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Standard Guide for Risk Characterization of Acute and Irritant Effects of Short-Term Exposure to Volatile Organic Chemicals Emitted from Bedding Sets¹

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1. Scope

1.1 This guide describes procedures for conducting risk characterization of exposure to volatile organic chemicals (VOCs) emitted from bedding sets or an ensemble of a mattress and supporting box spring.

1.2 This guide is for risk characterization of short-term exposures to a new bedding set brought into a residential indoor environment. The risk characterization considerations presented in this guide are applicable to both the general population and sensitive subgroups, such as convalescing adults.

1.3 The risk characterization addressed in this guide is limited to acute health and irritation effects resulting from short-term exposure to VOCs in indoor air. Although certain procedures described in this guide may be applicable to assessing long-term exposure, the guide is not intended to address cancer and other chronic health effects.

1.4 VOC emissions from bedding sets, as in the case of other household furnishings, usually are highest when the products are new. A used bedding set may also emit VOCs, either from the original materials or as a result of its use. The procedures presented in this guide also are applicable to used bedding sets.

1.5 Risk characterization procedures described in this guide should be carried out under the supervision of a qualified toxicologist or risk assessment specialist, or both.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the*

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responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

D1356 Terminology Relating to Sampling and Analysis of Atmospheres

D6177 Practice for Determining Emission Profiles of Volatile Organic Chemicals Emitted from Bedding Sets

D6178 Practice for Estimation of Short-term Inhalation Exposure to Volatile Organic Chemicals Emitted from Bedding Sets

E609 Terminology Relating to Pesticides

E943 Terminology Relating to Biological Effects and Environmental Fate

2.2 Government Standards:³

EPA 600/R 92/047 Reference Guide to Odor Thresholds for Hazardous Air Pollutants Listed in the Clean Air Act Amendments of 1990

29 CFR 1910 Occupational Safety and Health Standards

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology D1356.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *acute exposure guideline levels (AEGLs), n*—represent short-term threshold or ceiling exposure values intended for the protection of the general public, including susceptible or sensitive individuals, but not hypersusceptible or hypersensitive individuals (1).⁴

3.2.1.1 *Discussion*—AEGLs are for once-in-a-lifetime exposure due to accidental releases. Three AEGLs, each representing distinct biological endpoints (sensory irritation or notable discomfort, irreversible or serious effect, and life-threatening effects or death) for four different exposure periods ranging from 30 min to 8 h, are derived.

3.2.2 *bedding set, n*—an ensemble that includes a mattress for sleeping and a supporting box spring.

3.2.3 *ceiling limit, n*—a maximum allowable air concentration, established by the Occupational Safety and Health Administration (OSHA), that must not be exceeded during any part of the workday.

3.2.4 *emission profile, n*—a time-series of emission rates for one or more chemicals.

3.2.5 *hazard index (HI), n*—a summation of hazard quotients (see 3.2.6) for chemicals potentially having similar target organ effects or for chemicals that are considered to have additive effects.

3.2.6 *hazard quotient (HQ), n*—the ratio of the exposure calculated for a chemical to the toxicity/irritancy threshold or reference value for that chemical.

3.2.6.1 *Discussion*—If a HQ exceeds a value of 1, there would be a concern for potential toxic/irritant effects. A HQ is not to be interpreted as a statistical probability, for example, a ratio of 0.001 does not mean that there is a one in a thousand chance of an effect occurring.

3.2.7 *inhalation reference concentration (RfC), n*—an estimate (with uncertainty spanning an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects.

3.2.7.1 *Discussion*—The time period under consideration is up to and including seven years, or a portion of a lifetime, for subchronic RfC and a lifetime for chronic RfC. In accordance with the U.S. Environmental Protection Agency (EPA) (2), the uncertainty in the estimates for RfC spans an order of magnitude.

3.2.8 *lethal concentration 50 (LC₅₀), n*—a calculated concentration of a chemical in air to which exposure for a specific length of time is expected to cause death in 50 % of a defined experimental animal population.

3.2.9 *lethal concentration low (LCL_o), n*—the lowest calculated concentration of a chemical in air to which exposure over any period of time is reported to have caused death in humans or animals.

