maximum application rate associated with the

representative use along with the corresponding EPA Registration number for the product label. For HHT handlers, the representative uses assessed include cleaning indoor hard surfaces, addition of the materials preservative to paints and metal working fluid as well as, the use of the bacteriostat in the oil field uses. Additionally, HHT handler exposures were assessed for the application of treated paint (paint brush/roller and airless sprayer). For HCOH occupational exposures, the representative uses assessed include the use of treated paint and metal working fluids.

Table 6.1a. Representative Uses Associated with HHT Occupational Exposure				
Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Material Preservatives (Use Site Category VII)				
Paints ¹	Handler: ST inhalation (aerosol); IT dermal and inhalation (aerosol)	<u>Preservation of paint</u> <ul style="list-style-type: none"> • Liquid pour • Liquid pump 	68868-1	0.24% a.i. by weight (78.5% a.i. x 0.3% product by weight of material)
	Painter: ST inhalation (aerosol)	<u>Professional painter</u> <ul style="list-style-type: none"> • Brush/Roller • Airless sprayer 		
Commercial/ household cleaners	Handler: ST inhalation (aerosol); IT dermal and inhalation (aerosol)	<ul style="list-style-type: none"> • mop • wipe • trigger pump/aerosol 	68868-1	0.16% a.i. by weight (78.5% a.i. x 0.2% product by weight of material)
Metal working fluids	Handler: ST inhalation (aerosol); IT dermal and inhalation (aerosol)	<u>Preservation of fluid</u> <ul style="list-style-type: none"> • Liquid pour • Liquid pump 	1839-99	0.16% a.i. by weight (78.5% a.i. x 0.2% product by weight of material)
	Machinist: IT/LT dermal and ST/IT/LT inhalation (aerosol)	<u>Professional machinist</u>		
Industrial Processes and Water Systems (Use Site Category VIII)				
Oil field	Handler: ST inhalation (aerosol); IT dermal and inhalation (aerosol)	<ul style="list-style-type: none"> • Liquid pour • Liquid pump 	1839-99	0.16% a.i. by weight (78.5% a.i. x 0.2% product by weight of material)

¹ The paint preservation scenario also represents preservation of other materials such as cleaners, adhesives, slurries, construction compounds, etc.

Table 6.1b. Representative Uses Associated with HCOH Occupational Exposure				
Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated paints	Handler and Bystander ¹ : ST inhalation (vapor) and cancer	NA	68868-1	0.03% - 0.1% a.i. by weight ²
Using treated metal working fluids	Handler: ST inhalation (vapor) and cancer	NA	1839-99	0.07% a.i. by weight ²

1 The bystander scenario in a paint manufacturing facility also represents all occupational bystander scenarios in a general industrial facility.

2 The method for estimating HCOH application rates is presented in section 4.1

It should be noted that although HHT is used in oil field applications, HCOH exposures resulting from these activities were not quantitatively evaluated because the activities occur outdoors where inhalation exposures are expected to be minimal.

6.1 Occupational Handler Exposures

The occupational HHT handler scenarios included in Table 6.1a were assessed to determine dermal and inhalation exposures. The general assumptions and equations that were used to calculate occupational handler risks are provided in Section 1.2, Criteria for Conducting the Risk Assessment. The majority of the scenarios were assessed using CMA and PHED data and Equations 1-3.

Unit Exposure Values (UE): Dermal unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999) or from the Pesticide Handler Exposure Database (USEPA, 1998).

- For the **mopping** scenarios, the CMA dermal and inhalation unit exposure values for ungloved mopping were used (71.6 mg/lb a.i. and 2.38 mg/lb a.i., respectively). These values are based on data collected from six replicates in which the applicator mopped the floor and received exposure via contact with the mop or with the bucket.
- For the **wiping** scenarios, the CMA dermal and inhalation unit exposure values for ungloved wiping were used (2,870 mg/lb a.i. and 67.3 mg/lb a.i., respectively). These values are based on data collected from six replicates (dental technicians) who used a finger pump sprayer to apply the product and then wiped the surfaces with a paper towel
- For the **aerosol sprays and trigger pump spray** scenarios, the PHED dermal and inhalation unit exposure values for aerosol applications (PHED scenario 10) were used. The dermal unit exposures (single layer of clothing) are 190 mg/lb a.i. for ungloved replicates. The inhalation unit exposure is 1.3 mg/lb a.i.
- For the **liquid pour** scenarios for materials preservatives, the unit exposure depends on the material being treated. The following CMA unit exposures were available

and used for the assessment of the risk associated with the treatment of the specified materials.

