EXAMPLE **

Initial Safety Assessment

for

Benyzl-Hen-House (BHH)

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Prepared for:
American Poultry-based Chemistry Confederation (APC^2)

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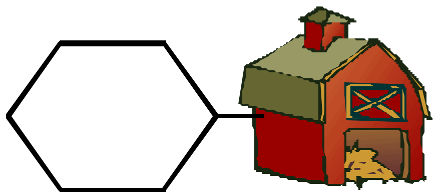
** This document is intended to generally illustrate the technical approach and communication of an evaluation using the ACA human exposure framework. While the chemical identity is not shown, all data for this illustration was taken from an actual case-study prepared for the ACA in 4/2000. This case study did not include environmental/ecological endpoints because this was outside the scope of the original work. In addition, the case study contained only limited human toxicity data (on reproduction), not the full SIDS dataset.
NOTE: There are a number of tables throughout this report that are numbered according to how they appeared in the original case study, not in a logical order as they appear in this example.

CHEMICAL NAME
Benyzl-Hen-House (BHH)

CAS No.:

STRUCTURAL FORMULA:



Introduction:

This report presents the results of a screening level human health exposure and safety assessment for Benzyl-Hen-House (BHH). BHH is used as an industrial chemical intermediate, and a carrier, emollient, and lubricant in a range of anti-perspirant/deodorant (AP/D) products and hair care/skin care (HC/SC) consumer products.

National production of the Hen-House family of materials is 153.1 thousand metric tonnes in the United States (1993 industry data). Of this, approximately 133.4 thousand metric tonnes is consumed in the production of other chemicals ("site limited intermediates"). The remainder is used in the above personal care products.

This assessment combines information on chemical hazard (toxicity) with an assessment of potential exposures to evaluate the risk/safety of the current use(s) of BHH in commerce. As such, it is intended to improve the public's understanding of the hazards of BHH in the context of how the chemical is used, and potential exposure to it, so that its risks can be more effectively understood and managed.

The technical approach to this preliminary human health risk assessment for BHH consisted of the following steps:

- A review of several rat reproductive toxicity studies, which were concluded to be the most sensitive and important toxicological endpoint from the SIDS dataset;
- Characterization of exposure scenarios and estimation of BHH intake for the selected receptors and modes of exposure. These focused on workers, the general public living in the vicinity of facilities producing or using BHH, and consumers of products containing BHH);
- Calculation of MOEs, which describe the ratio of the estimated no effect level, expressed as the NOAEL or the Benchmark Dose, Lower Limit (BMDL), with the estimated intake for each receptor and route of exposure *(Risk Characterization).*

Methods:

Hazard Data:

The hazard data used in this study were derived from a compilation of publicly available information, compiled under the voluntary U.S. High Production Volume (HPV) Chemicals Challenge program, summarized in Attachment 3. A detailed summary of the toxicity studies is publicly available, from The American Poultry-Based Chemistry Council (APC^2).

Based on these data, results from reproductive toxicity was judged to be the most toxicologically significant endpoint. These studies were conducted with male and/or female Sprague-Dawley rats exposed by whole body inhalation to BHH at concentrations ranging from 70 to 700 ppm (mass/volume airborne concentration) for 6 hours/day. The general protocol for each study was similar and included exposure for at least 28 or 70 days prior to mating, with exposure for females continuing in some studies throughout gestation and lactation. Results indicated that the No-Observed-Adverse-Effect-Level for BHH was approximately 500 ppm. However, effect thresholds varied from one endpoint and study to another. As a result, an alternative metric, the "Benchmark Response Dose, Lowest Confidence Limit" (BMDL) was employed.

Exposure Assessment:
Analyses of potential exposures to BHH have been summarized by Sears and Roebuck [1997] and Smith & Hawkens (1998), based on a broad-based review of the industry-supplied data for several workplace exposure scenarios, and a review of BHH use in selected consumer products. These analyses evaluated potential exposure (as shown by intake) for:

- persons who work in the production of BHH, in the formulation of this material into personal care products, or in the use of these products in professional settings;
- the general public living in the vicinity of a plant that produces or processes these materials and who may be exposed to ambient levels of BHH released to the environment during manufacturing activities.
- consumers who use personal care products containing BHH, including antiperspirant/deodorants (AP/Ds) and hair care/skin care (HC/SC) products;
- consumers who may be exposed in their diet to Hen-House antifoams used in food processing;

Estimates of intake were investigated by the inhalation route for workers and the general public; by both the dermal and inhalation routes for personal care product users; and the oral route for lipstick and antifoams in food products. The relative importance of these pathways differs, but in general the dermal pathway accounts for the majority of consumer exposure, while the inhalation pathway is the most significant contributor to worker exposure and exposure to the general public. The oral pathway was the only pathway of exposure for BHH studied in Hen-House food antifoams.

Estimates of exposure were compared to the BMDL via calculation of the Margin of Exposure (MOE). The MOE is the ratio of the predicted effects threshold (BMDL) to the predicted exposure value. Accordingly, without consideration of any uncertainties associated with the estimates, a margin greater than 1 indicates exposure is below the threshold causing harm.

Results and Conclusions:
The series of reproductive studies has provided consistent evidence that BHH caused decreases in mean live litter size, numbers of pups born, and numbers of uterine implantation sites in the Sprague-Dawley rat. The smallest BMDL estimated from these data was 51 mg/kg/day (323 ppm), expressed as intake. BMDLs ranged from 51-61 mg/kg/day.

Key findings from the exposure evaluations, expressed as Average Daily Intake (ADI)[1] are summarized as follows:

INDIVIDUAL	RANGE OF ESTIMATED EXPOSURES (INTAKE)
Worker ADI	0.0010 – 0.26 mg/kg/day
General public near BHH facilities	0.0036 – 0.0046 mg/kg/day
Consumer exposure (all uses)	0.00004 – 0.0737 mg/kg/day
Aggregate exposure for woman who uses multiple products, and is either an antiperspirant worker, OR a Hen-House production worker.	0.158 or 0.145 mg/kg/day

Overall, the MOEs for human exposures either in the workplace, through consumer products, or in the general environment were at least 100. Most were greater than 1000. These calculations conservatively assumed 100 % uptake for all dermal exposures, and equivalency of dose across all routes of exposure. When these factors are accounted for, MOEs for consumer use products are greater than 1000 and for many products, greater than 10,000.

Recommendation
This risk assessment is considered preliminary and THE CHEMICAL IS A CANDIDATE FOR FURTHER WORK, due primarily to the widespread use of BHH in “direct to human” applications. Specifically, effects thresholds are being reassessed in an ongoing two-generation reproductive toxicity study to further refine the toxicity evaluation. However, given the use of assumptions that result in overestimates of intake, preliminary MOEs are more likely to increase than to decrease. As a result, conclusions with regard to the lack of potential for adverse reproductive effects in populations exposed, as described in the exposure assessment, are likely to remain unchanged in the final risk assessment.

NOTE: The results of this assessment are not intended to rescind or modify any existing regulatory obligations with respect to BHH (e.g. labeling requirements). In the event that significant new hazard or exposure data or new applications for BHH arise, this assessment should be revisited.

[1] The ADI is the predicted level of BHH taken into the body via inhalation, dermal or oral exposure during the course of a day under a given scenario, based on the conditions of exposure, habits and practices, and human physiology (average weights, breathing rates, etc…).

ATTACHMENT 3
HAZARD AND EXPOSURE DATA SUMMARY TABLE

NOTE: NA means that this information was not included as part of the original Case Study, not that such data is not available from other sources. The original case study only contained hazard data on reproductive toxicity. For reference, in order to support the conclusion that the reproduction studies profiled in the case study represent the most sensitive toxicological endpoint, acute, repeat dose, and carcinogenecity data were taken from the scientific literature (BIBRA Abstracts).

CHEMICAL NAME: Benzyl Hen-House (BHH)			
CAS NO:			
PHYSICAL-CHEMICAL ELEMENTS			**RESULTS**
Melting Point	NA		°C
Boiling Point	NA		°F (at kPa)
Vapor Pressure	1.0		mm Hg @ 25 °C
Partition Coefficient	5.1		Log K_{ow}
Water Solubility	74		ug/l

ENVIRONMENTAL FATE AND PATHWAY ELEMENTS	CASE STUDY DID NOT INCLUDE ENVIRONMENTAL DATA		
Photodegradation	NA		In air T½ = hours
Stability in Water	NA		T½ =min
Transport and Distribution between Environmental Compartments	NA	Calculated Fugacity Level 1 Type (local exposure)	In Air % In Water % In Sediment % In Soil % In Biota %
Biodegradation	NA		
Additional data (as available)	NA		

ECOTOXICITY ELEMENTS	CASE STUDY DID NOT INCLUDE ENVIRONMENTAL DATA OR EXPOSURE ANALYSIS		
	SPECIES	**PROTOCOL**	**RESULTS**
Acute Toxicity to Fish	NA		LC_{50} (24 hr) = mg/l LC_{50} (48 hr) = mg/l LC_{50} (72 hr) = mg/l LC_{50} (96 hr) = mg/l
Toxicity to Aquatic Plants (Algae)	NA		EC_{50} (hr) = mg/l NOEC (hr) = mg/l
Acute Toxicity to Aquatic Invertebrates (Daphnia)	NA		LC_{50} (24 hr) = mg/l LC_{50} (48 hr) = mg/l

HEALTH ELEMENTS	**SPECIES**	**PROTOCOL**	**RESULTS**
Acute Toxicity	Rat	Oral	LD50 > 50,0000 mg/kg
Repeat Dose Toxicity	Mice, Guinea pig, rabbit	Subcutaneous injection of 13 – 50 g/kg body weight	No systemic toxicity observed over studies of up to 11 months
Genetic Toxicity	Rat	Carcinogenicity study – 400mg/kg/day administered in diet for two years	No evidence of carcinogenecity

Reproductive Toxicity	Rats	Six studies on male and/or female Sprague-Dawley rats were exposed by whole body inhalation to BHH at concentrations ranging from 70 to 700 ppm (mass/volume) for 6 hours/day. Exposure for at least 28 or 70 days prior to mating with exposure for females continuing in some studies throughout gestation and lactation	NOAEL = 500 ppm BMDL = 51-61 mg/kg/day
Developmental Toxicity/Teratogenecity	NA		

ADDITIONAL HAZARDS DATA (AS AVAILABLE)	SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL	NA		
ENVIRONMENTAL FATE AND PATHWAYS	NA		
ECOTOXICITY	NA		
HEALTH	Guinea Pig	Acute Oral toxicity	LD50 > 50,000 mg/kg
	Rabbit	Acute Oral toxicity	LD50 > 50,000 mg/kg

EXPOSURE INFORMATION (AS AVAILABLE)	KEY RESULTS
Evaluation of Human Exposures	Exposure analysis was conducted for the following scenarios: • persons who work in the production of BHH, in the formulation of this material into personal care products, or in the use of these products in professional settings; • consumers who use these personal care products, including antiperspirant/deodorants (AP/Ds) and hair care/skin care (HC/SC) products; • consumers who may be exposed to Hen-House antifoams used in food processing; and • the general public living in the vicinity of a plant that produces or processes these materials and who may be exposed to ambient levels of BHH released to the environment during manufacturing activities. Key findings (Average Daily Intake, ADI) are summarized as follows: • Worker ADI — 0.0010 – 0.26 mg/kg/day • General public near BHH facilities — 0.0036 – 0.0046 mg/kg/day • Consumer exposure — 0.00004 – 0.0737 mg/kg/day • Aggregate exposure for women who uses multiple products, and is an antiperspirant <u>or</u> BHH production worker. — 0.158, or 0.145 mg/kg/day
Evaluation of Ecological Exposures	NA - CASE STUDY DID NOT INCLUDE ENVIRONMENTAL EXPOSURE ANALYSIS

ATTACHMENT 4
SUMMARY OF BHH HAZARD DATA AND KEY USE AND EXPOSURE INFORMATION, FOLLOWING FORMAT OF THE OECD SIDS INITIAL ASSESSMENT REPORT (SIAR)

1. IDENTITY

General Information/Physical Properties:

BHH is part of a family of Hen-House chemicals. Its physical/chemical properties are as follows:

- Molecular Weight: Smaller than a bread-box
- Boiling Point: NA
- Density/Specific Gravity: 0.95 @ 25 °C
- Vapor Pressure: 1.0 mm Hg @ 25 °C
- Flash Point/Flammability: NA
- Explosive Limits: NA
- Solubility: 74 ug/l

2. GENERAL INFORMATION ON EXPOSURE

Function:

BHH is used as an industrial chemical intermediate, and a carrier, emollient, and lubricant in a range of anti-perspirant/deodorant (AP/D) products and hair care/skin care (HC/SC) consumer products.