3.2.10 *lowest-observed-adverse effect level (LOAEL), n*—the lowest dose of a chemical in a study or group of studies

that produces statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control.

3.2.11 *minimal risk level (MRL), n*—an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

3.2.11.1 *Discussion*—MRLs are developed by the Agency for Toxic Substances and Disease Registry (ATSDR). They are intended to serve as a screening tool to help public health professionals and are derived for acute (1 to 14 days), intermediate (14 to 364 days), and chronic (365 days or longer) exposure durations and for oral and inhalation routes of exposure (3, 4).

3.2.12 *no-observed-adverse-effect level (NOAEL), n*—that dose of a chemical at which there are no statistically or biologically significant increases in frequency or severity of adverse effects seen between the exposed population and its appropriate control.

3.2.12.1 *Discussion*—Effects may be produced at this dose, but they are not considered to be adverse.

3.2.13 *potential inhaled dose, n*—the estimated dose of an airborne chemical that an individual is likely to have inhaled within a specified period of time.

3.2.13.1 *Discussion*—It is calculated as the product of air concentration to which an individual is exposed times breathing rate times duration of exposure. The potential inhaled dose can be different from the dose actually absorbed by a target organ.

3.2.14 *short-term exposure, n*—an exposure of one week or less in duration.

3.2.15 *toxic concentration low (TCL_o), n*—the lowest air concentration of a substance introduced by the inhalation route over any period of time that is reported to have produced any significant toxic effects in animals or humans.

3.2.16 *uncertainty factor, n*—number, greater than unity, to account for incomplete understanding of errors encountered in extrapolating exposure or health effects derived for one set of conditions or basis to another.

3.2.16.1 *Discussion*—An uncertainty or *safety factor* is used to account for differences in toxicological effects within a species or between two species. For example, a factor of 10 or 100 is used in the calculation of an RfC to account for uncertainties in the extrapolation from the experimental data and exposure conditions.

4. Summary of Guide

4.1 This guide describes procedures for conducting risk characterization of short-term exposures to VOCs emitted from new bedding sets in a residential environment. The risk characterization discussed in this guide addresses acute health and irritant effects of the short-term exposures.

4.2 Four major steps in risk assessment include hazard identification, evaluation of health effects data (including dose-response assessment), exposure assessment, and risk characterization (5, 6). This guide addresses hazard

⁴ The boldface numbers in parentheses refer to the list of references at the end of this standard.

assessment, evaluation of health effects data, and risk characterization. Companion documents (see Practices [D6177](#) and [D6178](#)) provide procedures for estimation of human exposure to emissions of VOCs from bedding sets when a new bedding set is first brought into a house.

5. Significance and Use

5.1 The objective of this guide is to describe procedures and data sources for conducting risk characterization of acute inhalation exposure to chemicals emitted from bedding sets. Risk characterization can be used to identify chemical(s) that pose potentially significant human health risks for the scenario(s) and population(s) selected for exposure assessment. Such identification of chemicals can help in identifying the components or materials used in the manufacture of bedding sets that should be further examined. Risk characterization also includes an assessment of potential odors associated with individual chemicals emitted by the bedding set.

6. Exposure and Effects

6.1 *Concepts of Exposure and Dose*—In very basic terms, exposure is defined as human contact with a chemical or physical agent (see Terminology [E943](#)). Exposure by means of the inhalation route is of interest in this document: It can be expressed as the product of airborne concentration times duration of exposure, provided that the concentration remains constant during the time period of interest. If the concentration varies over time, then exposure is defined as the area under the curve obtained when concentration values are plotted against time. Exposure is expressed as concentration multiplied by time with resultant units such as ppm-h or mg/m³-h. Dose is the quantity of chemical or physical agent that enters an organism or target organ (see Terminology [E943](#)), with units such as mg. Dose also can be expressed as rate, with mass/time units such as mg/day. The dose rate can be normalized in relation to body mass, with units such as mg/kg-day. A specific term that is used in risk characterization is potential inhaled dose—the product of average concentration in an environment times the duration in the environment times the average breathing rate while in the environment, commonly expressed in mass units such as milligrams. Chronic exposure generally refers to a long-term perspective, such as repeated exposures or exposures throughout an individual's lifetime, whereas acute exposure refers to a short-term perspective such as one week, one hour, or even an instantaneous exposure.