- *Metalworking fluid*: CMA metal fluid gloved data. The dermal UE is 0.184 mg/lb ai and the inhalation UE is 0.00854 mg/lb ai. The values are based on 8 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves.
- *Paint and Oil field uses*: CMA preservative gloved data. The dermal UE is 0.135 mg/lb ai and the inhalation UE is 0.00346 mg/lb ai. The values are based on 2 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves.
- For the **liquid pump** scenarios, the unit exposure depends on the material being treated. The following CMA unit exposures were available and used for the assessment of the risk associated with the treatment of the specified materials.
 - *Metalworking fluid*: CMA metal fluid gloved data. The dermal UE is 0.312 mg/lb a.i. and the inhalation UE is 0.00348 mg/lb a.i. The values are based on 2 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves.
 - *Paint*: CMA preservative gloved data. The dermal UE is 0.00629 mg/lb a.i. and the inhalation UE is 0.000403 mg/lb a.i. for inhalation. The values are based on two replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves.
 - *Oil field uses*: CMA dermal UE of 0.00454 mg/lb ai and inhalation UE of 0.000265 mg/lb ai from the pulp and paper preservative loading study were used. These were based on 7 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. It should be noted that the UE from the pulp and paper study were selected for this scenario rather than the materials preservative study because the pulp and paper scenario is more representative of large scale systems such as those in oilfields.
- For **roller/brush** scenarios, the occupational PHED dermal and inhalation unit exposure values for paintbrush applications (PHED scenario 22) were used (single layer of clothing). The inhalation exposure value is 0.28 mg/lb a.i. The dermal unit exposures are 180 mg/lb a.i. for ungloved replicates.
- For **airless sprayer** scenarios, the occupational PHED dermal and inhalation unit exposure values for airless sprayer application (PHED scenario 23) were used (single layer of clothing). The inhalation exposure value is 0.83 mg/lb a.i. The dermal unit exposures are 38 mg/lb a.i. for ungloved replicates.

Quantity handled/treated: The quantity handled/treated values were estimated based on information from various sources. The following assumptions were made:

- For the **mopping** scenario, it was assumed that 2 gallons of solution (16.7 lbs = 2 gal x 8.34 lb/gal where 8.34 = water density) are used in the food handling and commercial/institutional/industrial setting and 45 gallons (375 lbs = 45 gal x 8.34 lb/gal where 8.34 = water density) are used in the medical setting where a janitor cleans approximately 28 rooms a day and must change the cleaning water every three rooms (Helwig, 2003)

- For the *wiping* and *trigger pump spray* scenarios, it was assumed that 0.26 gallons (2.2 lbs = 0.26 gal x 8.34 lb/gal where 8.34 = water density) were used for cleaning of hard surfaces (Standard AD assumption).
- For the *liquid pour* scenarios, the quantity of the chemical that is handled depends on the material that is being treated. The following values were used for the different materials:
 - *Metalworking fluid*: 2,500 lbs (approximately 300 gallons, and the density of the fluid is assumed to be that of water, 8.34 lb a.i./gal) (Standard AD assumption)
 - *Paint*: The daily amount of coatings treated that was used in this assessment was based on information provided by Carl Watson of Buckman Laboratories (personal communication on 7/8/04). The volume of coatings treated can greatly range depending of the manufacturers' size and sophistication. The high-volume manufacturer could produce two 10,000 gallon batches in an 8-hour day where the liquid materials such as the biocide would be automatically pumped into the batch. Therefore, a high-volume manufacturer could produce approximately 20,000 gallons of preserved product (i.e., protective colloids, emulsion resins, water-thinned paints, etc.) in one day. The lower-volume manufacturer could make four 500 gallon batches in an 8-hour day where the liquid materials such as the biocide could be hand metered in or put in via 5 gallon buckets. Therefore, a lower-volume manufacturer could produce approximately 2,000 gallons (20,000 lbs = 2,000 gal x 10 lb/gal where 10 lb/gal = paint density) of product (i.e., paints, coatings, emulsions, etc.) in one day. Based on this information it was assumed that 2,000 gallons of coating was preserved using open loading techniques while 20,000 gallons of coating was preserved using metering pump techniques.
- For the *liquid pump* scenarios the quantity that is handled depends on the material that is being treated. The following values were used for the different materials:
 - *Metalworking fluid*: 2,500 lbs (approximately 300 gallons, weight and the density of the fluid is assumed to be that of water, 8.34 lb ai/gal) (Standard AD assumption)
 - *Paint*: 20,000 gallons (200,000 lbs = 20,000 gal x 10 lb/gal where 10 lb/gal = paint density) of coating was preserved using metering pump techniques (see paint discussion above)
 - *Oil field uses*: The following use information provided by Carl Watson of Buckman Labs via personal communication (7/14/04 and 10/29/04) was used to estimate the amount of product handled per day during oil-well activities. Biocide is typically added directly to drilling rig mud tanks via open pouring. Over a 3 to 6 week period, while a 13,000 ft well is being drilled, 1 to 2 drums (1 drum = 42 gallons) of biocide may be used if microbiological problems are encountered. Therefore, the short-term exposure assessment used 5.6 gallons for the amount of biocide handled per day by the drilling rig worker [i.e., (2 drums x 42 gal/drum) / (5 days/week x 3 weeks) = 5.6 gal/day] (47 lbs = 5.6 gal x 8.34 lb/gal where 8.34 lb/gal = water density). The intermediate-term exposure assessment used 2.8 gallons for the amount of biocide handled per day by the drilling rig worker [i.e., (2 drums x 42 gal/drum) / (5 days/week x 6