Applications:

National production of the Hen-House family of materials is 153.1 thousand metric tonnes in the United States (1993 industry data). Of this, approximately 133.4 thousand metric tonnes is consumed in the production of other chemicals ("site limited intermediates"). The remainder is used in the above personal care products, at concentrations shown below

Table 3.1-12
Hen-House Content of AP/D and HC/SC Products

Products Included	Percent BHH	
	In products made with CF A (*)	In products made with CF B (*)
Deodorants:		
Roll-on	54	-
Solid	50	6
Aerosols	11	
Hair Care:		
Spray shine	45	3
Finishing spritz; finishing spray; styling spritz; styling spray; curl revitalizer; conditioning spray; protective spray; curl activator; setting lotion; multifunctional shampoo; wash-off conditioner; leave-in conditioner	1.8	0.12
Cuticle coat	54	3.6
Brilliantine	25.2	1.7
Promade	17.1	1.14
Rinse	1.8	0.12
Skin Care:		
Antiwrinkle, antiaging lotions/creams/ alpha-hydroxy acid products; beauty lotions; bleaching, lightening lotions/creams/moisturizing lotions/creams; hormone lotions/creams; night lotions/creams/eye lotions/creams	13.5	0.9
Concealer/undereye cover; lipsticks	22.5	1.5
Mascara	13.5	0.9
Foundation	9	0.6
Hand/body lotion	7.2	0.48
Suntan/sunscreen cream/lotion	9	0.6
Nail polish driers; after-shave (gel)	36	2.4

* CF A and CF B are primary commercial formulations of BHH. CF A contains 90 % BHH; CF B contains 6 %.

2.1 Environmental Exposure and Fate

CASE STUDY DID NOT INCLUDE ENVIRONMNTAL DATA OR EXPOSURE ANALYSIS

2.2 Human Exposure

Human exposure assessment:

Comprehensive analyses of potential exposures to BHH have been conducted by Sears and Roebuck [1997] and Smith & Hawkens (1998). These analyses evaluated the production, formulation, and use of BHH in the United States and estimated the potential exposure (intake via inhalation, dermal, or oral routes, as described below) for:

- persons who work in the production of BHH, in the formulation of this material into personal care products, or in the use of these products in professional settings;
- consumers who use these personal care products, including antiperspirant/deodorants (AP/Ds) and hair care/skin care (HC/SC) products;
- consumers who may be exposed to BHH antifoams used in food processing; and
- the general public living in the vicinity of a plant that produces or processes these materials and who may be exposed to ambient levels of BHH released to the environment during manufacturing activities.

These exposure assessments provided estimates of Average Daily Intake (ADI) by the inhalation route for workers and the general public; both the dermal and inhalation routes for personal care product users; and the oral route for lipstick and Hen-House-based antifoams in food products. The ADI is the predicted level of BHH taken into the body via inhalation, dermal or oral exposure during the course of a day under a given scenario, based on the conditions of exposure, habits and practices, and human physiology (average weights, breathing rates, etc…). A general description of these analyses is contained in Attachment 5, with the details in Attachment 6. The following summarizes the key results.

Occupational exposure: In the Sears & Roebuck study (1997), workers were assumed to be exposed primarily by the inhalation route with limited dermal exposure. Workers engaged in the production of SC products had the highest estimated ADIs for all worker scenarios (0.26 and 0.20 mg/kg/day for women and men, respectively), while workers in the HC products industry had the lowest ADIs (0.0013 and 0.0010 mg/kg/day for women and men, respectively).

Community exposure: The inhalation route of exposure was the only relevant route for the general public in the vicinity of BHH production facilities or facilities where consumer products containing BHH are manufactured. Estimated ADIs for the general public were 0.0046 and 0.0036 mg/kg/day for women and men, respectively.

Consumer exposure: The dermal and inhalation routes were primary for all consumer personal care products, except lipstick (oral). Consumer use of AP/Ds, in particular the roll-on or aerosol types, followed by the use of hand and body lotions provided the highest estimates of intake for all the consumer products evaluated. Estimated dermal + inhalation ADIs for AP/Ds ranged from 0.0719 and 0.0737 mg/kg/day for women and men using roll-on APs to 0.0033 and 0.0042 mg/kg/day for women and men using the solid type. Estimates of ADIs for HC/SC products were based on only the contribution from dermal exposure, which was assumed to be the primary route of exposure to consumers. Of the products evaluated, use of hand and body lotion resulted in the highest estimated ADIs (0.03 mg/kg/day). Oral exposure to lipstick was 0.001 mg/kg/day.

In the above estimates, intake was estimated separately for each product or type of exposure. However, it is recognized that an individual may use several products on a regular basis. Therefore, a hypothetical person who used several products was considered. This person was assumed to be a woman who used roll-on antiperspirant, shampoo, leave-in conditioner, lipstick, and hand and body lotion, and who worked in a plant manufacturting either antiperspirants or Hen-

House products. The total ADI for this receptor would be 0.158 or 0.145 mg/kg/day for a woman working in antiperspirant or Hen-House manufacturing, respectively.

Indirect exposure: Persons may also be exposed to BHH by way of ingestion of food products processed using Hen-House antifoams. Estimates of exposure to BHH were based on the maximum allowable levels of Hen-House antifoams in food and assumed that 50% of all food ingested was processed with Hen-House antifoams. ADIs for this exposure were highest for children one year of age or younger (approximately 0.002 mg/kg/day) and lowest in the 14- to 18-year-old age group (0.0006 and 0.0007 mg/kg/day for men and women, respectively).

3. HUMAN HEALTH HAZARDS

3.1 Effects on Human Health

The following table summarizes the available toxicity data for BHH:

TEST TYPE	RESULTS
Acute Oral Toxicity, Rat	LD50 > 50,0000 mg/kg
Repeat Dose Toxicity, Mice, Guinea pig, rabbit. Subcutaneous injection of 13 – 50 g/kg body weight	No systemic toxicity observed over studies of up to 11 months
Genetic Toxicity, Rat, Carcinogenicity study – 400mg/kg/day administered in diet for two year	No evidence of carcinogenecity
Reproductive studies: A series of six reproductive toxicity studies was conducted in which male and/or female Sprague-Dawley rats were exposed by whole body inhalation to BHH at concentrations ranging from 70 to 700 ppm (mass/volume) for 6 hours/day. The general protocol for each study was similar and included exposure for at least 28 or 70 days prior to mating with exposure for females continuing in some studies throughout gestation and lactation	In all studies, except one, exposure to BHH at any concentration tested did not result in any treatment-related alterations in any of the reproductive parameters measured to include: the interval between pairing and mating, mating and fertility indices, gestation length, or parturition duration. The major findings noted in females exposed to BHH at 700 ppm in studies three studies, and at 500 and 700 ppm in one (Overall changes for specific endpoints were statistically significant treatment-related decreases in: • the number of corpora lutea (evaluated only in two studies); • the number of uterine implantation sites (four studies); • the total number of pups born (three studies); • the mean live litter size (three studies); and • the mean number of viable fetuses (one study).

Based on these studies, the reproductive findings were concluded to be the most toxicologically significant. In order to develop an threshold effect level that could be related to human exposures, the dose-response assessment step in this preliminary risk assessment consisted of the following:

- Selection of the critical study and critical endpoints from that study to be used in dose-response modeling;
- Conversion of the applied dose (in ppm) to the appropriate dose-metric that can be used to extrapolate across species and routes of exposure and to provide estimates of intake for each of the selected receptors, products/activities, and routes of exposure; and
- Characterization of the dose-response relationship for the selected endpoints using a "Benchmark Model" to estimate both the maximum likelihood estimate of the Benchmark Dose (BMD) and the 95% lower bound on that dose (BMDL).

For establishing the critical BMDL, results the female crossover study were selected. In this study, female Sprague-Dawley rats were exposed to 0, 70, 300, 500, or 700 ppm BHH by whole body inhalation for 6 hours/day for 70 days prior to mating, with exposure continuing through Post-Natal-Development (PND) Day 20 (except for the interval from Gestation-Development (GD) Day 20 through PND Day 4). The incidence of decreased mean live litter size, decreased number of pups born, and decreased number of uterine implantation sites were selected as the critical endpoints for dose-response modeling.

As an alternative to the NOAEL, a benchmark calculation was performed for all endpoints for which a significant dose-related trend ($p<0.05$) was present. A BMD is a dose (or exposure) that corresponds to a specified level of response called the benchmark risk or benchmark response (BMR). A BMD is calculated by fitting a mathematical dose-response model to dose-response data. A lower statistical confidence bound on the BMD, termed the BMDL, has been proposed as an alternative to the NOAEL in determining acceptable human intakes of xenobiotics (Crump 1984, 1995).

Experimental NOAELs were 500 ppm for each endpoint evaluated. The BMDLs ranged from 323 to 390 ppm, or when expressed as an intake, from approximately 51 to 61 mg/kg/day. A BMDL of 51 mg/kg/day was selected for use in comparison to exposure estimates, via the calculation of Margins of Exposure (MOE).

4. HAZARDS TO THE ENVIRONMENT

CASE STUDY DID NOT INCLUDE ENVIRONMENTAL ENDPOINTS.

5. CONCLUSIONS AND RECOMMENDATIONS

Human risk assessment

The series of reproductive studies has provided consistent evidence that BHH caused decreases in mean live litter size, numbers of pups born, and numbers of uterine implantation sites in the Sprague-Dawley rat. The smallest BMDL estimated from these data was 51 mg/kg/day (323 ppm).

MOEs, which are the ratios of the BMDL to the estimated intake, were calculated for all the selected exposure scenarios. All MOEs were greater than 100, and with few exceptions, were greater than 1000. When the impact of assumptions regarding dermal absorption and route equivalence is considered, all MOEs for consumer use products are greater than 1000 and for many products, greater than 10,000.

A MOE of a specified magnitude indicates that exposure at the corresponding estimated intake level or below is not expected to result in adverse effects in populations so exposed. A MOE of 100 is typically considered of sufficient magnitude when the basis of the toxicity threshold is animal data (USEPA 1994) – the typical factors of 10 for interspecies extrapolation (from animals to humans) and a factor of 10 for intrahuman variability. It could also be argued that applying an additional modifying factor of 3 is also warranted, because the toxicity study covered just one generation. Thus, a MOE of between 100 and 300 would be deemed acceptable.

Conclusion:

This risk assessment is considered preliminary and, due to the nature of BHH use and the observed MOEs for some products, THE CHEMICAL IS RECOMMENDED FOR FURTHER WORK. Specifically, the effects assessment will be refined by the results of a two-generation reproductive toxicity study. However, given the several major assumptions that result in overestimates of intake and the assumptions with regard to route and species extrapolation, preliminary MOEs for BHH are more likely to increase than to decrease.

ATTACHMENT 5
EXPANDED EXPOSURE ASSESSMENT ADDENDUM (EEAA) FOR BHH

Introduction:

The purpose of the EEAA is to provide a more detailed discussion of any exposure analysis that is available, beyond the information called for in the SIAR.

Human Exposure Assessment:
Identification of Key Human Exposures – Completeness of the Evaluation

The exposure assessments conducted on BHH by Sears & Roebuck (1997) and Smith and Hawkens (1998) provided estimates of BHH intake, quantified as the Average Daily Intake (ADI), based on a comprehensive review of the workplace for several exposure scenarios, as well as a review of the amount of BHH in selected consumer products and the use patterns for those products. The ADI is the predicted level of BHH taken into the body via inhalation, dermal or oral exposure during the course of a day under a given scenario, based on the conditions of exposure, habits and practices, and human physiology (average weights, breathing rates, etc…). The information for workplace activities and usage patterns was based on industry-supplied data and represents a compilation of data across companies and products. As such, some unifying and, in some cases, conservative assumptions were made to provide generic exposure scenarios that characterized these exposures to the selected target populations:

- persons who work in the production of BHH, in the formulation of this material into personal care products, or in the use of these products in professional settings;
- the general public living in the vicinity of a plant that produces or processes these materials and who may be exposed to ambient levels of BHH released to the environment during manufacturing activities.
- consumers who use these personal care products, including antiperspirant/deodorants (AP/Ds) and hair care/skin care (HC/SC) products;
- consumers who may be exposed to Hen-House antifoams used in food processing;

This exposure assessment provided estimates of intake by both the dermal and inhalation routes for personal care product users; the oral route for lipsticks and antifoams in food products; and by the inhalation route for workers and the general public. The relative importance of these pathways differs for each exposure group. The dermal pathway accounts for the majority of consumer exposure, while the inhalation pathway is the most significant contributor to worker exposure and exposure to the general public. The oral pathway is the only pathway of exposure for BHH in Hen-House antifoams.

