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Office of Chemical Safety and  
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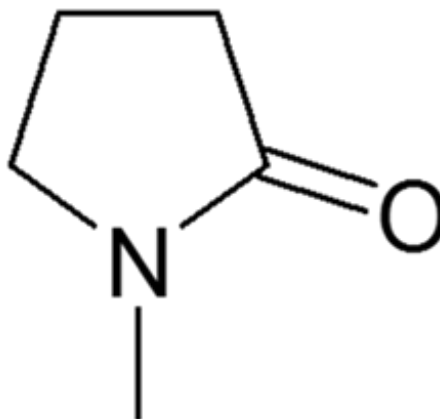
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**Draft Risk Evaluation for  
N-Methylpyrrolidone  
(2-Pyrrolidinone, 1-Methyl-)**

**Supplemental File:**

Supplemental Information on  
Consumer Exposure Assessment

**CASRN: 872-50-4**



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# 1 CONSUMER AND GENERAL POPULATION EXPOSURE

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The United States Environmental Protection Agency (U.S. EPA) evaluated N-methyl-2-pyrrolidone (NMP) exposure resulting from the use of consumer products and industrial processes. The U.S. EPA utilized a modeling approach to evaluate exposure because chemical specific personal monitoring data was not identified for consumers during data gathering and literature searches performed as part of Systematic Review.

## 1.1 CONSUMER EXPOSURE

Consumer products containing NMP are readily available at retail stores and via the internet for purchase and use. Use of these products can result in exposures of the consumer user and bystanders to NMP during and after product use. Consumer exposure can occur via inhalation, dermal, and oral routes.

Consumer products containing NMP were identified through review and searches of a variety of sources, including the National Institutes of Health (NIH) Household Products Database, various government and trade association sources for products containing NMP, company websites for Safety Data Sheets (SDS), Kirk-Othmer Encyclopedia of Chemical Technology, and the internet in general. Identified consumer products were then categorized into fourteen consumer use groups considering (1) consumer use patterns, (2) information reported in SDS, (3) product availability to the public, and (4) potential risk to consumers. Table 1-1 summarizes the fourteen consumer use groups evaluated as well as the routes of exposure for which they were evaluated.

*Table 1-1: Consumer Uses and Routes of Exposure Assessed*

<b>Consumer Uses</b>	<b>Routes of Exposure</b>
1. Glues, adhesives, caulk 2. Glues, adhesives, caulk - Azek 3. Adhesives Remover 4. Paint removers 5. Stains, varnishes, finishes 6. Paint 7. General Degreaser Cleaner 8. Engine Cleaner Degreaser 9. All-purpose liquid cleaner 10. All-purpose spray cleaner 11. Mold Cleaner Releaser 12. Arts and crafts paint (inhalation and dermal)	Inhalation and Dermal
13. Arts and crafts paint (ingestion and dermal)	Ingestion and Dermal
14. Children's articles	Ingestion

The U.S. EPA evaluated acute inhalation and dermal exposure of the consumer to NMP for this evaluation. Acute inhalation exposure is an expected route of exposure for twelve consumer use groups. Acute dermal exposure is also a possible route of exposure for thirteen consumer use

groups. The U.S. EPA evaluated the Arts and Crafts Paint and Children’s Articles exposure scenarios for oral exposure. The U.S. EPA does not expect exposure under any of the fourteen consumer use groups evaluated to be chronic in nature and therefore does not present chronic exposure for consumers.

The U.S. EPA evaluated inhalation and dermal exposure for the consumer user and evaluated only inhalation exposure for a non-user (bystander) located within the residence during product use. The consumer user consisted of three age groups (adult, greater than 21 years of age; Youth A, 16-20 years of age; and Youth B, 11-15 years of age) which includes the susceptible population woman of childbearing age. The bystander can include individuals of any age (infant through elderly).

## 1.2 CONSUMER MODELING

The model used to evaluate consumer exposures was EPA’s Consumer Exposure Model (CEM). Table 1-2 summarizes the specific models used for each consumer use group and the associated routes of exposure evaluated.