weeks) = 2.8 gal/day] (23 lbs = 2.8 gal x 8.34 lb/gal where 8.34 lb/gal = water density). For the secondary recovery application, the biocide is meter pumped into the produced water before it is reinjected into the formation or well. In large operations produced water volume can exceed 10,000 barrels/day (1 barrel = 42 gallons); therefore 420,000 gallons of water (3,500,000 lbs = 420,000 gal x 8.34 lb/gal where 8.34 lb/gal = water density) can be treated in secondary recovery operations.

- For the *roller/brush* painting scenario, it was assumed that 50 lbs (approximately 5 gallons of paint with a density of 10 lb/gal) of treated paint are used (USEPA 1997 and 2001)
- For the *airless sprayer* in the *painting* scenario, it was assumed that 500 lbs (approximately 50 gallons of paint with a density of 10 lb/gal) of treated paint are used. (USEPA 1997 and 2001).

Duration of Exposure: The MOEs were calculated for the short- and intermediate-term durations for occupational handlers. The intermediate-term duration was not evaluated for painters because it was assumed that not all paint used by a professional painter is treated with HHT. Therefore HHT exposures from treated paint would occur on an intermittent basis.

Results: The calculated dermal and inhalation MOEs are shown in Table 6.2. All MOEs in the occupational setting were above the target MOEs for dermal and inhalation exposures except for the following scenarios:

- IT dermal MOE for mopping in medical facilities = 400 (Target MOE = 1,000)
- IT dermal MOE for metering pump in secondary recovery activities = 690 (Target MOE = 1,000)

It should be noted that although the target inhalation MOE is 100, if the MOE is below 1,000 the Agency may request a confirmatory inhalation toxicity study because the current inhalation endpoint is based on an oral NOAEL. All of the occupational inhalation MOEs were above 1,000, therefore the inhalation study is not warranted to support these uses.

Table 6.2 Short-and Intermediate-Term Risks and MOE for HHT Occupational Handlers