Exposures Related to the Production, Handling, or Formulation of the Chemical in Industrial Facilities: Workers engaged in the production of SC products had the highest estimated ADIs (0.26 and 0.20 mg/kg/day for women and men, respectively), while workers in the HC products industry had the lowest ADIs (0.0013 and 0.0010 mg/kg/day for women and men, respectively) for the worker populations assessed (Table E-3a). In the Sears & Roebuck study (1997), workers were assumed to be exposed primarily by the inhalation route with limited dermal exposure. Therefore, the estimated ADIs shown in Table E-3a were based on the inhalation route only. Sears & Roebuck also crafted two dermal exposure scenarios to estimate the amount of dermal absorption, under the assumption that good manufacturing practices (GMPs) may not always be followed. Under those scenarios, the dermal pathway still contributed less than 1% to the total estimated exposure.

Community exposure: The inhalation route of exposure was the only relevant route for the general public. Estimated ADIs for the general public were 0.0046 and 0.0036 mg/kg/day for women and men, respectively (Table E-3a).

Table E-3a
Estimates of ADIs (mg/kg/day) for Selected Populations Exposed to BHH: Workers and the General Public

Population	Women	Men
Workers (a)		
Antiperspirants	0.035	0.027
Skin care products	0.26	0.20
Hair care products	0.0013	0.0010
Hen-House workers	0.022	0.017
Beauticians/Barbers	0.0071	0.0055
General Public (a)	0.0046	0.0036

(a) Inhalation route of exposure only.

Exposures Related to the Handling of Chemicals and Products During Transport: NOT CONDUCTED AS PART OF THE CASE STUDY

Exposures Related to the Handling and Use of End Products Containing the Chemical:
Industrial: NOT CONDUCTED AS PART OF THE CASE STUDY

Institutional/Commercial: SEE ABOVE UNDER WORKER EXPOSURE

Consumer exposure :
Due to their physical properties, Hen-Houses, a group of materials that include BHH, have been widely used in consumer products as carriers, emollients, and lubricants. For this assessment, consumer products evaluated included antiperspirants/deodorant products (AP/D), hair care products (HC) (shampoo, rinse-out conditioner, leave-in conditioner, and hair spray) and skin care products (SC) (lipstick, mascara, moisturizer, nail care, and foundation). While most all APs are formulated with Hen-Houses in general (not just BHH), this is not the case for all HC/SC products. However, for this assessment it was conservatively assumed that Hen-Houses are used in all HC/SC products, as well.

Potentially relevant exposure pathways for all consumer products included inhalation and dermal contact. Dermal exposure occurs through the direct application of the AP/D and HC/SC products to the skin. Inhalation occurs primarily for AP/D as the applied BHH residue volatilizes.

Consumer use of AP/Ds, in particular the roll-on or aerosol types, provided the highest estimates of intake for all the consumer products evaluated (Table E-3b). Estimated ADIs for AP/Ds ranged from 0.0719 and 0.0737 mg/kg/day for women and men using roll-on APs to 0.0033 and 0.0042 mg/kg/day for women and men using the solid type.

As noted above, estimates of ADIs for HC/SC products were based on only the contribution from dermal exposure, which was assumed to be the primary route of exposure to consumers. For lipsticks, however, oral exposure was used in the calculation. Of the products evaluated, use of hand and body lotion resulted in the highest estimated ADIs (Table E-3b).

Table E-3b
Estimates of ADIs (mg/kg/day) for Selected Populations Exposed to BHH:
Consumers Exposed Using Personal Care Products

Population	Women	Men
Consumers: Antiperspirants/Deodorants (a)		
Solid	0.0033	0.0042
Roll-on	0.0719	0.0737
Aerosol	0.0329	0.0280
Consumers: Skin Care Products (b,c)		
Hand and body lotion	0.030	--
Lipstick (also considerd oral exposure)	0.011	--
Nail care	0.00004	--
Consumers: Hair Care Products (b,c)		
Spray shine	0.0134	0.009
Cuticle coat	0.0095	0.0076
Shampoo	0.0002	0.00017

(a) Dermal and inhalation routes of exposure.
(b) Represents the products with the two highest estimated intake and product with the lowest estimate intake for the group of products evaluated.
(c) Dermal route of exposure only.

In the above estimates, intake was estimated separately for each product or type of exposure. However, it is recognized that an individual may use several products on a regular basis. Therefore, a hypothetical peson who used several products was considered (Table E-3c). This was assumed to be a woman who used roll-on antiperspirant, shampoo, leave-in conditioner, lipstick, hand and body lotion, and who worked in a plant manufacturting antiperspirants or Hen-House products. Assuming the highest predicted exposure occurred for each of these situations, the maximum total ADI would be 0.158 or 0.145 mg/kg/day for a woman using these products, and working in either antiperspirant formulation, or Hen-House manufacturing, respectively.

Table E-3c
Estimate of ADI (mg/kg/day) for a Woman Who Used Multiple Products

Source	ADI
Antiperspirant product worker OR a Hen-House worker	0.035 or 0.022
Roll-on antiperspirant	0.0719
Hand and body lotion	0.030
Lipstick	0.011
Moisturizer	0.0097
Leave-in conditioner	0.00084
Shampoo	0.0002
TOTAL	0.158 or 0.145

Indirect exposure :
Persons may also be exposed to BHH by way of ingestion of food products processed using Hen-House antifoams (Smith and Hawkens, 1998). Estimates of exposure to BHH were based on the maximum allowable levels of Hen-House antifoams in food and assumed that 50% of all food ingested was processed with Hen-House antifoams. ADIs for this exposure were highest for children one year of age or younger (approximately 0.002 mg/kg/day) and lowest in the 14- to 18-year-old age group (0.0006 and 0.0007 mg/kg/day for men and women, respectively) (Table E-3d).

Table E-3d
Estimates of ADIs (mg/kg/day) for Selected Populations:
Consumers Exposed to BHH in Food Products Processed with Hen-House Antifoams

Age (years)	Women	Men
<1	0.002063	0.001907
1–6	0.001630	0.001507
6–14	0.000844	0.000823
14–18	0.000723	0.000594
18–45	0.000841	0.000705
45–75	0.000699	0.000603

Ecological Exposure Assessment:
CASE STUDY DOES NOT INCLUDE ECOLOGICAL EXPOSURES

Hazard/Exposure-Based Human Safety Assessment:
In order to evaluation risks, MOEs, which are the ratios of the BMDL to the estimated intake, were calculated for all the selected receptors. The MOEs for all of the worker populations as well as the three categories of AP/Ds evaluated are presented in Tables E-5a to E-5d. For both the HC/SC products, only the two products with the highest and the one product with the lowest estimates of BHH intake, and consequently, the largest and smallest MOEs for each category are reported in Table E-5.

The series of reproductive studies has provided consistent evidence that BHH caused decreases in mean live litter size, numbers of pups born, and numbers of uterine implantation sites in the Sprague-Dawley rat. The smallest BMDL estimated from these data was 51 mg/kg/day. Human exposures either in the workplace, through consumer products, or in the general environment that result in estimates of intake at least 100-fold lower than the BMDL, i.e., a MOE of 100 or greater, are not expected to cause any adverse reproductive effects in those populations. All MOEs calculated for the selected receptors were greater than 100 and with few exceptions were greater than 1000. When the impact of assumptions regarding dermal absorption and route equivalence is considered, all MOEs for consumer use products are greater than 1000 and for many products, greater than 10,000.

A MOE of a specified magnitude indicates that exposure at the corresponding estimated intake level or below is not expected to result in adverse effects in populations so exposed. A MOE of 100 is typically considered of sufficient magnitude when the basis of the BMDL is animal data (USEPA 1994) – the typical factors include 10 for interspecies extrapolation (from animals to humans) and a factor of 10 for intrahuman variability. It also could be argued, since this is a preliminary risk assessment, that applying an additional modifying factor of 3, since only a one generation reproductive study was conducted, would be prudent, thereby resulting in a MOE of 300.

As stated, at a MOE of 100, the estimated BHH intake for all workers, consumer product users, and the general public evaluated would be well below levels expected to be health protective. For those receptors with a MOE greater than 100 but less than 300, a closer look at the underlying assumptions used to develop those scenarios would be warranted. Only workers in the category designated as SC workers fell into that category. However, in each step in the calculation of each MOE, conservative, assumptions were made that would tend to over-predict exposure. Some of these assumptions were based on current practices in screening level risk assessment (e.g., the assumpiton of 100 % uptake of applied chemical), while other assumptions were based on preliminary data, e.g., with regard to route-to-route extrapolation. Refinement of these assumptions would likely lead to lower estimates of delivered dose to the target species and, hence, larger estimated MOEs for each scenario.

Table 5.1-1
Estimates of MOE for Selected Populations Exposed to BHH:
Workers and the General Public

Population	Women	Men
Workers (a)		
Antiperspirants	1457	1889
Skin care products	196	255
Hair care products	39231	51000
Hen-House workers	2318	3000
Beauticians/Barbers	7186	9273
General Public (a)	11087	14167

(a) Inhalation route of exposure only.

Table 5.1-2
Estimates of MOE for Consumers Exposed to BHH from the Use of Selected Personal Care Products

POPULATION	CFA		CF B	
	Men	Women	Men	Women
Consumers: Antiperspirants/Deodorants				
(a)	12232	15464	NC	NC
Solid	692	709	NC	NC
Roll-on	1821	1551	NC	NC
Aerosol				
Consumers: Skin Care Products (b)				
Mascara	NC	33628	NC	508617
Moisturizer	NC	5259	NC	79008
Nail care	NC	1436094	NC	24413595
Foundation	NC	20077	NC	301402
Hand/body lotion	42607	1677	NC	11979
Sunscreen	469492	23565	NC	168370
Undereye cover	NC	36168	NC	256985
Lipstick	NC	4602	NC	66522
After-shave gel	31259	NC	NC	NC
Consumers: Hair Care Products (b)				
Shampoo	297727	251687	NC	4068933
Conditioner (rinse out)	393768	301402	NC	4882719
Conditioner (leave in)	78500	60430	NC	904207
Hair spray	141119	95366	NC	1436094
Cuticle coat	6746	5355	NC	80308
Brillinatine	14454	11473	NC	171927
Pomade	21303	16907	NC	254308
Spray shine	5655	3812	NC	57175

NC Not Calculated
(a) Dermal and inhalation routes of exposure.
(b) Dermal route of exposure only.

Table 5.1-3
Estimate of MOE for a Woman Who Used Multiple Products

Exposure Routes	MOE
Antiperspirant or Hen-House manufacturing worker who uses roll-on antiperspirant, hand and body lotion, moisturizer, lipstick, conditioner, and shampoo	323 or 352

Table 5.1-4
Estimates of MOE for Persons Exposed to BHH
in Food Products Processed Using Hen-House Antifoams

Age (years)	Men	Women
<1	26738	24720
1–6	33833	31291
6–14	61942	60394
14–18	85853	70571
18–45	72335	60612
45–75	84566	72966

ATTACHMENT 6
INDIVIDUAL EXPOSURE EVALUATIONS FOR CONSUMER PRODUCTS USE OF BHH

Overview:
NOTE: Case Study was not prepared directly according to the proposed ACA study summary outline. The following contains overview information, with individual study details appearing afterwards.

(1) **Category:**	Hen-House
(2) **Chemical Name:**	Benzyl-Hen-House
(3) **CAS Number:**	
(4) **Physical Form:**	Volatile liquid or solid.
(5) **Modeling Study Objective:**	To predict human exposure for: • Workers who manufacture BHH or BHH-containing products, and users of professional products • General public living near BHH production or formulation facilities. • Consumers using personal care products containing BHH • Consumers of food that is processed with Hen-House compounds
(6) **Medium:**	Dermal, inhalation or oral exposure
(7) **Function**	Carrier, emollient, and lubricant
(8) **Description of Use/Activity:**	See summaries below
(9) **Tool or Model:**	Calculations using standard formulae for dermal, inhalation, or oral exposures, and industry data on habits and practices for specific products. See below for datails.
(10) **Validation/Peer Review**	NOT SUPPLIED BY CASE STUDY REPORT
(11) **Availability and Documentation:**	NOT SUPPLIED BY CASE STUDY REPORT
(12) **Inputs:**	See summaries below
(13) **Results:**	ADI, in mg/kg/day). See summaries below
(14) **Reliability:**	See summaries below
(15) **Remarks:**	See summaries below

SUMMARIES OF INDIVIDUAL BHH EXPOSURE EVALUATIONS

3.1 PERSONAL CARE PRODUCTS

Due to its physical properties, Hen-Houses, a group of materials that includes BHH, have been widely used in consumer products as carriers, emollients, and lubricants. For this assessment, consumer products containing BHH included anit-perspirants/deodorants (AP/D), hair care (HC) products (shampoo, rinse-out conditioner, leave-in conditioner, and hair spray) and skin care (SC) products (mascara, moisturizer, nail care, lipsticks and foundation). While most all AP/D are formulated with Hen-Houses, this is not the case for HC/SC products. However, for this assessment it was assumed that Hen-Houses are used in all HC/SC products, will will conservatively estimate exposures. Potentially relevant exposure pathways for all consumer products included inhalation and dermal contact. The purpose of the exposure analysis was to estimate Average Daily Intake (ADI) for each product, using information on how these products are used, and the conditions of exposure developed by Sears & Roebuck (1997).