*Table 1-2: Models Used for Routes of Exposure Evaluated*

Consumer Uses	Routes of Exposure		
	Inhalation	Dermal	Ingestion
1. Glues, adhesives, caulk	CEM	CEM	
2. Azek	CEM	CEM	
3. Adhesives Remover	CEM	CEM	
4. Paint removers	CEM	CEM	
5. Stains, varnishes, finishes	CEM	CEM	
6. Paint	CEM	CEM	
7. General Degreaser Cleaner	CEM	CEM	
8. Engine Cleaner Degreaser	CEM	CEM	
9. All-purpose liquid cleaner	CEM	CEM	
10. All-purpose spray cleaner	CEM	CEM	
11. Mold Cleaner Releaser	CEM	CEM	
12. Arts and crafts paint (inhalation and dermal)	CEM	CEM	
13. Arts and crafts paint (ingestion and dermal)		CEM	CEM
14. Children's articles			CEM

Readers are referred to each model’s user guide and associated user guide appendices for details on each model, as well as information related to equations used within the models, default values, and the basis for default values. Each model is peer reviewed. Default values within CEM are a combination of high end and mean or central tendency values derived from U.S. EPA’s Exposure Factors Handbook, literature, and other studies.

### 1.2.1 CEM APPROACH

CEM is a deterministic model which utilizes user provided input parameters and various assumptions (or defaults) to generate exposure estimates. In addition to pre-defined scenarios,

which align well with the fourteen consumer uses identified in Table 1-1, CEM is peer reviewed, provides flexibility to the user allowing modification of certain default parameters when chemical-specific information is available and does not require chemical-specific emissions data (which may be required to run more complex indoor/consumer models).

CEM predicts indoor air concentrations from consumer product use through a deterministic, mass-balance calculation derived from emission calculation profiles within the model. There are six emission calculation profiles within CEM (E1-E6) which are summarized in the CEM users guide and associated appendices <https://www.epa.gov/tsca-screening-tools>. If selected, CEM provides a time series air concentration profile for each run. These are intermediate values produced prior to applying pre-defined activity patterns.

CEM uses a two-zone representation of the building of use when predicting indoor air concentrations. Zone 1 represents the room where the consumer product is used. Zone 2 represents the remainder of the building. Each zone is considered well mixed. CEM allows further division of Zone 1 into a near field and far field to accommodate situations where a higher concentration of product is expected very near the product user when the product is used. Zone 1-near field represents the breathing zone of the user at the location of the product use while Zone 1 far field represents the remainder of the Zone 1 room.

Inhalation exposure is estimated in CEM based on zones and pre-defined activity patterns. The simulation run by CEM places the product user within Zone 1 for the duration of product use while the bystander is placed in Zone 2 for the duration of product use. Following the duration of product use, the user and bystander follow one of three pre-defined activity patterns established within CEM, based on modeler selection. The selected activity pattern takes the user and bystander in and out of Zone 1 and Zone 2 for the period of the simulation. The user and bystander inhale airborne concentrations within those zones, which will vary over time, resulting in the overall estimated exposure to the user and bystander.

All consumer use groups identified in Table 1-2 (with the exception of Children's Articles) were evaluated with CEM's E1, E2, or E3 emission model and profile for inhalation exposure. For the E1 emission model, the model assumes a constant application rate over a user-specified duration of use. Each instantaneously applied segment has an emission rate that declines exponentially over time, at a rate that depends on the chemical's molecular weight and vapor pressure. For the E2 emission model, the model assumes an initial fast release by evaporation followed by a slow release dominated by diffusion. Finally, the E3 emission model assumes a percentage of a consumer product used is aerosolized (e.g. overspray) and therefore immediately available for uptake by inhalation. The associated inhalation model within CEM for all three emission models used for NMP is P-INH2. The U.S. EPA also used the near-field and far-field option within CEM for all consumer use groups evaluated with CEM.

The Children's Articles scenario was a scenario with entirely unique input parameters. The emission model used for Children's Articles was CEM's E6 emission model which incorporates emission from an article placed in an environment. The subsequent inhalation model in the A\_INH1 model. Additionally, Children's Articles used three ingestions models within CEM: A\_ING1, A\_ING2, and A\_ING3. These three models looked at ingestion after inhalation,

ingestion of an article that is mouthed, and incidental dust ingestion. Additionally, the article users were only youth and children for this scenario.