6.2 *Chronic Toxic Effects*—In the United States and in many other countries, two forms of health effects assessment are used, depending on the nature of the toxic effect under consideration: one is used for cancer and the other for toxic effects other than cancer ([6](#)). This is primarily because for cancer (a chronic toxic effect), a threshold for dose-response relationship may not exist, or if one does exist, it is very low and may not be reliably identified. During the 1970s and 1980s, the emphasis of risk assessment was on cancer as the end point. On the other hand, for toxic effects other than cancer, a standard procedure used for evaluating health effects involves identifying the highest exposure among all experimental studies at which no toxic effect was observed, that is, the NOAEL.

Much of the emphasis related to non-cancer effects has been on chronic effects ([6](#)). In recent years, however, researchers such as Berglund et al. ([7](#)) have been giving increased attention to acute effects by categorizing the effects of indoor air pollutants on human health into groups, such as reversible effects, including general symptoms, such as headache, inflammatory irritation such as rashes, and perceptions including odors.

6.3 *Acute Effects*—The scope of this guide relates to effects of short-term exposure to airborne chemicals in indoor spaces. Specific guidelines available for considering acute effects of exposure to chemicals in air are quite limited. Minimal risk levels (MRLs) are derived for acute exposure of 1 to 14 days ([3](#), [4](#)). Other guidelines, such as AEGLs, developed by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) are applicable only for one-time, short-term hazardous exposures during chemical emergency situations ([1](#)). EPA's non-chronic reference concentrations for inhalation (RfCs) may exist for acute and subchronic exposures of less than seven years ([2](#)). CalEPA has developed acute dose-response assessments for many substances, expressing the results as acute inhalation reference exposure levels (RELs). American Industrial Hygiene Association (AIHA) has developed emergency response planning guidelines (ERPGs) for acute exposures at three different levels of severity. These values represent concentrations for exposure of the general population for up to 1 hour associated with effects expected to be mild or transient (ERPG-1), irreversible or serious (ERPG-2), and potentially life-threatening (ERPG-3).

7. Procedures for Hazard Identification

7.1 Identification of Chemicals:

7.1.1 Compile a list of target chemicals that are identified through screening tests of emissions. Target chemicals are to be selected by a qualified toxicologist or a risk assessment specialist based on their presence in the screening samples and their expected irritant or health effects. Information on procedures for emissions testing, including screening samples, is given in Practice [D6177](#).

7.1.2 All target chemicals for which emissions data have been collected may be of interest, potentially even those with measured air concentrations that are below their respective detection limits.

7.2 *Compilation of Inhalation Toxicity and Odor Thresholds*—Using data sources, such as those listed in [7.3](#) through [7.5](#) (these lists are not exhaustive), collect, compile and document with references the following information for each chemical noting when exposure levels and limits are derived from animal, rather than human, studies:

7.2.1 Exposure levels reported to produce adverse health effects in humans,

7.2.2 Human exposure limits specified in regulatory standards and guidelines,

7.2.3 Toxicological values for humans and experimental mammals, and

7.2.4 Human odor threshold values.

7.3 *Published Literature and databases for Health Effect, Toxicity, and Odor Threshold Information useful for the general population*—There are many sources of health effects, toxicity, and odor threshold information, some of which are updated periodically. A number of important resources and databases are summarized below in 7.3.1 – 7.3.7. The Uniform Resource Locators (URLs) for websites where most of these resources can be accessed or purchased are provided solely for convenience and may become obsolete as websites are modified.

7.3.1 *TOXNET System*—The National Library of Medicine’s (NLM) Toxicology Data Network (TOXNET),⁵ consists of a number of individual databases that are periodically extracted from the biomedical, toxicology and other literature.