EXPOSURES OF CONSUMERS TO BHH VIA THE USE OF AP/DS

BHH is widely used in the formulation of many different AP/Ds. Exposure occurs dermally through the direct application of the AP/Ds to the skin and via inhalation as the AP/D residue volatilizes. There are three principal forms of AP/Ds, solids, roll-ons, and aerosols. The BHH content and application rates vary with each form of AP/Ds; therefore, separate dermal and inhalation exposure analyses were conducted for consumers using each of the three principal forms of AP/Ds. Therefore, in the calculation of a ADI for the use of APs, different exposure parameters were used for the different types of APs. A discussion of the values used by Sears & Roebuck (1997) for each of these parameters is provided below.

3.1.1 Dermal Exposures to BHH from Use of AP/Ds

The dermal ADI s from the use of AP/Ds were calculated using the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{\text{AR x CF x AF x } Dep_f \text{ x } Res_f \text{ x A x D} 4_f}{\text{BW x DW}}$$

where:
AR = application rate (g/application)

CF = conversion factor (1000 mg/g)
AF = application frequency (applications/week)
Dep_f = deposition fraction (unitless)
Res_f = residue fraction (unitless)
A = dermal absorption fraction (unitless)
BHH_f = fraction of product applied that is BHH (unitless)
BW = body weight (kg)
DW = adjustment to daily intake (7 days/week)

Application Rate (AR)

The application rate of AP/Ds is the average number of grams of AP/D used each time it is applied. Information on application rates of the various forms of AP/Ds was available from numerous volunteer studies (Sears & Roebuck (1997) 1997). In these studies, groups of participants (n=30 to 50) were provided with one or more AP/D products and asked to apply these products as they would in normal use for a defined period of time, such as 1 to 2 weeks. The amount that each participant used in the defined period of time was determined from the difference in container contents before and after use by the participant, with average application amounts determined by dividing the amount used by the number of applications the participant reported that they used (Table 3.1-1). For men, the average application rate ranged from 1.99 g/application for aerosols to 1.22 and 1.29 g/application for roll-ons and solids. For women, the application rates for the various products followed the same order. Aerosols had the greatest average (1.54 g/application), followed by roll-ons (0.79 g/application), with solids having the smallest average application rates (0.65 g/application).

Table 3.1-1
Average Application Rates for AP/Ds (a)

Product Form	Gender	Average Amount / Application (grams)	Average Amount / Application (mg/cm^2) (b)	N (c)
Solid	Men Women	1.29 0.65	10.8 10.7	17 11
Roll-on	Men Women	1.22 0.79	10.2 13.0	4 4
Aerosol	Men Women	1.99 1.54	16.7 25.2	3 3

(a) Source: Sears & Roebuck (1997).
(b) Estimated amount per skin surface area for axillary area.
(c) N = number of studies with 30 to 50 participants per study.

Application Frequency (AF)

The application of AP/Ds is generally associated with a showering or bathing event. Approximately 70–75% of the American population bathes or showers every day, with 20–25% bathing or showering more than once a day (USEPA 1997). However, AP/Ds may be applied more often and applied in between a bath or shower, depending on a person's activity. Clousers, Adams and Hendrickson, Inc. (1995) conducted a consumer survey on the purchases and use of AP/Ds. The results of this survey are presented in Table 3.1-2. To determine the mean application frequency per group, the percentage of the population that fit into each range of application frequencies was multiplied by the midpoint of that range of frequencies (i.e., column 3 multiplied by column 4). These population-weighted frequencies were then added together to result in a mean for the group. These data indicated that the mean frequencies of AP/D application are 7.1 and 6.9 times/week for women and men, respectively.

Deposition Fraction (Dep_f)

The deposition fraction of the AP/D is the fraction of product that is deposited onto the skin during a typical application. Sears & Roebuck (1997) assumed that 100% of the amount of product applied will be deposited onto the skin.

Table 3.1-2
Usage Survey Data for AP/Ds for U.S. Population Age 18 or Older (a)

Reported AP/D Applications in Last 7 Days	Sex	Weighted # in Population (000)	Percent in Population	Mid-Point of Range	Extension
0	F	3,953	4.4	0	0.0
	M	3,686	4.6	0	0.0
1 – 3	F	3,287	3.6	2	0.1
	M	3,812	4.7	2	0.1
4 – 7	F	56,914	62.7	5.5	3.4
	M	51,431	63.6	5.5	3.5
8 – 11	F	10,320	11.4	9.5	1.1
	M	7,962	9.8	9.5	0.9
12 – 14	F	11,700	13.0	13	1.7
	M	10,727	13.3	13	1.7
15 or more (b)	F	4,498	5.0	16	0.8
	M	3,252	4.0	16	0.6
Subtotal	F	90,742	100.0	Mean of Group	7.1
	M	80,870	100.0		6.9

(a) Source: Clousers, Adams and Hendrickson (1995) as reported in Sears & Roebuck (1997).
(b) No upper-bound given for those in application frequency group "15 or more." Mid-point of range arbitrarily set at 16.

Deposition Fraction (Dep$_f$)
The deposition fraction of the AP/D is the fraction of product that is deposited onto the skin during a typical application. Sears & Roebuck (1997) assumed that 100% of the amount of product applied will be deposited onto the skin.

Dermal Absorption Fraction (A$_f$)
The dermal absorption fraction (A) is the amount of BHH applied to the skin that is absorbed. In the University of Rochester studies (Cabelas, 1996a,b;1997;1998) the dermal absorption of BHH following application of a typical roll-on AP formulation was examined in the human skin/nude mouse model. The roll-on formulation contained approximately 60% BHH, with the remainder consisting of BHH-A, BHH-B, di-Hen-House 50 cs, and aluminum zirconium tetrachlorohydrex-gly. In an initial study, BHH dermal absorption was estimated to be approximately 3.5%, which is the value used to estimate intake by the dermal route in the exposure assessment conducted by Sears & Roebuck (1997). However, in a more recent study at the University of Rochester, the mean dermal absorption of BHH measured was approximately 1.09% (Cabelas 1998). This is in agreement with other dermal absorption values obtained in *in vitro* studies using human skin, in which dermal absorption values of 0.5% (Smith and Hawkens 1998b) to 1% (Food and Drug Administration 1997) have been reported. The midpoint of this range, 0.75%, was assumed for this risk assessment.

Fraction Applied That is BHH (BHH$_f$)
The fraction of the AP/D applied that is BHH consists of two factors, the fraction of the formulation that consists of all Hen-house compounds combined with the fraction of Hen-House compounds that consists of BHH. Solid APs are estimated to contain 40–60% Hen-Houses (i.e., a blend of BHH, BHH-A, and BHH-B), with the average or base case of 50% assumed by Sears & Roebuck (1997). It was then assumed that CF B Fluid containing 6% BHH, the typical choice for this product, was used to make the AP. Therefore, Sears & Roebuck (1997) assumed the percent of AP/D applied that is BHH for solid AP/Ds to be 3%.

For roll-on APs, whose formulation is approximately 60% Hen-Houses (midpoint of 50–70%), the base fluid was assumed to be CF A Fluid. CF A Fluid consists of approximately 90% BHH. Therefore, for roll-on APs, Sears & Roebuck (1997) assumed the percent of AP/D applied that was BHH to be 54%.

The base fluid for aerosol AP/D was also assumed to be CF A Fluid. The percentage of aerosol AP formulations that are Hen-Houses ranged from 5% to 20%. Sears & Roebuck (1997) assumed a midpoint of 12.5% for the amount of the formulation that consists of cyclics, and of that, 90% was assumed to be BHH. Thus, Sears & Roebuck (1997) assumed (1997) that 11.25% of the aerosol AP/D applied was BHH.

Body Weight (BW)
The body weights assumed by Sears & Roebuck (1997) for users of AP/Ds were based on data contained in the second National Health and Nutrition Examination Survey (NHANES II). This survey was conducted between 1976 and 1980 with 20,322 U.S. residents, ranging in age from 6 months to 74 years. For men, aged 19 to 75, body weights for the 5th and 95th percentiles were 57.7 and 101.7 kg, respectively. The median or 50th percentile body weight was 75.9 kg. For females, the 5th, 50th, and 95th percentile values were 45.6, 57.1, and 82.2 kg, respectively. For this assessment, the median values were used for men and women of 75.9 and 57.1 kg, respectively.

Estimation of Dermal ADIs
The summary of the parameters used in the estimation of dermal ADIs for AP/D consumers is provided in Table 3.1-3. Using Equation 3-1 and the values reported in Table 3.1-3, dermal ADIs were calculated for consumers using each type of AP/D (solid, roll-on, aerosol) and are summarized in Table 3.1-4. The use of roll-on AP/Ds resulted in the highest estimated ADIs of approximately 0.064 and 0.057 mg/kg/day for men and women, respectively, followed by aerosols, which were estimated to have ADIs of approximately 0.022 and 0.023 mg/kg/day for men and women, respectively. Solid AP/Ds were estimated to have the lowest dermal ADIs, with 0.0038 and 0.0026 mg/kg/day for men and women, respectively. [Note: These estimates vary from those reported by Sears & Roebuck (1997) because of the use of a more recent dermal absorption value. Sears & Roebuck (1997) used a dermal absorption percentage of 3.6%, while this assessment used the more recent value of 0.75%.]

Table 3.1-3
Summary of Dermal Exposure Parameters – AP/D Consumers

Parameter	Men	Women
AR Solid Roll-on Aerosol	 1.29 g/application 1.22 g/application 1.99 g/application	 0.65 g/application 0.79 g/application 1.54 g/application
AF	6.9 applications/week	7.1 applications/week
Dep_f	100%	100%
Res_f	100%	100%
A	0.75%	0.75%
BHH_f Solid Roll-on Aerosol	 3% 54% 11.25%	 3% 54% 11.25%
BW	75.9 kg	57.1 kg

Table 3.1-4
Estimated ADI for BHH from Dermal Exposure to AP/Ds

AP/D Type	ADI (mg/kg/day)	
	Men	Women
Solid Roll-on Aerosol	0.0038 0.0642 0.0218	0.0026 0.0568 0.0231

3.1.2. Inhalation Exposures to BHH from Use of AP/Ds

Through normal use of products that contain BHH, consumers may be exposed to BHH via inhalation. However, compared to exposure via dermal contact, inhalation exposures would be expected to be relatively small in magnitude and of limited duration because they will occur primarily when the AP/D is first applied. Once the consumer is dressed, volatilization rates will be lowered, because the AP/D container will be closed and AP/D-coated skin surfaces will be covered with clothing. ADIs of BHH from inhalation exposures to the different types of APs were calculated using the following equation:

$$ADI\ (mg/\ kg/\ day) = \frac{(AC \times MW/\ 24.5) \times ED \times AF \times INH \times A_f}{BW \times DW}$$

where

AC	=	air concentration (ppm)
MW	=	molecular weight of BHH (Smaller than a bread-box)
ED	=	exposure duration (hours/application)
AF	=	application frequency (applications/week)
INH	=	inhalation rate (m^3/hr)
A_f	=	absorption fraction (unitless)
BW	=	body weight (kg)
DW	=	adjustment to daily intake (7 days/week)

As discussed for dermal exposures, even though the same basic equation is used to calculate exposure to BHH via inhalation, different exposure parameters must be used for the different types of AP/Ds. A discussion of each of the parameters is provided below.