In an effort to characterize a potential range of consumer inhalation exposures, the EPA varied three key parameters within the CEM model while keeping all other input parameters constant. The key parameters varied were duration of use per event (minutes/use), amount of chemical in the product (weight fraction), and mass of product used per event (gram(s)/use). These key parameters were varied because they provide representative consumer behavior patterns for product use. Additionally, CEM is highly sensitive to two of these three parameters (duration of use and weight fraction). A summary of a sensitivity analysis performed of CEM within the CEM users guide and associated CEM user guide appendices. Finally, all three parameters had a range of documented values within literature identified as part of Systematic Review allowing the EPA to evaluate inhalation exposures across a spectrum of use conditions.

Once the data was gathered for the parameters varied, modeling was performed to cover all possible combinations of these three parameters. This approach results in a maximum of 27 different iterations for each consumer use. Certain uses, however, only had a single value for one or more of the parameters varied which reduces the total number of iterations.

Once the data was gathered for the parameters varied, modeling was performed to cover all possible combinations of these three parameters. This approach results in a maximum of 27 different iterations for each consumer use. Certain uses, however, only had a single value for one or more of the parameters varied which reduces the total number of iterations. Table 1-3 summarizes the potential iterations.

*Table 1-3: Example Structure of CEM Cases for Each Consumer Use Group Scenario Modeled*

CEM Set	Scenario Characterization (Duration-Weight Fraction- Product Mass)	Duration of Product Use Per Event (min/use) [not scalable]	Weight Fraction of Chemical in Product (unitless) [scalable]	Mass of Product Used (g/use) [scalable]	
Set 1 (Low Duration)	Case 1: Low-Low-Low	Low	Low	Low	
	Case 2: Low-Low-Mid			Mid	
	Case 3: Low-Low-High			High	
	Case 4: Low-Mid-Low		Mid	Mid	Low
	Case 5: Low-Mid-Mid				Mid
	Case 6: Low-Mid-High				High
	Case 7: Low-High-Low		High	High	Low
	Case 8: Low-High-Mid				Mid
	Case 9: Low-High-High				High
Set 2 (Mid Duration)	Case 10: Mid-Low-Low	Mid	Low	Low	
	Case 11: Mid-Low-Mid			Mid	
	Case 12: Mid-Low-High			High	
	Case 13: Mid-Mid-Low		Mid	Low	
	Case 14: Mid-Mid-Mid			Mid	

	Case 15: Mid-Mid-High		High	High
	Case 16: Mid-High-Low			Low
	Case 17: Mid-High-Mid			Mid
	Case 18: Mid-High-High			High
Set 3 (High Duration)	Case 19: High-Low-Low	High	Low	Low
	Case 20: High-Low-Mid			Mid
	Case 21: High-Low-High			High
	Case 22: High-Mid-Low		Mid	Low
	Case 23: High-Mid-Mid			Mid
	Case 24: High-Mid-High			High
	Case 25: High-High-Low		High	Low
	Case 26: High-High-Mid			Mid
	Case 27: High-High-High			High

The U.S. EPA utilized an option within CEM to obtain the intermediate time series concentration values from each model run. These values are calculated for every 30 seconds (0.5 minute) period for each zone for the entire length of the model run. This approach allowed the U.S. EPA to perform post-processing within Excel to determine personal concentration exposures for the user and bystander. This post-processing was conducted by independently assigning the Zone 1, Zone 2, and outside (zero) concentration to the user and bystander. These zone concentrations were assigned based on the pre-defined activity patterns within CEM. Time-weighted average concentration exposures were then calculated from the personal exposure time series to develop estimates for all iterations within each consumer use category. Time weighted average (TWA) concentrations were determined for 1 hour, 3 hours, 8 hours, and 24 hours, although for this evaluation the 8-hour and 24-hour TWA concentration were utilized based on health endpoints used to calculate risks.

### ***1.2.1.1 CEM Inputs***

Numerous input parameters are required to generate exposure estimates within CEM. These parameters include physical chemical properties of the chemical of concern, product information (product density, water solubility, vapor pressure, etc.), model selection and scenario inputs (pathways, CEM emission model(s), emission rate, activity pattern, product user, background concentration, etc.), product or article property inputs (frequency of use, aerosol fraction, etc.), environmental inputs (building volume, room of use, near-field volume in room of use, air exchange rates, etc.), and receptor exposure factor inputs (body weight, averaging time, exposure duration inhalation rate, etc.). Several of these input parameters have default values within CEM based on the pre-defined use scenario selected. Default parameters within CEM are a combination of high end and mean or median values found within the literature or based on data taken from U.S. EPA’s Exposure Factors Handbook ([U.S. EPA, 2011](https://www.epa.gov/tsca-screening-tools)). Details on those parameters can be found within the CEM Users Guide and associated Users Guide Appendices at <https://www.epa.gov/tsca-screening-tools>, or can be cross referenced to U.S. EPA’s Exposure

Factors Handbook ([U.S. EPA, 2011](#)). As discussed earlier, while default values are initially set in pre-defined use scenarios, CEM has flexibility which allows users to change certain pre-set default parameters and input several other parameters.