7.3.1.1 *Hazardous Substances Data Bank (HSDB)*,⁶ a TOXNET database that contains toxicology information on over 5000 potentially hazardous chemicals. Each record includes excerpted toxicology information on human exposure, detection methods, odor thresholds, and regulatory information. Information included in the HSDB is peer reviewed by expert toxicologists.

7.3.1.2 *International Toxicity Estimates for Risk (ITER)*, a collaborative public/private partnership has centralized authoritative chemical toxicity values from worldwide organizations into a curated, global database, ITER.⁷ ITER includes Health Canada Tolerable Concentrations (inhalation) for Priority Substances published in 1996.⁸

7.3.2 *Agency for Toxic Substances and Disease Registry (ATSDR)* maintains toxicological profiles for hazardous substances, which provide an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations of hazardous substances. The ATSDR includes, as a screening tool, MRLs that are estimates of the daily human exposures to hazardous substances that are unlikely to result in appreciable risks of adverse, non-cancer health effects over a specified duration of exposure including acute exposures.⁹

7.3.3 *Integrated Risk Information System (IRIS)*, a database created by EPA (also part of TOXNET) that contains EPA’s official repository of agency-wide consensus information on potential adverse human health effects that may result from chronic or lifetime exposure to environmental contaminants. It includes carcinogenic and non-carcinogenic risk assessment values for oral and inhalation routes of exposure; unit-risk values for carcinogenic substances and reference doses for non-carcinogenic substances. IRIS data is reviewed by EPA scientists and represents EPA consensus.¹⁰

7.3.4 *CalEPA Office of Environmental Health Hazard Assessment (OEHHA)* maintains a chemical database on toxicity criteria on chemicals evaluated by OEHHA.¹¹ Included in the

database are acute, 8-hour and chronic RELs developed by OEHHA and their documentation, most of which is peer reviewed.¹²

7.3.5 *American Industrial Hygiene Association (AIHA) Emergency Response Planning Guidelines (ERPGs)*—The ERP Committee develops guidelines for responding to potential releases of airborne substances for use in community emergency planning. ERPGs are air concentration guidelines for single exposures to agents and are intended for use as tools to assess the adequacy of accident prevention and emergency response plans. Current values are published online and documentation is available for purchase.¹³

7.3.6 *Health Effects Assessment Summary Tables (HEAST)*, a comprehensive listing of provisional risk assessment information concerning inhalation and oral routes of exposure for chemicals published by EPA in 1997 (currently inactive). Although the provisional values in HEAST have undergone review and have the concurrence of individual EPA Program Offices, and each is supported by an EPA reference, they have not had sufficiently thorough review to be recognized as high quality, EPA-wide consensus information.¹⁴

7.3.7 To supplement published information obtained from the above sources, relevant but unpublished information submitted to EPA under statutory requirements of the Toxic Substances Control Act (TSCA) can be examined. These TSCA requirements include Section 4 Study Reports, Section 8 Master Testing List, Section 8e Notices, Section 8 FYI Submissions, and Screening Information Data Sets (SIDS).

7.4 *Sources of Occupational Health Effects Information*—(See 8.4 regarding precautions when applying occupational exposure limits to the general population):

7.4.1 *Permissible Exposure Limits (PELs)* published by Occupational Health and Safety Administration (OSHA) are intended to be protective of worker safety and health over a working lifetime. OSHA states these values¹⁵ are outdated and recommends referring to Cal/OSHA PELs,¹⁶ National Institute for Occupational Safety and Health (NIOSH) RELs,¹⁷ or ACGIH TLVs in 7.4.2.

7.4.2 *Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Values*, a report by the American Conference of Governmental Industrial Hygienists (ACGIH), gives 8-h time-weighted-average occupational Threshold Limit Values (TLVs) and 15-min Short-term Exposure Limits (STELs).¹⁸

7.4.3 *Registry of Toxic Effects of Chemical Substances (RTECS)*, published by the NIOSH in 1997 (currently inactive), contains acute and chronic toxic-effects data on more than 111 000 chemicals.¹⁹

¹² Accessible from <http://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary>.

¹³ Accessible from <https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Pages/default.aspx>.

¹⁴ Accessible from <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2877&CFID=82192367&CFTOKEN=47069679>.