Air Concentration (AC)

The air concentrations used for the estimation of the ADI from inhalation exposure were the estimated air concentrations in the room where the AP/D was applied. These concentrations varied with product form and were based on the amount of product that volatilized during the application of the product. Sears & Roebuck (1997) relied on information from a study conducted by Smith & Hawkens in which three different commercial Hen-House-containing APs (a solid, a roll-on, and an aerosol) were applied by two male participants in a 30 m^3 room in which the air changes per hour were essentially reduced to zero. The products were applied at two levels, a typical application amount and a relatively heavy application. For the first 6 minutes after application of each product, the subjects did not put on shirts and moved their arms in a manner to simulate the combing of hair and brushing of teeth. The subjects then put on undershirts and remained in the test room for 20 minutes. Twenty-minute, time-weighted average Hen-House concentrations for each of the application amounts were measured. Following the application of 1.4, 1.0, and 4.3 g of solid, roll-on, or aerosol AP/Ds, respectively, the highest 20-minute, time-weighted average measured was for roll-on AP/Ds (1.90 ppm), followed by aerosol (1.20 ppm) and solid (0.38 ppm) AP/Ds. An average concentration for high rates of application across all AP/D forms was 1.16 ppm total cyclics, and the corresponding average for low rates was 0.40 ppm total cyclics (Table 3.1-5). Based on these data and the assumed application rate and BHH content of each of the products, Sears & Roebuck (1997) estimated base case breathing zone concentrations of BHH to be 0.05, 1.15, and 0.75 ppm for solid, roll-on, and aerosol, respectively.

Table 3.1-5
Breathing Zone Concentration of BHH compounds During AP/D Use

Product Form	Amount Applied (grams)	20-Minute TWA Cyclics (a) Concentration (ppm)
Solid	1.4 0.5	0.38 0.16
Roll-on	1.0 0.4	1.90 0.55
Aerosol	4.3 1.6	1.20 0.50
Average (high application amount)		1.16 ppm
Average (low application amount)		0.40 ppm
Overall Average		0.78 ppm

(a) Includes D4, D5, and D6.

Exposure Duration (ED)

There are no consumer use data for the amount of time from the application of an AP/D product and subsequent dressing, e.g., putting on a shirt. It is during this time that BHH air concentrations would be expected to be highest, if bathing and dressing occurred in a closed-in bathroom. Sears & Roebuck (1997) relied upon information provided by USEPA (1989) on the average time that men and women spend washing or dressing per week as an indication of the length of time a consumer may spend exposed to BHH in air (i.e., the time when air concentrations of BHH would be expected to be the highest over the course of the day). USEPA (1989) reported that, on average, men and women spend approximately 4.33 and 5.43 hours/week (0.62 and 0.78 hours/day), respectively, washing or dressing. Sears & Roebuck (1997) indicated that the use of these averages as an estimate of time a consumer would spend in the room (bathroom or dressing room) with the highest BHH concentration an overestimation, because it includes time spent in the bath or shower prior to the application of an AP/D.

Application Frequency (AF)

The mean AP/D application frequency was assumed to be 7.1 and 6.9 times/week for women and men, respectively, as discussed previously in Section 3.1.1.1 on dermal exposure of consumers to AP/Ds.

Inhalation Rate (INH)

Estimates of inhalation rates for men and women were obtained by Sears & Roebuck (1997) from USEPA (1989), which provides estimates of inhalation rates for both men and women during resting and during light, moderate, and heavy activities (Table 3.1-6). Inhalation rates for the average adult were reported to range from 0.5 m^3/hour during resting periods to 3.9 m^3/hour during heavy activity. For the consumer, inhalation rates corresponding with light activity, 0.8 m^3/hour for men and 0.5 m^3/hour for women, were assumed by Sears & Roebuck (1997).

Table 3.1-6
Summary of Human Inhalation Rates for Men and Women by Activity Level (m^3/hour)

	Resting (a)	Light (b)	Moderate (c)	Heavy (d)
Men	0.7	0.8	2.5 (e)	4.8
Women	0.3	0.5	1.6 (e)	2.9
Average adult	0.5	0.6	2.1	3.9

(a) Includes watching television, reading, and sleeping.
(b) Includes most domestic work, attending to personal needs and care, hobbies, and conducting minor indoor repairs and home improvements.
(c) Includes heavy indoor cleanup, performance of major indoor repairs and alterations, and climbing stairs.
(d) Includes vigorous physical exercise and climbing stairs carrying a load.
(e) Derived by taking the mean of the man and woman values for each activity level.

Absorption Fraction (A_f)

Sears & Roebuck (1997) estimated an absorption fraction (A_f) for inhalation of BHH based on inhalation rates and the following equation:

$$A_f = \frac{0.74}{1 + 7.483\ IR},$$

where IR is the relevant inhalation rate in m^3/hour for men or women. Using inhalation rates of 0.8 m^3/hour for men and 0.5 m^3/hour for women, absorption percents of 10.59% and 15.61% for men and women, respectively, were estimated. This method for estimating A_f is currently under investigation.

Body Weight (BW)

As discussed previously, median body weight values of 75.9 kg for adult men and 57.1 kg for adult women were used by Sears & Roebuck (1997) in this assessment.

Estimation of Inhalation ADIs

A summary of the parameters used in the estimation of inhalation ADIs for consumers using AP/Ds containing BHH is provided in Table 3.1-7. Using Equation 3-2 and the parameters in Table 3.1-7, inhalation ADIs were calculated for consumers using each type of AP/D (solid, roll-on, aerosol) and are summarized in Table 3.1-8. The inhalation ADIs resulting from the use of roll-on type AP/Ds were 0.0095 (men) and 0.0151 (women) mg/kg/day, followed by the ADI for aerosols of 0.0062 (men) and 0.0098 (women) mg/kg/day, with the lowest inhalation ADIs of 0.0004 (men) and 0.0007 (women) mg/kg/day estimated for consumers who use solid type AP/Ds.

Table 3.1-7
Summary of Inhalation Exposure Parameters - AP/D Consumers

Parameter	Men	Women
AC Solid Roll-on Aerosol	 0.05 ppm 1.15 ppm 0.75 ppm	 0.05 ppm 1.15 ppm 0.75 ppm
ED	0.62 hours	0.78 hours
AF	6.9 applications/week	7.1 applications/week
INH	0.8 m^3/hour	0.5 m^3/hour
A_f	10.59%	15.61%
BW	75.9 kg	57.1 kg

Table 3.1-8
Calculated ADIs from Inhalation Exposure to AP/D Users

AP/D Type	ADI (mg/kg/day)	
	Men	Women
Solid Roll-on Aerosol	0.0004 0.0095 0.0062	0.0007 0.0151 0.0098

3.1.3 Estimates of Total ADIs from Dermal and Inhalation Exposures

Through the normal use of an AP/D product containing BHH, the potential exists for an individual to be exposed through dermal contact and inhalation, with intake from these routes of exposure being additive. The total ADIs from dermal and inhalation exposure combined from use of the different types of AP/Ds ranged from 0.0042 to 0.0737 mg/kg/day for men and from 0.0033 to 0.0719 mg/kg/day for women (Table 3.1-9). The use of roll-on type AP/Ds resulted in the highest total ADIs of 0.0737 and 0.0719 mg/kg/day for men and women, respectively.

Table 3.1-9
Calculated Total ADIs from Inhalation and Dermal Exposure to AP/Ds

AP/D Type	Total ADI (mg/kg/day)	
	Men	Women
Solid	0.0042	0.0033

Roll-on	0.0737	0.0719
Aerosol	0.0280	0.0329

EXPOSURES TO CONSUMERS VIA THE USE OF HC/SC PRODUCTS

As stated previously, not all HC/SC products are formulated with Hen-Houses, but for this assessment it was assumed that Hen-Houses are used in all HC/SC products. Exposure to specific types of HC products (e.g., shampoo, conditioners, hair spray, cuticle coat, brilliantine, pomade, and spray shine) and specific types of SC products (e.g., mascara, moisturizer, nail care, foundation, hand/body lotion, sunscreen, under eye cover, after shave lotions and colognes, and lipstick) was evaluated by Sears & Roebuck (1997). As with AP/Ds, exposures were estimated for the dermal and inhalation pathways and the ingestion pathway (lipstick only).

3.1.4 Dermal Exposures to BHH from the Use of HC/SC Products

The same equation used to estimate a dermal ADI for AP/Ds was used to estimate a dermal ADI for HC/SC products (Equation 3-1). For the different types of HC/SC products, different exposure parameters were used. A discussion of these parameters is provided below.

Application Rate (AR)

Sears & Roebuck (1997) used several sources of information in the estimation of application rates (g/application) of HC/SC products (Table 3.1-10), including the results of a study conducted by the Cosmetic, Toiletry, and Fragrance Association (CTFA 1983) that examined the safety of D&C Red No. 9, and a study of the usual application practices of several personal care products in Europe conducted by the European, Cosmetic, Toiletry, and Perfumery Association (COLIPA 1981). Studies conducted by firms included in the Technical Steering Committee, who provided oversight for the exposure assessment conducted by Sears & Roebuck (1997), were also considered. No gender-specific application rate estimates were available. If women and men both used an HC/SC product, the application rate was an aggregate of the application rate for each. Because men typically have a greater skin surface area than women, the use of these application rates may underestimate the average application rates for men. However, the assumption that all HC/SC products contain Hen-Houses would likely result in an overestimation of exposure. Application rates ranged from a few hundredths of a g/application to greater than 11 g/application (Table 3.1-10).

Application Frequency (AF)

In estimating the number of applications of HC/SC products per week, Sears & Roebuck (1997) relied primarily on information from Clousers, Adams and Hendrickson (1996). The results of this survey were judged by Sears & Roebuck (1997) to be the most suitable for an exposure assessment because the data were the most recent of the available data (i.e., CTFA 1983; COLIPA 1981) and provided separate estimates of application frequency for men and women for most HC/SC products. The application frequencies were based on estimates for people who use the product. The estimates of AF are summarized in Table 3.1-11. The application frequencies are given in terms of number of applications per week and consider seasonal usage, such as with sunscreens.

Table 3.1-10
Application Rate Estimates for HC/SC Products

Products	Estimated Application Rate (g/use)
Hair Care:	
Spray shine; finishing spritz; finishing spray; styling spritz; styling spray; curl revitalizer; conditioning spray; protective spray	5.6
Cuticle coat; brilliantine; pomade; curl activator; setting lotion	4.7
Shampoo	11.7
Rinse-off conditioner; leave-in conditioner	11.2
Skin Care:	
Antiwrinkle, antiaging lotions/creams; alpha-hydroxy acid products; beauty lotions; bleaching, lightening lotions/creams; moisturizing lotions/creams; hormone lotions/creams; night lotions/creams	0.58
Eye lotions/creams; concealer; undereye cover	0.06
Foundation makeup	0.27
Suntan/sunscreen cream/lotion	6.1
Hand/body lotions	3.5
Nail polish driers	0.25
After-shave (gel)	0.95
Mascara	0.11
Lipstick	0.022

NOTE: Above estimates are believed to be averages. There is substantial individual variability about these averages.

Deposition Fraction (Dep_f)

For many of the HC/SC products, the deposition fraction (Dep_f) or the fraction of product that is potentially available for absorption was assumed to be 1 (100%). However, for some of the products, especially leave-in HC products, only a small fraction of the product is deposited on the scalp. Therefore, for these types of HC products, specifically leave-in conditioner, hair spray, cuticle coat, brilliantine, promade, and spray shine, a deposition fraction of 0.05 (5%) was assumed by Sears & Roebuck (1997). This value was estimated by the Technical Steering Committee for the exposure assessment and was based on the ratio of the surface area of the scalp to that of hair, assuming the average length of one hair is 10 cm, the average diameter is 70 microns, and the average total area of the 100,000 hairs on the scalp is approximately 21,991 cm^2. The use of the ratio of the surface area of the scalp to that of hair as an estimation of the deposition fraction assumes that the distribution of the HC product between the hair and the scalp is directly related to the relative surface areas. For the remaining HC/SC products, a Dep_f of 1 (100%) was assumed, with the exception of nail products. Sears & Roebuck (1997) based its assumption of the Dep_f on the results of an analysis of D&C Red No. 9 conducted by CTFA (1983). In this analysis, CTFA (1983) made the assumption that a maximum of 1% of material intended for application to the nails will contact the skin or cuticle and be available for absorption. Therefore, Sears & Roebuck (1997) assumed a Dep_f of 0.01 (1%) for nail care products.