Key input parameters for the fourteen consumer uses identified in Table 1-5 evaluated with CEM are discussed below. Detailed spreadsheets of all input parameters used for each consumer use evaluated with CEM are provided in NMP Supplemental File: Information on Consumer Exposure Assessment Model Input Parameters.

Physical chemical properties of NMP were kept constant across all consumer uses and iterations evaluated. The saturation concentration in air (one of the factors considered for scaling purposes) was estimated by CEM as 1840 milligrams per cubic meter. A chemical-specific skin permeability coefficient of 8.86E-04 centimeters per hour was estimated within CEM and utilized for all scenarios modeled for dermal exposure. This estimate is calculated using the log octanol-water partition coefficient and the molecular weight of the chemical.

Model selection is discussed in the previous section (CEM modeling approaches). Scenario inputs were also kept constant across all consumer uses and iterations. Emission rate was estimated using CEM. The activity pattern selected within CEM was stay-at-home. The start time for product use was 9:00 AM and the product user was adult (>21 years of age) and Youth (16 through 20 years of age). The background concentration of NMP for this evaluation was considered negligible and therefore set at zero milligrams per cubic meter.

Frequency of use for acute exposure calculations was held constant at one event per day. The aerosol fraction (amount of overspray immediately available for uptake via inhalation) selected within CEM for all consumer uses evaluated was six percent. Building volume used for all consumer uses was the default value for a residence within CEM (492 cubic meters). The near-field volume selected for all consumer uses was one cubic meter. Averaging time for acute exposure was held constant at one day.

Certain model input parameters were varied across consumer use scenarios but kept constant for all model iterations run for that particular consumer use. These input parameters include product density, room of use, and pre-defined product scenarios within CEM. Product densities were extracted from product-specific SDS. Room of use was extracted from an EPA directed survey of consumer behavior patterns in the United States titled Household Solvent Products: A National Usage Survey ([U.S. EPA, 1987](#)) (Westat Survey), identified in the literature search as part of systematic review. The Westat survey is a nationwide survey which provides information on product usage habits for thirty-two different product categories. The information was collected via questionnaire or telephone from 4,920 respondents across the United States. The Westat Survey was rated as a high-quality study during data evaluation within the systematic review process. The room of use selected for this evaluation is based on the room in which the Westat Survey results reported the highest percentage of respondents that last used a product within the room. When the Westat Survey identified the room of use where the highest percentage of respondents last used the product as “other inside room”, the utility room was selected within CEM for modeling. The pre-defined product scenarios within CEM were selected



based on a cross-walk to similar product categories within the Westat Survey. A crosswalk between the NMP Consumer Use Scenarios and the corresponding Westat product category selected to represent the exposure scenario is provided below. In instances where a pre-defined product was not available within CEM, a generic model scenario was assigned in CEM with would run the requisite inhalation, emission, and dermal models.

*Table 1-4: Crosswalk Between NMP Consumer Use Scenarios and Westat Product Category*

NMP Consumer Use Scenario	Representative Westat Product Category
1. Glues, Adhesives, Caulk	Glues, Adhesives, Caulk
2. Azek	Glues, Adhesives, Caulk
3. Adhesives Remover	Adhesive Removers
4. Paint Removers	Paint Removers
5. Stains, Varnishes, Finishes	Stains, Varnishes, Finishes
6. Paint	Latex Wall Paint
7. General Degreaser Cleaner	Solvent-type Cleaning Fluids or Degreasers
8. Engine Cleaner Degreaser	Engine Cleaner/Degreaser
9. All-Purpose Liquid Cleaner	All Purpose Liquid Cleaner
10. All-Purpose Spray Cleaner	All Purpose Spray Cleaner
11. Mold Cleaner Releaser	Mold Cleaning/Release Prdt
12. Arts And Crafts Paint (Inhalation And Dermal)	Latex Wall Paint
13. Arts And Crafts Paint (Ingestion And Dermal)	Latex Wall Paint
14. Children's Articles	Children's articles