¹⁵ Available from <https://www.osha.gov/dsg/annotated-pels>.

¹⁶ Available from http://www.dir.ca.gov/title8/5155table_ac1.html#_blank.

¹⁷ Available from <http://www.cdc.gov/niosh/npg>.

¹⁸ Available from <http://www.acgih.org>.

¹⁹ Available from <https://www.cdc.gov/niosh/docs/97-119>.

⁵ Accessible from <https://toxnet.nlm.nih.gov>.

⁶ Accessible from <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>.

⁷ Accessible from <https://toxnet.nlm.nih.gov/newtoxnet/iter.htm>.

⁸ Also accessible from <http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/hbct-jact/index-eng.php>.

⁹ Accessible from <https://www.atsdr.cdc.gov>.

¹⁰ Accessible from <https://www.epa.gov/iris>.

¹¹ Accessible from <http://oehha.ca.gov/chemicals>.

7.5 Sources of Information on Odor Thresholds:

7.5.1 AIHA, *Odor Thresholds for Chemicals with Established Occupational Health Standards, 2nd Addition*, a peer-reviewed document that contains odor thresholds for a wide variety of chemicals.²⁰

7.5.2 EPA, *Reference Guide to Odor Thresholds for Hazardous Air Pollutants Listed in the Clean Air Act Amendments of 1990 EPA 600/R 92/047*, a guide for odor thresholds for hazardous air pollutants.²¹

7.5.3 Devos *et al.*, 1990, *Standardized Human Olfactory Thresholds*, a compilation of weighted and averaged odor detection thresholds for 529 chemical substances (8).

8. Procedures for Compilation and Evaluation of Data

8.1 Based on the objective(s) of risk characterization, select data for evaluation. Human data for a chemical are preferred to data generated using experimental animals in determining an acceptable level of exposure to that chemical for humans. Epidemiologic studies clearly provide the most relevant kind of information for hazard identification because they involve observations of human beings, not laboratory animals. That obvious and substantial advantage is offset to various degrees by the difficulties associated with obtaining and interpreting epidemiologic information. If adequate human data are not available, data derived from one or more studies with experimental animals are commonly used. An advantage of animal studies is that they can be controlled, so establishing causation generally is not difficult (6).

8.2 Compile data for relevant parameters (such as acute RfCs, MRLs, and TLVs) for each target chemical into a summary table. The databases identified in 7.3 through 7.5 have reviewed a variety of health-effect studies, primarily toxicological studies. Acute toxicological end-points, such as histopathological changes in nasal cavity or eye irritation resulting from exposure of laboratory animals to airborne chemicals, are of interest. However, chronic values can also be used if no other data is available, understanding that these values are conservative for this acute scenario.

8.3 Evaluate data for selected toxicity endpoints. Select relevant and conservative (that is, the smallest) toxicological values (for example, regulatory standards/guidelines available for each chemical, thresholds for eye irritation, or TCL_o). Human data are preferred over experimental animal data.

8.4 Establish a hierarchy or order of priority to select end-point values based on those that are typically used by air pollution control agencies to develop ambient air pollutant concentration limits (9). One example of the order of priority (highest to lowest) is as follows: (1) established acute or subchronic RfCs; (2) ASTDR MRLs and AEGLs; (3) human inhalation toxicity endpoint values— TCL_o ; (4) animal inhalation toxicity endpoint values— TCL_o . Because only short-term exposure is considered for risk characterization in this guide, use of acute or subchronic RfCs is preferred to chronic or

subchronic RfCs. However, if chronic or subchronic RfC values are the only data available, it should be understood that they are conservative for acute exposure and more analysis may be needed by a toxicologist. This type of hierarchy reflects the degree of confidence in the validity of the endpoint values obtained from the four types of data. This general hierarchy is more applicable to chronic effects; a similar hierarchy for acute effects of exposures due to accidental releases has recently been established (1).

8.5 A safety or uncertainty factor is considered to account for the uncertainty associated with intraspecies and interspecies extrapolation and other factors, such as the quality of data (6). Uncertainty factors are built into health-effect standards or guidelines. The following discussion provides some background on consideration of the uncertainty factor.