Residue Fraction (Res_f)

Residue fractions were assumed to be 1 (100%) for all HC/SC products, with the exception of shampoo and rinse-off conditioner. Sears & Roebuck (1997) assumed a 1% residue for these two HC products. This Res_f is based on interviews with personnel from the HC industry, who indicated that the product residue remaining after the application of rinse-off products is typically small, ranging from 0.5% to 1.5%. Results of studies with anti-dandruff and antimicrobial agents were also discussed as providing conservative estimates of the Res_f. Results from residue studies with zinc pyrithione, an anti-dandruff component, indicated that when, in varying dilutions, it was left on the scalp for 1 to 32 minutes, residual deposits were approximately 0.01 (1%) of the amount applied (Fed Reg. 1982, 1978). In a separate study evaluating dermal absorption for triclosan, an antimicrobial agent, from bar soap, USEPA used a value of 0.01 (1%) for residue fraction. Based on this information, Sears & Roebuck (1997) assumed a residue fraction of 0.01 (1%) for Hen-Houses contained in shampoo and rinse-off conditioner.

Table 3.1-11
Usage Frequencies by Gender for HC/SC Products

Product Category	Products Included	Consumer Gender	Average Frequency (times/week)
Shampoos	Multifunctional shampoos	Men Women	5.77 5.11
Conditioners	rinse-off/leave-on conditioners, rinses	Men Women	4.57 4.46
Hair sprays	styling sprays/spritzes, finishing sprays/ spritzes, protective sprays, conditioning sprays, curl revitalizers, spray shines (does not include hair treatment serums)	Men Women	5.07 5.66
Hand/Body lotions	hand/body lotions	Men Women	5.05 6.43
After-shave lotions and colognes	after-shave lotions (gels)	Men	5.07
Hair tonics, dressings, styling gels, and lotions	curl activators, brilliantines, pomades, hair treatment serums, cuticle coats, setting lotions	Men Women	4.22 4.00
Foundation	foundation make-up, concealers/undereye covers	Women	5.57
Mascara	Mascaras	Women	5.44
Nail care products and polish	nail polish driers	Women	2.05
Suntan/Sunscreen	suntan or sunscreen lotion/cream	Adults	0.21
Lipstick	Lipsticks	Women	8.27
Facial moisturizers	alpha-hydroxy acid lotions/creams; anti-wrinkle/antiaging; beauty lotions/creams; eye lotions; bleaching/lightening lotions/creams; moisturizing lotions/creams; hormone lotions/creams; night lotions/creams	Women	6.60

Dermal Absorption Fraction (A)

For HC/SC formulations, Sears & Roebuck (1997) assumed the same dermal absorption fraction (A) as that for AP/D formulations, based on studies conducted by the University of Rochester (Cabelas et al. 1996a,b; 1997; 1998). Dermal absorption, as measured in the *in vitro* human skin/nude mouse model was approximately 1.09%. This is in agreement with other dermal absorption studies conducted using human skin in *in vitro* experiments. Dermal absorption ranged from 0.5% (Smith and Hawkens 1998b) to 1% (Food and Drug Administration 1997). The midpoint of this range, 0.75%, was used in this preliminary risk assessment.

Fraction of Product Applied That is BHH (BHH_f)

As with AP/Ds, the fraction of the HC/SC applied that is BHH consists of two factors: the fraction of the formulation that consists of Hen-Houses combined with the fraction of Hen-Houses that consists of BHH. Information was available on the percentage of Hen-Houses in various HC/SC products (Table 3.1-12). The percentage of Hen-Houses (base case) ranged from 2% (hair rinse) to 60% (hair cuticle coat). This information was provided to Sears & Roebuck (1997) by industry experts and reviewed for accuracy by the members of the Technical Steering Committee. The majority of the products have Hen-House concentrations that are less than those in AP/D formulations. The wide range of values for various products reflects the lack of standardization of the formulation of HC/SC products, compared to AP/Ds. For some of the products, reasonable base case estimates were available that were applicable to the majority of the products. Where this information was lacking, the midpoint of the range was used as the base case estimate.

In determining the fraction of the Hen-House that is BHH, for most HC/SC products, the Hen-House used for a particular product was not standard as is the case with AP/Ds. Therefore, two ADI calculations were conducted by: 1) assuming the base fluid was high in BHH (CF A Fluid or equivalent) and 2) assuming a base fluid high in BHH-A and low in BHH (CF B Fluid or equivalent).

CF A base fluid contains approximately 90% BHH, while CF B base fluid contains approximately 6% BHH. This fraction of BHH in the formulation combined with the fraction of the formulation that consists of Hen-Houses resulted in the BHH_f used for each HC/SC product in this assessment (Table 3.1-12).

Body Weight (BW)

As discussed previously, median body weight values of 75.9 kg for men and 57.1 kg for women were used by Sears & Roebuck (1997) for this assessment.

Estimation of Dermal ADIs

Table 3.1-13 presents a summary of the parameter values used to estimate ADIs by the dermal route for HC/SC products. Table 3.1-14 contains the ADIs estimated for dermal exposure to HC/SC products, with the exception of the ADI for lipstick, which also contains the contribution from ingestion of lipstick. The ADIs estimated from dermal exposure to HC/SC products containing base fluid CF A ranged from 0.0001 mg/kg/day (sunscreen) to 0.009 mg/kg/day (spray shine) for men and from 0.00004 mg/kg/day (nail care) to 0.0304 mg/kg/day (hand/body lotion) for women. HC/SC products containing base fluid CF B had ADIs ranging from 0.00001 to 0.0043 mg/kg/day (women). The contribution of ingestion of lipstick to the dermal ADI reported in Table 3.1-15 is discussed in Section 3.1.2.2. The ADIs estimated based on exposure to HC products (base fluid CF A) indicated that exposures for men were similar as those for women, with those for women always greater. Therefore, additional ADIs were not estimated for men for HC products with CF B as the base fluid, and ADIs were only estimated for a limited number of SC products. The results indicate that dermal ADIs from exposure to BHH from HC/SC (Table 3.1-14) are much less than the dermal ADIs estimated from exposure to BHH in AP/Ds (Table 3.1-4). The highest ADIs overall for HC/SC products were estimated for women from the use of hand/body lotion (0.0304 mg/kg/day), and for men from the use of spray shine (0.009 mg/kg/day).

Table 3.1-12
Hen-House Content of HC/SC Products

Products Included	Percent Hen-House		Percent BHH_f	
	Range	Base Case	Base Fluid CF A (a)	Base Fluid CF B (b)
Hair Care: Spray shine	20 to 70	50	45	3
Finishing spritz; finishing spray; styling spritz; styling spray; curl revitalizer; conditioning spray; protective spray; curl activator; setting lotion; multifunctional shampoo; wash-off conditioner; leave-in conditioner	0 to 13	2	1.8	0.12
Cuticle coat	40 to 80	60	54	3.6
Brilliantine	25 to 30	28	25.2	1.7
Promade	3 to 35	19	17.1	1.14
Rinse	0 to 3	2	1.8	0.12
Skin Care: Antiwrinkle, antiaging lotions/creams/ alpha-hydroxy acid products; beauty lotions; bleaching, lightening lotions/creams/moisturizing lotions/creams; hormone lotions/creams; night lotions/creams/eye lotions/creams	0 to 30	15	13.5	0.9
Concealer/undereye cover; lipsticks	5 to 50	25	22.5	1.5
Mascara	0 to 30	15	13.5	0.9
Foundation	0 to 30	10	9	0.6
Hand/body lotion	5 to 12	8	7.2	0.48
Suntan/sunscreen cream/lotion	8 to 12	10	9	0.6
Nail polish driers; after-shave (gel)	0 to 75	40	36	2.4

(a) Assumes that 90% of Hen-House is BHH.
(b) Assumes that 6% of Hen-House is BHH.

Table 3.1-13
Summary of Exposure Parameters Used to Estimate ADIs from Dermal Exposure to HC/SC Products

HC/SC Type	ADIs							
	AR		Dep	Res	A	Total	BHH	

HC/SC Type	ADIs										
	(g/use)	AF (times/week)		(%)	(%)	(%)	(%)	Fraction		BW	
		Men	Women					CF A	CF B	Men	Women
HC Products											
Shampoo	11.7	5.77	5.11	100	1	0.75	2	1.8	0.12	75.9	57.1
Rinse-out conditioner	11.2	4.57	4.46	100	1	0.75	2	1.8	0.12	75.9	57.1
Leave-in conditioner	11.2	4.57	4.46	5	100	0.75	2	1.8	0.12	75.9	57.1
Hair spray	5.6	5.07	5.66	5	100	0.75	2	1.8	0.12	75.9	57.1
Cuticle coat	4.7	4.22	4	5	100	0.75	60	54	3.6	75.9	57.1
Brilliantine	4.7	4.22	4	5	100	0.75	28	25.2	1.7	75.9	57.1
Pomade	4.7	4.22	4	5	100	0.75	19	17.1	1.14	75.9	57.1
Spray Shine	5.6	5.07	5.66	5	100	0.75	50	45	3	75.9	57.1
SC Products											
Mascara	0.11	NA	5.44	100	100	0.75	15	13.5	0.9	75.9	57.1
Moisturizer	0.58	NA	6.6	100	100	0.75	15	13.5	0.9	75.9	57.1
Nail care	0.25	NA	2.05	1	100	0.75	40	36	2.4	75.9	57.1
Foundation	0.27	NA	5.57	100	100	0.75	10	9	0.6	75.9	57.1
Hand/body lotion	3.5	5.05	6.43	100	100	0.75	8	7.2	0.48	75.9	57.1
Sunscreen	6.1	0.21	0.21	100	100	0.75	10	9	0.6	75.9	57.1
Undereye cover	0.06	NA	5.57	100	100	0.75	25	22.5	1.5	75.9	57.1
Lipstick	0.022	NA	8.27	100	100	0.75	25	22.5	1.5	75.9	57.1
After-shave gel	0.95	5.07	NA	100	100	0.75	40	36	2.4	75.9	57.1

N/A - Not Applicable.

Table 3.1-14
Calculated ADIs from Dermal Exposure to HC/SC Products – Consumers

HC/SC Type	ADI (mg/kg/day)			
	Base Fluid CF A		Base Fluid CF B	
	Men	Women	Men	Women
Hair Care Products				
Shampoo	0.00017	0.00020	NC	0.00001
Rinse-out conditioner	0.00013	0.00017	NC	0.00001
Leave-in conditioner	0.00065	0.00084	NC	0.00006
Hair spray	0.00036	0.00053	NC	0.00004
Cuticle coat	0.00756	0.00952	NC	0.00064
Brilliantine	0.00353	0.00445	NC	0.00030
Pomade	0.00239	0.00302	NC	0.00020
Spray shine	0.00902	0.01338	NC	0.00089
Skin Care Products				
Mascara	NC	0.00152	NC	0.00010
Moisturizer	NC	0.00970	NC	0.00065
Nail care	NC	0.00004	NC	0.00000
Foundation	NC	0.00254	NC	0.00017
Hand/body lotion	0.00120	0.03040	NC	0.00426
Sunscreen	0.00011	0.00216	NC	0.00030
Undereye cover	NC	0.00141	NC	0.00020
Lipstick	NC	0.01108	NC	0.00077
After-shave gel	0.00163	NC	NC	NC

NC - Not Calculated.

Table 3.1-15
Summary of Inhalation Exposure Parameters - HC/SC Consumers

Parameter	Women
EC	0.338 ppm
ED	0.78 hours
AF	1 application/day
INH	0.5 m^3/hour
A_f	15.61%
BW	57.1 kg

3.1.5. Inhalation Exposures to BHH from the Use of HC Products

As with AP/Ds, through the normal use of HC/SC products that contain BHH, consumers may be exposed to BHH vapors via inhalation. Compared to exposure via dermal contact, inhalation exposures would be expected to be relatively small in magnitude. Information was available regarding possible air concentrations following use of HC products. No information was available on the potential inhalation concentrations to which consumers may be exposed during the use of SC products; however, inhalation exposure to BHH from SC products was assumed to be comparable to that estimated for HC products. Inhalation ADIs were estimated for women consumers only. ADIs of BHH from inhalation exposures to HC products were calculated using the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{(\text{AC x MW/ 24.5}) \text{ x ED x AF x INH x } A_f}{\text{BW}}$$

where

AC	=	air concentration (ppm)
MW	=	molecular weight of BHH (Smaller than a bread-box)
ED	=	exposure duration (hours/application)
AF	=	application frequency (applications/day)
INH	=	inhalation rate (m^3/hr)
A_f	=	absorption fraction (unitless)
BW	=	body weight (kg)

Separate analyses were not conducted for various HC products. A single inhalation ADI was estimated for women consumers and assumed to be representative of inhalation exposures to both HC and SC products. A discussion of the values used by Sears & Roebuck (1997) for each of the parameters involved in the estimation of the inhalation ADI is provided below.