Additional key model input parameters were varied across both consumer use scenario and model iterations. These key parameters were duration of use per event (minutes/use), amount of chemical in the product (weight fraction), and mass of product used per event (gram(s)/use). Duration of use and mass of product used per event values were both extracted from the Westat Survey ([U.S. EPA, 1987](#)). To allow evaluation across a spectrum of use conditions, the EPA chose the Westat Survey results for these two parameters from the above cross-walked product categories representing the tenth, fiftieth (median), and ninety-fifth percentile data, as presented in the Westat Survey.

The amount of chemical in the product (weight fraction) was extracted from product specific SDS. This value was varied across the given range of products within the same category to obtain three values, when available. Unlike the Westat survey results which gave percentile data, however, product specific SDS across products did not have percentile data so the values chosen represented the lowest weight fraction, mean weight fraction (of the range available), and the highest weight fraction found. Even using this approach, some SDS were only available for a single product with a single weight fraction or very small range, or multiple products which only provided a single weight fraction or a very small range. For these product scenarios, only a single

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weight fraction was used in CEM for modeling. The following table summarizes the input parameter values used for these three parameters by consumer use.

*Table 1-5: Model Input Parameters Varied by Consumer Use*

Consumer Use	Duration of Use			Mass of Product Used			Amount of Chemical In Product		
	(minutes/use)			(gram(s)/use)			(weight fraction)		
	10 <sup>th</sup>	50 <sup>th</sup>	95 <sup>th</sup>	10 <sup>th</sup>	50 <sup>th</sup>	95 <sup>th</sup>	Low	Mean	High
Glues, Adhesives, Caulk	0.33	4.25	60	0.92	7.69	132.87	0.0077 (Single)		
Azek	0.5	4.25	60	0.92	7.69	132.87	0.85 (Single)		
Adhesives Remover	3	60	480	17.85	21317	1705.33	0.128	0.189	0.25
Paint Removers	5	60	420	79.66	477.34	3818.73	0.264	0.3356	0.425
Stains, Varnishes, Finishes	10	60	360	61.07	366.42	3908.44	0.0278	0.0497	0.0825
Paint	30	180	810	349.63	4194.24	23068.31	0.0130	0.0203	0.0363
General Degreaser Cleaner	2	15	120	16.23	94.19	927.43	0.2217	0.2546	0.2987
Engine Cleaner Degreaser	5	15	120	73.15	291.6	1206.6	0.15	0.275	0.4
All-Purpose Liquid Cleaner	2	15	120	16.56	96.11	946.35	0.01	0.03	0.05
All-Purpose Spray Cleaner	2	15	120	15.88	92.14	907.18	0.01 (Single)		
Mold Cleaner Releaser	0.08	2	30	3.4	18.71	170.05	0.3	0.35	0.4
Arts And Crafts Paint (Inhalation And Dermal)	30	180	810	5.44	65.27	358.98	0.001	0.0055	0.01
Arts And Crafts Paint (Ingestion And Dermal)	30	180	810	5.44	65.27	358.98	0.001	0.0055	0.01
Children's Articles	1.1	10	22.5	N/A			0.0001	0.00055	0.001

**1.2.2 Consumer Exposure Results**

All modeling results were exported into Excel workbooks for additional processing and summarizing. All modeling outputs for each condition of use evaluated are included by condition of use in NMP Supplemental File: Information on Consumer Exposure Assessment Model Outputs.

## 2 MODEL SENSITIVITY ANALYSES

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Model sensitivity analyses conducted on the models used for this evaluation enable users to identify what input parameters have a greater impact on the model results (either positive or negative). This information was used for this evaluation to help justify the approaches used and input parameters varied for our modeling.

### 2.1 CEM SENSITIVITY ANALYSIS

The CEM developers conducted a detailed sensitivity analysis for CEM version 1.5, as described in Appendix C of the CEM User Guide.