8.5.1 The magnitude of the uncertainty usually is expressed in terms of a factor, such as 10 (one order of magnitude), to reflect the lack of confidence about how a chemical may affect individuals. Sources of uncertainty include extrapolating toxicological data from controlled animal testing to estimated health effects in humans, extrapolating LOAELs to a NOAEL, and variations in individual responses. Regulatory agencies usually require uncertainty factor values of 3 (one-half order of magnitude), 10, 100, or 1000 in different situations.

8.5.2 If the NOAEL has been derived from high-quality data in humans, then a factor less than 10 may be appropriate, provided test conditions are similar to conditions under investigation. If the NOAEL is derived from less similar or less reliable studies, then a factor, such as 100 or 1000, may be required (6).

8.5.3 In deriving MRLs, ATSDR generally uses an uncertainty factor of 10 to account for variability in human response, but may apply 3 or 1 when a large epidemiologic study or a study of sensitive population is used (10).

8.5.4 In using a TLV, which is a recommended time-weighted-average air concentration of a chemical for a normal 8-h workday and 40-h week for healthy workers, the toxicologist needs to understand the basis for the guideline value and then determine the appropriate uncertainty factor to apply. A safety factor of 10 has been used for the general population to account for human variability including consideration of age differentials; however, this is not universally applicable.

8.5.5 The selection and use of a safety factor should be done by a qualified toxicologist or health-effects specialist, and the scientific rationale for the selected uncertainty factor must be documented.

8.6 Present the toxicological end-point values for use in risk assessment, using the above-selected hierarchy and include the uncertainty and assumptions that went into each assessment.

8.7 *Odor Thresholds for Target Chemicals*—Establish a hierarchy or order of priority to select odor threshold end-point values. For example, the lowest acceptable odor threshold value for a given chemical in air recognized by the AIHA (11) is given higher priority than an odor threshold for that chemical extracted from the TOXNET HSDB database. Because an odor-perception level for a given chemical may have no relationship to the hazards of exposure to that chemical, safety factors for odor threshold are not necessary.

²⁰ Available from <https://www.aiha.org/marketplace/Pages/default.aspx>.

²¹ Available from <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=40610&CFID=82193578&CFTOKEN=66427748>.

9. Procedures for Health Risk Characterization

9.1 The objective of the risk characterization is to integrate chemical-specific toxicity from the hazard assessment with estimated chemical-specific inhalation exposures derived from the human exposure assessment (see Practice D6178). This integration can provide a quantitative evaluation of the potential risks of adverse human health impacts, if any, that may be associated with exposure to chemicals emitted from new bedding sets.

9.2 Use toxicity/irritancy levels at which there is no expected appreciable risk of deleterious effects, as reference levels or benchmarks for risk characterization.

9.3 Evaluate the potential for adverse impacts of target chemicals by comparing the estimated inhalation exposure, in terms of either potential inhaled dose or maximum indoor concentration, (see Practice D6178) with reference levels. The potential for acute human health effects (toxicity and irritancy) is estimated by dividing each exposure estimate by its respective reference level. The resultant ratios are reported as hazard quotients (HQs). The value of each HQ should be evaluated for each chemical emitted from the bedding set. An HQ value below 1 for a particular chemical implies that the chemical does not pose significant health risk for the scenario(s) and population(s) for which exposure estimates were developed. The greater the value of the HQ above 1, the greater the potential concern.

9.4 Further, consider additivity of acute health effects of different chemicals affecting the same target organ by computing a hazard index (HI). Due to the general lack of information on synergistic or other interaction effects, a HI is created by just summing the HQs for appropriate chemicals. A value of 1 is used as a benchmark; the greater the value of the HI above 1, the greater the potential concern. Individual chemicals often affect more than one target organ, and thus calculation of the HI needs to be performed for each potentially affected organ.

9.5 The results of risk characterization should be discussed in light of the uncertainties associated with each step of the risk assessment process, including chamber emission testing, exposure estimation, and interspecies and intraspecies extrapolation (see 8.5). A generalized list of uncertainty issues is given by the National Research Council (6).