Exposure Scenario	Application Method	Dermal Unit Exposure (mg/lb ai)	Inhal. Unit Exposure (mg/lb ai)	Amount treated/handled (lbs/day)	Use Rate (%ai)	Dermal Daily Dose (mg/kg/day) ^a	Inhalation Daily Dose (mg/kg/day) ^a	ST MOEs ^b		IT MOEs ^b	
								Target MOE = 100		Dermal Target MOE = 1,000	Inhalation Target MOE = 100
								Dermal	Inhalation		
Materials Preservative											
Metal working fluids	Open pour - liquid	0.184	0.00854	2,500	0.16%	1.1E-02	4.9E-04	NA	100,000	24,000	100,000
	Metering Pump	0.312	0.00348	2,500	0.16%	1.8E-02	3.2E-07	NA	160,000,000	14,000	160,000,000
Cleaners	Mop	71.6	2.38	16.7	0.16%	2.7E-02	1.5E-06	NA	34,000,000	9,200	34,000,000
	Mop-medical	71.6	2.38	375	0.16%	6.1E-01	3.3E-05	NA	1,500,000	400	1,500,000
	Wipe	2870	67.3	2.2	0.16%	1.4E-01	5.3E-06	NA	9,400,000	1,800	9,400,000
	Trigger pump	190	1.3	2.2	0.16%	9.4E-03	1.0E-07	NA	490,000,000	27,000	490,000,000
Paint	Open pour - liquid	0.135	0.00346	20,000	0.24%	9.3E-02	5.7E-06	NA	8,800,000	2,700	8,800,000
	Metering Pump	0.00629	0.000403	200,000	0.24%	4.3E-02	6.6E-06	NA	7,500,000	5,800	7,500,000
	Airless Sprayer	38	0.83	500	0.24%	6.5E-01	3.4E-05	NA	1,500,000	NA	NA
	Brush/roller	180	0.28	50	0.24%	3.1E-01	1.2E-06	NA	43,000,000	NA	NA
Oil Field Uses											
Water-based drilling fluids (ST)	Open pour - liquid	0.135	0.00346	47	0.16%	NA	3.7E-06	NA	14,000,000	--	--
Water-based drilling fluids (IT)	Open pour - liquid	0.135	0.00346	23	0.16%	7.2E-05	1.8E-06	NA	--	3,500,000	27,000,000
Secondary recovery	Metering Pump	0.00454	0.000265	3,500,000	0.16%	3.6E-01	2.12E-02	NA	2,400	690	2,400

a Daily dose (mg/kg/day) = Unit Exposure (mg/lb ai) x Amt treated/handled (lb/day) x Use rate (%ai) / Body weight (70 kg).

b MOE = NOAEL (mg/kg/day) / Daily Dose [Where ST/IT Inhal NOAEL = 50 mg/kg/day; IT dermal NOAEL = 50 mg/kg/day]

6.2 Machinist Exposures

6.2.1 HHT Machinist Exposures

There is a potential for dermal and inhalation exposure when a worker handles treated HHT metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-product.

Dermal Exposures

Exposure Calculations

An intermediate- and long-term exposure estimate was derived using the 2-hand immersion model from ChemSTEER. The model is available at www.epa.gov/opptintr/exposure/docs/chemsteer.htm. The 2-hand immersion equation is as follows:

$$\text{PDR} = \frac{\text{SA} \times \% \text{ ai} \times \text{FT} \times \text{FQ}}{\text{BW}}$$

where:

PDR	=	Potential dose rate (mg/kg/day);
SA	=	Surface area of both hands and forearms (cm ²);
% ai	=	Fraction active ingredient in treated metalworking fluid (unitless)
FT	=	Film thickness of metal fluid on hands (mg/cm ²)
FQ	=	Frequency of events (event/day);
BW	=	Body weight (kg)

Assumptions

- The surface of area of both hands and forearms is 2013 cm² (US EPA 1997b)
- The body weight of an adult is 70 kg (US EPA 1997b)
- The HHT percent active ingredient of 0.16% was selected from EPA Registration No. 1839-99
- For intermediate- and long-term durations, the film thickness on the hands is 1.75 mg/cm², which was extracted from the document titled, “*A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands*” (Cinalli, 1992). The film thickness is based on a machinist immersing both hands in metalworking fluid and then partially cleaning hands with a rag. The film thickness was chosen because the dermal endpoint for the intermediate- and long-term durations is based on systemic effects.

Results

Table 6.3 shows the calculation of the dermal dose and MOE for a machinist working with HHT treated metal working fluids. The MOE value is above the target MOE of 1,000 for intermediate- and long-term exposures (MOE = 3,100).

Table 6.3. Intermediate- and Long-Term Dermal Exposure and MOE for Machinist's Exposure to Metalworking Fluids Treated With HHT						
Exposure Scenario	% ai	Skin Surface Area (cm ²)	Film thickness (mg/cm ²)	Frequency (event/day)	Daily Dose ^a (mg/kg/day)	Dermal MOE (Target MOE = 1,000) ^b
					IT/LT	IT/LT
Machinist - immersion	0.16%	2013	1.75	1	0.081	3,100

- a Daily Dose (mg/kg/day) = (% ai x skin surface area (cm²) x film thickness (mg/cm²) x Frequency (event/day)] / Body weight (70 kg).
- b MOE = NOAEL (mg/kg/day) / Daily Dose (mg/kg/day) [Where: IT/LT dermal NOAEL = 250 mg/kg/day].