In brief, the analysis was conducted on non-linear, continuous variables and categorical variables that were used in CEM models. A base run of different models using various product or article categories along with CEM defaults was used. Individual variables were modified, one at a time, and the resulting Chronic Average Daily Dose (CADD) and Acute Dose Rate (ADR) were then compared to the corresponding results for the base run. Two chemicals were used in the analysis: bis(2-ethylhexyl) phthalate was chosen for the SVOC Article model (emission model E6) and benzyl alcohol for other models. These chemicals were selected because bis(2-ethylhexyl) phthalate is a SVOC, better modeled by the Article model, and benzyl alcohol is a VOC, better modeled by other equations.

All model parameters were increased by 10% except those in the SVOC Article model (increased by 900% because a 10% change in model parameters resulted in very small differences). The measure of sensitivity for continuous variables was elasticity, defined as the ratio of percent change in each result to the corresponding percent change in model input. A positive elasticity means that an increase in the model parameter resulted in an increase in the model output whereas a negative elasticity had an associated decrease in the model output. For categorical variables such as receptor and room type, the percent difference in model outputs for different category pairs was used as the measure of sensitivity. The results are summarized below for inhalation vs. dermal exposure models and for categorical vs. continuous user-defined variables.

#### Exposure Models

For the first five inhalation models (E1-E5) a negative elasticity was observed when increasing the use environment, building size, air zone exchange rate, and interzone ventilation rate. All of these factors decrease the chemical concentration, either by increasing the volume or by replacing the indoor air with cleaner (outdoor) air. Increasing the weight fraction or amount of product used had a positive elasticity because this change increases the amount of chemical added to the air, resulting in higher exposure. Vapor pressure and molecular weight also tended to have positive elasticities.

For most inhalation models, the saturation concentration did not have a notable effect on the ADR or the CADD. Mass of product used and weight fraction both had a positive linear relationship with dose. All negative parameters had elasticities less than 0.4, indicating that

some terms (e.g., air exchange rates, building volume) mitigated the full effect of dilution. That is, even though the concentration is lowered, the effect of removal/dilution is not stronger than that of the chemical emission rate. Most models had an increase in dose with increasing duration of use. Increasing this parameter typically increases the peak concentration of the product, thus giving a higher overall exposure.

The results for the dermal model were different from the inhalation models, in that the elasticities for CADD and ADR were nearly the same. This outcome is consistent with the model structure, in that the chemical is placed on the skin so there is no time factor for a peak concentration to occur. The modeled exposure is based on the ability of a chemical to penetrate the skin layer once contact occurs. Dermal permeability had a near linear elasticity whereas log Kow and molecular weight had zero elasticities.

#### User-defined Variables

These variables were separated into categorical vs. continuous. For categorical variables there were multiple parameters that affected other model inputs. For example, varying the room type changed the ventilation rates, volume size and the amount of time per day that a person spent in the room. Thus, each modeling result was calculated as the percent difference from the base run. For continuous variables, each modeling result was calculated as elasticity.

Among the categorical variables, both inhalation and dermal model results had a positive change when comparing an adult to a child and to a youth, with dermal having a smaller change between receptors than inhalation and the largest difference occurring between an adult and a child for both models. The time of day when the product was used and the duration of use occurred while the person was at home; thus, there was no effect on the ADR because the acute exposure period was too short to be affected by work schedule. Most rooms had a negative percent difference for inhalation, with the single exception of the bedroom where the receptor spent a large amount of time with a smaller volume than the living room. For dermal, the only room that resulted in a large percent difference was office/school, due to the fact that the person spent only ½ hour at that location when the stay-at-home activity pattern was selected. For inhalation, changing from a far field to a near field base resulted in a higher ADR and CADD, likely because the near field has a smaller volume than that of the total room.

There are three input parameters for the near-field, far-field option for CEM product inhalation models. To determine the sensitivity of model results to these inputs, CEM first was run in base scenario with the near-field option, after which separate runs were performed whereby the near-field volume was increased by 10%, the far-field volume was increased by 10%, and the air exchange rate was increased by 10%. For inhalation, both the air exchange rate and volume had negative elasticities, but the air exchange rate had a much higher elasticity (near one) than the volume (0.11).

References

U.S. EPA. (1987). Household solvent products: A national usage survey. (EPA-OTS 560/5-87-005). Washington, DC: Office of Toxic Substances, Office of Pesticides and Toxic Substances. <https://ntrl.ntis.gov/NTRL/dashboard/searchResults.xhtml?searchQuery=PB88132881>

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