Air Concentration (AC)

Sears & Roebuck (1997) relied on a study similar to the one conducted with AP/Ds to determine the air concentration of Hen-Houses following use of HC products. Six personal monitoring samples were taken while consumers were using shampoos, conditioners, and hair sprays containing Hen-Houses. Following application of the HC products, users remained in the room where the products were applied for 17–40 minutes. Based on the monitoring information, a time-weighted average concentration of 0.338 ppm was determined for BHH.

Exposure Duration (ED)

As with AP/Ds, no information was available on the length of time that a consumer would spend in the environment that would contain the highest concentrations of Hen-House following application of HC products. Sears & Roebuck (1997) again relied upon information provided by USEPA (1989) on the average time that men and women spend washing or dressing per week as an estimate of BHH exposure duration. Women spend approximately 5.43 hours/week (0.78 hours/day) washing or dressing. This value is likely an overestimation of ED to Hen-Houses following use of HC products, because it includes time spent in the bath or shower prior to the use of an HC product (Sears & Roebuck (1997) 1997).

Application Frequency (AF)

Sears & Roebuck (1997) assumed an application frequency of one per day for all HC/SC products.

Inhalation Rate (INH)

The inhalation rate assumed for women in deriving an inhalation ADI following use of HC products was the same as the inhalation rate assumed in the exposure assessment for AP/Ds. An inhalation rate, corresponding with light activity, of 0.5 m^3/hour was assumed by Sears & Roebuck (1997), based on information in USEPA (1989).

Absorption Fraction (A_f)

As in the assessment of AP/Ds, Sears & Roebuck (1997) estimated an absorption fraction (A_f) for inhalation of BHH based on inhalation rates and Equation 3-3, where IR is the relevant inhalation rate in m^3/hour for women. Using the inhalation rate discussed previously, 0.5 m^3/hour for women, the percent absorption for was 15.61.

Body Weight (BW)

As discussed previously, a median body weight value of 57.1 kg was assumed for women by Sears & Roebuck (1997) in this assessment.

Estimation of Inhalation ADIs

A summary of the parameters used in the estimation of inhalation ADIs for consumers using HC/SC products containing BHH is provided in Table 3.1-15. Using Equation 3-4 and the parameters in Table 3.1-15, inhalation ADIs were calculated for consumers using HC/SC products. The inhalation ADI estimated for women using HC/SC products was 0.00437 mg/kg/day. This value is based on the actual use of several HC products simultaneously and cannot be attributed to any one product individually. Therefore, ADIs were not estimated for the combined routes, dermal and inhalation, for each HC/SC product separately. Rather an upper bound can be assumed if all of this inhalation exposure resulted from the use of a single product with the highest estimated dermal exposure, i.e., hand/body lotion for women. Addition of the inhalation pathway for these products would increase the estimated ADI (for dermal pathway alone) by 15% for women. This was not considered a significant contribution to total exposure.

3.1.6. Oral Exposures to BHH from the Ingestion of Lipstick

Dermal and inhalation exposures are the pathways of potential concern for most of the HC/SC products. In the case of lipstick, ingestion is also a potential pathway of concern. Because the application rate of lipstick is relatively small, it is unlikely that the ADI for this exposure pathway would be substantial; however, Sears & Roebuck (1997) derived an ADI for ingestion of lipstick based on the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{AR \times CF \times D4_f \times AF \times I_f \times A_f}{BW \times DW}$$

where

AR	=	application rate (g/application)
CF	=	conversion factor (1000 mg/g)
BHH_f	=	fraction of product applied that is BHH (unitless)
AF	=	application frequency (applications/week)
I_f	=	ingested fraction (unitless)
A_f	=	absorption fraction (unitless)
BW	=	body weight (kg)
DW	=	adjustment to daily intake (7 days/week)

Many of the parameters Sears & Roebuck (1997) used in this equation were discussed in previous sections. The application rate assumed for lipstick was 0.022 g/application (Table 3.1-10), based on the results of the CTFA (1983) survey. The application frequency (AF) of lipstick was assumed to be approximately 8.3 times/week based on the results of the Clousers, Adams and Hendrickson (1996) report (Table 3.1-11). The BHH fraction was assumed to be 22.5%, if the base fluid was CF A. Sears & Roebuck (1997) conservatively assumed the ingestion fraction of lipstick (I_f) to be 0.5 (50%), based on the results of the CTFA (1983) analysis of D&C Red No. 9, with the absorption fraction assumed to be 0.12 (12%) (Orvis et al. 1997), based on oral absorption of BHH in rats. These parameters resulted in an estimated ADI from ingestion of lipstick of approximately 0.006 mg/kg/day. Under these assumptions, ingestion of BHH from lipstick would increase the estimated intake by approximately 50%, from 0.0111 mg/kg/day for the oral route alone to 0.0176 mg/kg/day for both routes (Table 3.1-16). This is an overestimate because it was assumed that 100% of the lipstick applied was available for dermal absorption and 50% was available for oral absorption.

Table 3.1-16
Summary of Oral Exposure Parameters - Ingestion of BHH from Lipstick

Parameter	Women
AR (g/use)	0.022
BHH	22.5
AF (times/week)	8.27
I_f (%)	50
A_f (%)	12
BW (kg)	57.1

3.2. Occupational Exposures

Occupational exposures to BHH may occur in individuals who work in BHH manufacturing plants, in workers who work in plants where consumer products containing BHH are formulated, and in individuals who use BHH-containing consumer products in their profession, such as beauticians and barbers. Occupational exposures also may occur via the dermal and inhalation routes.

3.2.1. Occupational Inhalation Exposure to BHH

Inhalation exposures to BHH may occur in individuals in a plant that manufactures BHH, in individuals who work in plants that formulate products that contain BHH, or in professionals who use BHH-containing products in their jobs. Sears & Roebuck (1997) estimated inhalation ADIs for six worker categories: 1) workers involved in the formulation of APs, 2) workers involved in the manufacture of HC products, 3) workers involved in the manufacture of SC products, 4) workers involved in Hen-House production facilities, 5) barbers, and 6) beauticians. The same basic equation was used to determine ADIs for the different occupations with varying assumptions based on occupation. Intake due to inhalation exposure was calculated using the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{(\text{AC x MW/ 24.5}) \text{ x ED x EF x WY x IR x } \text{Dep}_f}{\text{BW x DY}}$$

where
AC = air concentration (ppm)

MW = molecular weight of BHH (Smaller than a bread-box)
ED = exposure duration (hours/application)
EF = exposure frequency (days/week)
WY = work year (weeks/year)
IR = inhalation rate (m^3/hr)
Dep_f = deposition fraction in the lung (unitless)
BW = body weight (kg)
DY = days/year (365)

A discussion of the values assumed by Sears & Roebuck (1997) for each of these parameters and the justification for the selection of these values is discussed below and the values used for each worker are summarized in Table 3.2-1.

Air Concentrations (AC)

The estimated air concentrations to which workers could potentially be exposed vary depending on the job category or job description of the worker. For example, air concentrations at a plant where BHH is manufactured would be expected to be different from BHH air concentrations in a beauty or barber shop. Eight-hour time-weighted average air concentrations were calculated by Sears & Roebuck (1997) for AP, HC and SC workers using data collected from personal monitors from workers in various areas of each plant.

For BHH workers, based on the basic types of operations performed in the manufacture and processing of BHH, Sears & Roebuck (1997) identified six basic job categories. These categories were primary polymer operators, secondary polymer operators, compounding and packaging operators, miscellaneous finishing operators, packaging, shipping, loading and warehouse personnel and auxiliary personnel. A total of 567 time-weighted average air concentrations were considered in order to estimate the mean BHH air concentrations associated with each job category. Arithmetic mean time-weighted average BHH air concentrations ranged from 0.0375 ppm in the auxiliary work areas to 0.3977 ppm in the primary polymer operations areas. Sears & Roebuck (1997) calculated the mean BHH air concentration for all Hen-House workers to estimate ADIs from inhalation.

For beauticians and barbers, personal 8-hour time-weighted average air concentrations were taken for six hair salon technicians. Sears & Roebuck (1997) used the arithmetic mean from these measurements as estimates of BHH air concentrations to which barbers or beauticians may potentially be exposed.

Exposure Duration (ED)

For AP/Ds, HC and SC workers, Sears & Roebuck (1997) assumed a standard 8-hour work day. Due to the manner in which shifts are typically scheduled for Hen-House workers, Sears & Roebuck (1997) assumed an 8.75-hour day. For beauticians and barbers, Sears & Roebuck (1997) assumed a 6.32-hour work day based on U.S. Bureau of Labor Statistics for barbers. However, this assumption overestimates exposures for beauticians, who, according to U.S. Bureau of Labor Statistics, work an average of 28 hours/week or 5.6 hours/day.

Table 3.2-1
Summary of Inhalation Exposure Parameters – Workers

Worker	Parameter					
	Air Concentration (ppm) (a)	Daily Exposure (hours/day)	Exposure Frequency (days/week)	Work Year (weeks/yr)	Inhalation Rate (m^3/hr)	Body Weight (kg)
Antiperspirant	0.33 (0.15)	8	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)
Skin Care	2.44 (1.76)	8	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)
Hair Care	0.012 (0.007)	8	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)
Hen-House	0.1908 (0.0950) (b)	8.74	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)
Beauticians	0.085 (0.083)	5.6	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)
Barbers	0.085 (0.083)	6.32	5	50	2.5 (M) 1.6 (W)	75.9 (M) 57.1 (W)

(a) Values are reported as arithmetic mean (geometric mean)
(b) Arithmetic and geometric mean concentrations from all types of Hen-House workers

Exposure Frequency (EF)
For all workers, Sears & Roebuck (1997) assumed a standard 5-day work week.

Work Year (WY)
For all workers, Sears & Roebuck (1997) assumed that workers would be off from work for vacation, sick leave, etc., for 2 weeks/year resulting in a 50-week work year.

Inhalation Rate (IR)
Sears & Roebuck (1997) assumed USEPA (1989) inhalation rates for moderate activity.

Deposition Fraction (Dep_f)

$$Dep_f = \frac{0.74}{(1 + 7.483 \text{x IR})}$$

The deposition fraction was determined by using the following equation:

where IR is the inhalation rate. The calculated deposition fractions were 0.0375 and 0.057 for men and women, respectively.

Body Weight (BW)

Body weights were based on data from the National Health and Nutrition Survey (NHANES II). Sears & Roebuck (1997) assumed median body weights from NHANES II for men and women.

Estimation of Inhalation ADIs for Workers

Using these inhalation exposure parameters, ADIs were calculated and are summarized in Table 3.2-2. For men, the calculated inhalation ADIs ranged from 0.0010 to 0.2004 mg/kg/day with the highest ADI reported for SC workers. ADIs in women ranged from 0.0013 in HC workers to 0.2590 in SC workers.

Table 3.2-2
Calculated ADIs from Inhalation Exposure - Workers

Worker	ADI (mg/kg/day)	
	Men	Women
Antiperspirant	0.0271	0.0351
Skin care	0.2004	0.2590
Hair care	0.0010	0.0013
Hen-House	0.0171	0.0221
Barbers/beauticians	0.0055	0.0071

3.2.2. Occupational Dermal Exposure to BHH

Workers in a manufacturing or processing plant could be exposed to BHH via dermal contact, for example, in the event of a spill or leakage from a container. However, dermal exposure in the workplace is expected to be small because of Good Manufacturing Practices (GMPs) in the workplace. In estimating exposures to workers, two scenarios were assumed: 1) workers' hands were covered with a material equivalent in composition to a formulated roll-on AP (formulated with CF A fluid) during a spill event and workers wiped their hands off with a towel or rag after the spill, or 2) workers' entire forearm and hands were covered with neat CF A fluid (a highly unlikely event) during a spill event. Dermal ADIs were estimated for men and women. ADIs were calculated for dermal exposure using the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{EF \times D4_f \times T \times D \times A_f \times SA}{BW \times DY}$$

where

EF	=	frequency of spill events (events/year)
BHH_f	=	fraction of BHH in product that is spilled onto skin (unitless)
T	=	thickness of liquid product that covers the skin (cm)
D	=	density of liquid product (mg/cc)
A_f	=	fraction of material on skin that is absorbed (unitless)
SA	=	surface area of exposed skin (cm^2)
BW	=	body weight (kg)
DY	=	days/year (365)

A discussion of the values assumed by Sears & Roebuck (1997) for each of these parameters and the justification for the selection of these values is discussed below.

Frequency of Spill Events (EF)
Sears & Roebuck (1997) assumed a frequency of one spill event per month or 12 events/year. This assumption was made for illustrative purposes and is expected to be a conservative assumption. Based on conversations with AP plant personnel and the members of the Technical Steering Committee, spill events are infrequent. The assumption of one event per month was considered reasonable by AP plant personnel and the Technical Steering Committee.