Inhalation Exposures

A screening-level short-, intermediate- and long term inhalation exposure estimate for treated metalworking fluids has been developed using the OSHA PEL for oil mist. The equation used for calculating the inhalation dose is:

$$\text{PDR} = \frac{\text{PEL} \times \text{IR} \times \% \text{ ai} \times \text{ED}}{\text{BW}}$$

where:

- PDR = Potential dose rate (mg/kg/day);
- PEL = OSHA PEL (mg/m³);
- IR = Inhalation rate (m³/hr)
- % ai = Fraction active ingredient in treated metalworking fluid (unitless)
- ED = Exposure duration (hrs/day);
- BW = Body weight (kg)

Assumptions

- The high-end oil mist concentration is based on OSHA's Permissible Exposure Limit (PEL) of 5 mg/m³ (NIOSH, 1998).
- The percent active ingredient was selected from the label that provides an application rate for the non-concentrate fluid (EPA Registration No. 1839-99).
- The inhalation rate for a machinist is 1.25 m³/hr.
- A machinist is exposed to the metalworking fluid 8 hours a day, for 5 days a week.
- The body weight of an adult is 70 kg.

Results

Table 6.4 shows the calculation of the inhalation dose and MOE for a machinist working with HHT treated metalworking fluids. The inhalation MOE values for ST/IT/LT exposures to HHT are above the target MOE of 100 (ST/IT/LT MOE = 44,000). Furthermore, this MOE is also above 1,000 therefore a confirmatory inhalation toxicity study is **not** warranted based on the results of this scenario.

Table 6.6. Short-,Intermediate- and Long Term Inhalation Exposure and MOE for Machinist's Exposure to Metalworking Fluids Treated With HHT						
Exposure Scenario	% a.i.	OSHA PEL (mg/m³)	Inhalation rate (m³/hr)	Exposure Duration (hrs/day)	Daily Dose^a (mg/kg/day)	Inhalation MOE (Target MOE = 100)^b
					ST/IT/LT	ST/IT/LT
Machinist	0.16%	5	1.25	8	0.00114	44,000

a Daily dose (mg/kg/day) = % active ingredient x OSHA PEL (mg/m³) x Inhalation rate (m³/hr) x exposure duration (hr/day) / body weight (70 kg)

b MOE = NOAEL (mg/kg/day) / daily dose (mg/kg/day) [Where: ST/IT/LT inhalation NOAEL = 50 mg/kg/day].

6.2.2 HCOH Machinist Exposures

Since HHT hydrolyzes to form HCOH, it was necessary to evaluate HCOH exposures resulting from the use of HHT treated metal working fluids. The inhalation exposure (vapor) is the primary route of exposure of HCOH from metal working fluids due to its high vapor pressure (1 mm Hg). The registrants of the metal working fluid uses have submitted a published article providing information on the worker/machinist HCOH exposures in metal working facilities that use HHT preserved fluids. Currently, this is the only study available to use for this assessment. However, AD can not consider using this data until the ethics review for the use of human subjects for this specific study has been completed.

6.3 Professional Painter Inhalation Exposures

As previously discussed, HHT hydrolyzes to form HCOH. Therefore, exposure to HCOH can also occur as a result of using or handling HHT treated products such a paint. Thus, it was necessary to evaluate HCOH exposures resulting from the use of HHT treated products. Since HCOH has such a high vapor pressure (1 mm Hg), the vapor inhalation exposure is the primary route of exposure. Inhalation exposure to the vapor is considered to be representative of exposure to the aerosol paint as well as vapor.