10. Procedures for Odor Characterization

10.1 The objective of odor characterization is to integrate odor-threshold information into a quantitative evaluation of a

perception of odor associated with exposure to chemicals emitted from new bedding sets.

10.2 Use odor threshold levels at which no odor is detected as reference levels.

10.3 Evaluate the odor potential by comparing the indoor concentrations (see Practice D6178) with reference levels. The odor potential is estimated by dividing each estimated concentration by its respective odor threshold.

10.4 Odor thresholds also can be considered as additive if individual chemicals are related in terms of their olfactory receptors, for example, belonging to the same homologous series (12).

11. Report

11.1 The report on risk characterization of short-term inhalation exposure to VOCs should contain the following component.

11.2 *Hazard Identification and Evaluation of Health Effects Data*—Provide a list of chemicals of potential concern. For each chemical, include a compilation of toxicity, irritancy and odor threshold data, and data sources used in compiling reference values. Provide information and rationale for the hierarchy of toxicological end-points established for each chemical. Summarize the selected threshold values for characterizing risks.

11.3 *Summary of Exposure Assessment*—Describe the methodology and assumptions used in conducting the exposure assessment. Include brief descriptions of exposure scenarios that were used. Present results of the exposure assessment.

11.4 *Risk Characterization*—Describe the methodology and assumptions used in risk characterization. Describe results of the risk characterization, including HQs and the values used to calculate these ratios, and discuss results with respect to associated uncertainties. Present considerations related to additivity of effects and values of HIs as appropriate. State conclusions and summarize limitations of the data and methodology utilized in the risk characterization.

12. Keywords

12.1 acute toxicity; air concentration; emissions; exposure assessment; hazard assessment; health effect; inhalation; irritant effect; odor characterization; odor threshold; risk characterization

REFERENCES

- (1) “National Advisory Committee for Acute Exposure Guidelines Levels for Hazardous Substances,” *Federal Register*, Vol 62, No. 210, 58839-58851, October 30, 1997.
- (2) U.S. Environmental Protection Agency, *Health Effects Assessment Summary Tables*, EPA 540/R-94/020, Office of Solid Waste and Emergency Response, Washington, D.C., 1994.
- (3) Agency for Toxic Substances and Disease Registry, “Minimal Risk Levels for Hazardous Substances,” Atlanta, GA, March 2016.
- (4) Chou, S. J., Holler, J. and De Rosa, C. T. “Minimum Risk Levels (MRLs) for Hazardous Substances,” *Journal of Clean Technology, Environmental Toxicology and Occupational Medicine*, Vol 7, No. 1, 1998, pp. 1–24.
- (5) National Research Council, *Risk Assessment in Federal Government*, National Academy Press, Washington, D.C., 1983.
- (6) National Research Council, *Science and Judgement in Risk Assessment*, National Academy Press, Washington, D.C., 1994.
- (7) Berglund, B., Brunekreef, B., Knoppel, H., Lindvall, T., Maroni, M., Molhave, M., and Skov, P. “Effects of Indoor Air Pollution on Human Health,” *Indoor Air*, Vol 2, 1992, pp. 2–25.
- (8) Devos, M., Patte, F., Rouault, J., Laffort, P., and Van Gemert, L. J., *Standardized Human Olfactory Thresholds*, Oxford University Press, New York, NY, 1990.
- (9) Patrick, D. R., *Toxic Air Pollution Handbook*, Van Nostrand Reinhold, New York, N.Y. 1994.
- (10) “Minimal Risk Levels for Priority Substances and Guidance for Derivation,” Agency for Toxic Substances and Disease Registry, Republication, *Federal Register* 62: 40820-40828.
- (11) *Odor Thresholds for Chemicals with Established Occupational Health Standards*, American Industrial Hygiene Association, Fairfax, VA 1993
- (12) Hau, K. M., and Connell, D. W., “Quantitative Structure-Activity Relationships(QSARs) for Odor Thresholds of Volatile Organic Compounds (VOCs),” *Indoor Air*, Vol 8, 1998, pp. 22–33.

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