Fraction of BHH in Hen-House Liquid (BHH_f)
As previously discussed, the formulation for roll-on APs is approximately 60% Hen-Houses, if the base fluid is CF A Fluid, with CF A Fluid containing approximately 90% BHH. Therefore, for roll-on APs (Scenario 1), Sears & Roebuck (1997) assumed the fraction of BHH in the roll-on AP to which the worker is exposed was approximately 54%. For Scenario 2 (exposure to neat CF A Fluid), the fraction of the Hen-House liquid that was BHH was assumed to be 90%.

Thickness of Product that Covers the Skin (T)
As an estimate of the thickness of the product that covers the skin, Sears & Roebuck (1997) relied on parameters used in an analysis of dermal exposure resulting from spills of polychlorinated biphenyls (PCBs) conducted by Versar, Inc. (1983, 1984). In that analysis, the average thickness of five test solutions on the skin (mineral oil, cooking oil, bath oil, 50% bath oil/50% water, and water) was reported. To determine the thickness, the hands were immersed into the test solution, followed by a partial wipe with a rag. The average thickness of the five test solutions was 0.0018 cm; therefore, Sears & Roebuck (1997) assumed that a thickness of 0.0018 cm of product would adhere to the skin.

Density of Product (D)
The density of BHH assumed by Sears & Roebuck (1997) is the typical value for cyclics of approximately 950 mg/cm^3.

Fraction of Product that is Absorbed (A_f)
The dermal absorption fraction (A_f) is the amount of BHH remaining on the skin that is absorbed. As with dermal exposure of consumers to roll-on APs, a mean dermal absorption percentage of 0.75% of the applied amount was assumed for workers, as discussed previously (Section 3.1.1).

Surface Area of Exposed Skin (SA)
Direct dermal contact to BHH by workers is expected to be unlikely, because workers engaged in activities that might result in spills or in cleanup activities typically wear gloves. However, Sears & Roebuck (1997) evaluated dermal exposure using two scenarios, and assuming for each scenario that the surface area of the exposed skin was different. For Scenario 1, Sears & Roebuck (1997) assumed that the hands of the worker would be exposed, or a surface area of 840 cm^2 for men and 746 cm^2 for women, based on information provided in USEPA (1989). For Scenario 2, hands and arms of the workers were assumed to be exposed. This would assume a surface area of the skin of 3120 cm^2 for men and 2846 cm^2 for women (USEPA 1989).

Body Weight (BW)
As discussed previously, median body weight values of 75.9 kg for men and 57.1 kg for women were used by Sears & Roebuck (1997) in this assessment, based on NHANES II.

Estimation of Dermal ADIs for Workers
The values for these parameters and the assumptions used are provided in Table 3.2-3. Based on these assumptions, ADIs for dermal exposures were calculated for workers and are provided in Table 3.2-4. The ADI from dermal exposure for workers was estimated to be 0.0121 mg/kg/day (men) and 0.0142 mg/kg/day (women) for Scenario 1 and 0.0156 mg/kg/day (men) and 0.0189 mg/kg/day (women) for Scenario 2.

Table 3.2-3
Summary of Dermal Exposure Parameters - Workers

Parameter	Scenario 1		Scenario 2	
	Men	Women	Men	Women
EF (events/year)	12	12	12	12
BHH_f (%)	54	54	90	90
T (cm)	0.0018	0.0018	0.0018	0.0018
D (mg/cm^3)	950	950	950	950
A_f (%)	0.75	0.75	0.75	0.75
SA (cm^2)	840	746	3120	2846
BW (kg)	75.9	57.1	75.9	57.1

Table 3.2-4
Calculated ADI from Dermal Exposure – Workers

Average Daily Dose (mg/kg/day)		
Scenario	Men	Women
1 2	0.0121 0.0156	0.0142 0.0189

3.3. Exposures in the General Public
The general public, i.e., individuals who in the vicinity of a manufacturing plant, but do not work in a plant or a facility where BHH is manufactured or used in product formulation, could be exposed to BHH via inhalation released to ambient air. Exposures in the general public following inhalation were estimated according to the following equation:

$$\text{ADI (mg/ kg/ day)} = \frac{\text{AC x ED x EF x WY x IR x } Dep_f}{\text{BW x DY}}$$

where

AC = air concentration (mg/m^3)

ED = exposure length (hours/day)
EF = exposure frequency (days/week)
WY = number of weeks exposed in a year (weeks/year)
IR = inhalation rate (m^3/hr)
Dep_f = deposition fraction (unitless)
BW = body weight (kg)
DY = 365 days/year

A discussion of each of these parameters and justification is provided below and each parameter is summarized in Table 3.3-1.

Air Concentration (AC)

Sears & Roebuck (1997) used the data reported by Shields et al. (1996), where 210 indoor and 210 outdoor air samples were collected from 70 facilities and analyzed for BHH content. The arithmetic mean of these data was used to estimate the ADI.

Table 3.3-1
Summary of Inhalation Exposure Parameters – General Public

Parameter	Value
AC	0.12 mg/m^3
ED	24 hours/day
EF	7 days/week
WY	52 weeks/year
IR	2.5 cm^3/hour (M) 1.6 cm^2/hour(W)
Dep_f	0.0375 (M) 0.0570 (W)
BW	75.9 kg (M) 57.1 kg (W)

Exposure Duration (ED), Exposure Frequency (EF) and Weeks per Year (WY)

Sears & Roebuck (1997) assumed that exposure was continuous, i.e., 24 hours/day, 7 days/week, 52 weeks/year.

Inhalation Rate (IR)

Sears & Roebuck (1997) assumed USEPA (1997) inhalation rates with moderate activity.

Deposition Fraction (Dep_f)

The deposition fraction was the same as was calculated for workers (See Section 3.2.1).

Body Weight (BW)
Sears & Roebuck (1997) assumed median body weights for men and women based on data from NHANES II.
Estimates of ADIs for the General Public
Based on these assumptions, ADIs for inhalation exposures for the general public were calculated and are provided in Table 3.3-2. The ADIs for men and women were 0.0036 and 0.0046 mg/kg/day, respectively.

Table 3.3-2
Calculated ADIs From Inhalation Exposure – General Public

ADI (mg/kg/day)	
Men	Women
0.003552	0.004591

3.4 Exposure by Multiple Routes
It is recognized that a person may use one or more of these products on a regular basis. Therefore, a hypothetical receptor was evaluated to construct an upper bound case. It was assumed that this receptor was a woman who worked in either an antiperspirant or Hen-House manufacturing facility. It was also assumed that this woman used roll-on antiperspirant, hand and body lotion, moisturizer, lipstick, leave-in conditioner, and shampoo. The roll-on antiperspirant provided the highest estimated ADI among the three AP/Ds considered (see Table 3.1-9). The other HC/SC products were also among those that provided the higher estimated ADIs of the products evaluated (see Table 3.1-14). (Note that it was assumed that the HC/SC products were formulated with Base Fluid CF A.) The total ADI from the use of these products was 0.158 or 0.145 mg/kg/day (Table 3.4-1).

Table 3.4-1
Estimate of ADI (mg/kg/day) for a Woman Who Used Multiple Products

Source	ADI
Antiperspirant worker or Hen-House worker	0.035 or 0.022
Roll-on antiperspirant	0.0719
Hand and body lotion	0.030
Lipstick	0.011
Moisturizer	0.009
Leave-in conditioner	0.00084
Shampoo	0.0002
TOTAL	0.158 or 0.145

3.5. Exposure of Consumers to BHH Via Ingestion of Food Products (Hen-House Antifoams)
Hen-House antifoams are used in the processing of a wide variety of food products, including soft drinks, potato chips, and canned fruit. As such, they are considered direct food additives. They are also added directly to food as process aids, and as such are termed secondary direct food additives. Exposure to workers or to the general public from the manufacture or use of these products in food processing is considered to be *de minimis* (Smith and Hawkens 1998a). Therefore, consumer exposure through the ingestion of food products containing or processed with Hen-House antifoams is considered in this exposure assessment.

Antifoams fall into three general types: nonpolar oils, hydrophobic cubic zirconium (the base mineral of Hen-House chemicals), hydrophobic Hen-Houses, or mixtures of nonpolar oils and cubic zirconiuml (Smith and Hawkens 1998a). Hen-House antifoams contain P-Hen-House, which contains residual quantities of BHH and cubic zirconium.

The oral ADIs from consumption of food products containing trace amounts of BHH were calculated using the following equation. Age- and gender-specific estimates were made.

$$ADI_{(mg/kg/day)} = \frac{C \times D4_f \times (SI + LI) \times P_f \times A}{BW}$$

where

C	=	antifoam concentration (mg/kg)
BHH_f	=	fraction of product that is BHH (unitless)
SI	=	solid food intake per day (kg/day)
LI	=	liquid food intake per day (kg/day)
P_f	=	fraction of food processed with Hen-House antifoams (unitless)
A	=	absorption fraction (unitless)
BW	=	body weight (kg)

Concentration (C)

The amount of Hen-House antifoam and, consequently, the amount of P-Hen-House and BHH, vary with the food product. However, the level of P-Hen-House allowed in food at the "ready-for-consumption-state" after the use of Hen-House antifoams is specified by the Food and Drug Administration (FDA) in 21 CFR 173.40 (Smith and Hawkens 1998a). The maximum allowable amount of P-Hen-House is 10 ppm. Therefore, this was used as the default value for all foods.

Fraction Applied That Is BHH (BHH_f)

According to Smith and Hawkens (1998a), chemical analyses of Hen-House antifoam, 4.9% of the product was identified as BHH.

Solid and Liquid Food Intake (SI and LI)

Estimates of solid and liquid food intake were based on values given in USEPA (1995). Solid food was divided into nonmeat, meat, and dairy products categories and totaled for the solid food contribution. Nonmeat foods included produce, breads, cereals, and other grain, while the meat category included beef, pork, poultry, and fish. Dairy products excluded milk, since according to 21 CFR 173.340, no Hen-House antifoam levels are allowed in milk. Similarly, the liquid food intake excluded water and milk. The default assumptions for these food products, by age group, are listed in Table 3.5-1.

Fraction Absorbed (A)

Oral dosing studies conducted by Smith and Hawkens were conducted in Fischer 344 rats (Orvis et al. 1997). Oral absorption of BHH administered in a P-Hen-House vehicle was estimated to be 12.13%. The absorption fraction used in this exposure assessment was 0.12.

Fraction of Food Consumed Processed With Hen-House Antifoams (P_f)

It was assumed that 50% of the liquid (except water and milk) and solid food consumed had been processed with a Hen-House antifoam. Fifty percent was used as a conservative estimate based on the low market share for Hen-House antifoams in the overall antifoam food processing market, which is approximately 10–20% (Smith and Hawkens 1998a).

Table 3.5-1
Default Assumption for Age-Specific Food Consumption

	Solid and Liquid Food Intake (kg)				
Age (years)	Nonmeat	Meat	Dairy Products	Total Solid Food	Liquid Food
<1	0.211	0.050	0.297	0.558	0.130
1 - 6	0.439	0.092	0.046	0.577	0.310
6 - 14	0.511	0.156	0.053	0.720	0.400
14 - 18	0.511	0.252	0.053	0.816	0.580
18 - 45	0.508	0.250	0.052	0.810	1.010
45 - 75	0.515	0.250	0.055	0.820	0.780

Body Weight (BW)

Because age-specific food consumption rates were used, age- and gender-specific body weights were also used in this assessment. The values used are taken from USEPA (1995) and are given in Table 3.5-2.

Table 3.5-2
Default Assumption for Age- and Gender-Specific Body Weights

Age (years)	Body Weight (kg)	
	Men	Women
<1	10.6	9.8
1 - 6	17.3	16
6 - 14	40	39
14 - 18	69.1	56.8
18 - 45	75.9	63.9
45 - 75	78	67.3

Estimation of Oral ADIs

Using Equation 3-10 and the parameter values described above and listed in Tables 3.5-1 and 3.5-2, oral ADIs were calculated for consumers exposed to BHH from the consumption of food products processed with Hen-House antifoams

(Table 3.5-3). The ADIs ranged from approximately 0.002 mg/kg/day for infants and children (less than 6 years old) to 0.0008 mg/kg/day for adults (18 years and older).

Table 3.5-3
Estimates of ADIs (mg/kg/day) for Selected Populations:
Consumers Exposed to BHH in Food Products Processed with Hen-House Antifoams

Age (years)	Men	Women
<1	0.001907	0.002063
1–6	0.001507	0.001630
6–14	0.000823	0.000844
14–18	0.000594	0.000723
18–45	0.000705	0.000841
45–75	0.000603	0.000699