Section 6.1 presents the exposures and risks associated with the application of HHT preservative to the paint as well as the actual painting activities. In this section, the professional painter inhalation exposure to HCOH vapors during paint activities was assessed. AD utilized WPEM to estimate HCOH air concentrations resulting from the

use of paint preserved with HHT. For this professional painter exposure assessment, the WPEM default scenario for the residential professional painter (RESPROF) was used. This WPEM default scenario assumes that two professional painters are exposed to a chemical in paint while painting an entire apartment per working day which is approximately 9 hours. For a detailed description of the default RESPROF scenario, see the WPEM User’s Guide. The following chemical-specific inputs were used in the model:

- HCOH’s molecular weight (30 amu) and vapor pressure (1 mm Hg)
- The weight fraction of HCOH in paint (EPA Reg. 68868-1 contains 0.24% HHT which is equivalent to 0.03% - 0.1% HCOH by weight - see section 4.1 for details on the conversion of HHT to HCOH)

The model provides several dose measures (i.e., LADD, ADD), air concentration measures (i.e., peak, 15-min, 8hr), and a comma-separated (.csv) file as outputs. The comma-separated file contains details on time-varying concentrations within the modeled building as well as concentrations to which the individual is exposed. This file can be read directly into spreadsheet software (e.g., Excel) for calculating additional summary statistics. The air concentrations calculated by the model were used by AD to estimate inhalation exposures, MOEs, and cancer risks. The peak air concentration was used to estimate non-cancer risks (MOEs) while a 9-hr time weighted average (TWA) was used to estimate cancer risks (see Appendix A).

Since the actual amount of HCOH formation in the paint is not well documented, the inhalation exposures and risks were estimated assuming 100% HCOH formation and 30% HCOH formation. The 30% formation is the minimum amount of HCOH formation however, the HCOH formation could be even higher depending on the length of storage (see section 4.1). The model results and risk calculations are summarized in Table 6.7a and 6.7b for non-cancer and cancer, respectively

At 100% HCOH formation professional painter inhalation (vapor) MOE is 0.05 and at 30% HCOH formation the MOE is 0.18. Since the target MOE is 1, both exposure scenarios are of concern. A study is needed to ascertain the actual amount of HCOH formation in the paint in order to estimate a more accurate exposure value.

Table 6.7a. Inhalation (vapor) Exposures and MOEs for Professional Painters			
HCOH Formation	Peak Air Conc. (mg/m³)^a	Peak Air Conc. (ppm)^b	Inhal. MOE^c Target MOE = 1
100%	2.28	1.85	0.05
30%	0.68	0.56	0.18

^a The peak air concentration during 9-hr work day

^b HCOH air conc 1.85 ppm = HCOH air conc 2.28 mg/m³ x 24.45 / HCOH MW (30 g/mol)

^c Inhalation MOE = Inhalation NOAEL (0.1 ppm based on 15-min exposure) / Peak Air Conc. where Target MOE = 1

For the cancer exposure calculations, standard AD assumptions for exposure frequency (the number of days per year painting activities occur), exposure time, exposure duration, and lifespan were used to estimate exposure because the cancer unit risk was based on a continuous inhalation exposure. The following equation was used to estimate cancer exposures:

$$\text{LADC} = \text{ADC} \times \frac{\text{ET} \times \text{EF} \times \text{ED}}{365 \text{ days/year} \times \text{Lifetime}}$$

where:

- LADC = Lifetime average daily concentration ($\mu\text{g}/\text{m}^3$)
- ADC = Average daily concentration ($\mu\text{g}/\text{m}^3$) from WPEM model (Appendix A)
- ET = Exposure time (9hr/day painting based on WPEM assumption; where 9hr/24 hr is used in the equation)
- EF = Exposure Frequency (number of working days per year): 240 days/year
- ED = Exposure Duration: 35 years
- Lifetime = average lifetime expectancy: 70 years

To assess cancer risks the lifetime average daily air concentration ($\mu\text{g}/\text{m}^3$) is multiplied times the unit risk of $(1.3 \times 10^{-5} \mu\text{g}/\text{m}^3)^{-1}$. Cancer risks that are less than 1.0×10^{-4} are generally not of concern for occupational populations. AD/HED has defined a range of acceptable cancer risks based on a policy memorandum issued in 1996 by then Office of Pesticides Programs director, Mr. Dan Barolo. This memo refers to a predetermined quantified “level of concern” for occupational carcinogenic risk. In summary, this guidance memo indicates occupational carcinogenic risks that are 1×10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, AD/HED is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection would be warranted as is commonly applied with non-cancer risk estimates (i.e., additional PPE or engineering controls).

Cancer risks were calculated using the following equation:

$$\text{Cancer Risk} = \text{LADC} (\mu\text{g}/\text{m}^3) \times \text{Unit Risk} (\mu\text{g}/\text{m}^3)^{-1}$$

Cancer risks were also estimated using the CIIT modeling presented in Table 8B (hockey stick-shaped; nonsmoking) of Conolly 2004.

Table 6.7b. Inhalation (vapor) Exposure and Cancer Risks for Professional Painters					
HCOH Formation	Average Daily Concentration (9-hour TWA) ($\mu\text{g}/\text{m}^3$)	Days Exposed per Year	Years Exposed per Lifetime	Life Time Average Daily Concentration ^a ($\mu\text{g}/\text{m}^3$)	Cancer Risk ^{b,d}
IRIS					
100%	1790	240	35	220	2.9×10^{-3}
30%	540	240	35	67	8.7×10^{-4}
CIIT					
100%	1790	240	35	0.18 ppm ^c	1.11×10^{-7}
30%	540	240	35	0.054 ppm ^c	3.13×10^{-8}

^a LADC = ADC x (9/24) x (240/365) x (35/70)

^b IRIS Cancer Risk = LADC ($\mu\text{g}/\text{m}^3$) x Unit Risk ($1.3 \times 10^{-5} \mu\text{g}/\text{m}^3$)⁻¹

^c LADC (ppm) = LADC ($\mu\text{g}/\text{m}^3$) x (mg/1000 μg) x 24.45 / HCOH MW (30 g/mol)

^d CIIT Cancer Risks are presented in Table 8B (hockey stick-shaped CRCP; nonsmoking) of Conolly et al., 2004

At 100% and 30% HCOH formation, the cancer risks using the IRIS unit risk are 2.9×10^{-3} and 8.7×10^{-4} both of which exceed the Agency's level of concern of 1.0×10^{-4} . However, at 100% and 30% HCOH formation, the cancer risks using the CIIT modeling are 1.11×10^{-7} and 3.13×10^{-8} neither of which exceeds the Agency's level of concern of 1.0×10^{-4} . It should be noted that it was conservatively assumed that every painting event utilized HHT treated paint. If specific HHT treated paint use information were available the assessment could be refined resulting in more accurate estimates of exposures and risks.

6.4 Industrial Bystander Inhalation Exposure

HCOH inhalation exposures are expected to occur to bystanders as a result of HHT material preservative applications in industrial settings. Currently, no data are available to assess these bystander exposures and therefore, monitoring data are needed.

6.5 Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the occupational handler exposure assessments. These include:

- Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998) (See Appendix A for summaries of these data sources). Since the CMA data are of poor quality, the Agency requests that confirmatory data be submitted to support the occupational scenarios assessed in this document.
- AD can not consider using the metal working fluid exposure data provided by the registrants until the ethics review for the use of human subjects for this specific study has been completed.

- Currently, no exposure data are available to assess the bystanders' inhalation exposure to HCOH vapors resulting from HHT uses in industrial settings. Appropriate air monitoring data in the manufacturing setting are needed to support the preservative uses.
- The Wall Paint Exposure Model is designed to estimate indoor-air concentrations and associated inhalation exposures for interior applications involving alkyd or latex primer/paint. The chamber tests on which the emission algorithms are based involve a limited set of chemicals with a correspondingly limited range of properties (molecular weight and vapor pressure). Further, the emission algorithms are valid only for chemicals that are formulated into alkyd/latex primers or paints. Actual monitoring data or a chamber study is needed to determine the amount of HCOH off-gassing from HHT treated paint.

7.0 REFERENCES

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**APPENDIX A:
Wall Paint Exposure Model (WPEM) Outputs**

Air Concentrations for Professional Painters from WPEM

Time (hrs) ^a	100% HCOH Formation <u>Conc@Person</u> (mg/m ³) ^b	30% HCOH Formation <u>Conc@Person</u> (mg/m ³) ^b
0	0	0
1	0.760689	0.228207
2	1.26024	0.378071
3	1.59066	0.477199
4	1.81324	0.543971
5	1.96702	0.590105
6	2.07691	0.623074
7	2.15881	0.647642
8	2.22282	0.666847
9	2.27542	0.682626
9-hr TWA	1.79	0.54
peak	2.28	0.68

a Time (hrs) = Hours after painting activities begin; note that time 0 represents the time when the painting begins

b Air concentration inhaled by painter

c 9-hr TWA (Time Weighted Average) = average concentration over an 9-hr period (e.g. hours 1 through 9)