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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 Sets[1]

This standard is issued under the fixed designation D 6485; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides guidance to individuals and organizations 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 does not 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 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to its use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 1356 Terminology Relating to Sampling and Analysis of Atmospheres[2]

D 6177 Practice for Determining Emission Profiles of Volatile Organic Chemicals Emitted from Bedding Sets[2]

D 6178 Practice for Estimation of Short-Term Inhalation Exposure to Volatile Organic Chemicals Emitted from Bedding Sets[2]

E 609 Terminology Relating to Pesticides[3]

E 943 Terminology Relating to Biological Effects and Environmental Fate[3]

E 1542 Terminology Relating to Occupational Health and Safety[2]

2.2 *Government Standards:*[4]

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

16 CFR 1500 Federal Hazardous Substances Act Regulations

29 CFR 1910 Safety and Health Standards for General Industry

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology D 1356.

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)**.[5]

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.

[1] This test method is under the jurisdiction of ASTM Committee D-22 on Sampling and Analysis of Atmospheres and is the direct responsibility of Subcommittee D22.05 on Indoor Air.

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[2] *Annual Book of ASTM Standards*, Vol 11.03.

[3] *Annual Book of ASTM Standards*, Vol 11.05.

[4] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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

3.2.3 *ceiling*, *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 **(2)**.

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 **(2)**.

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) **(3)**, the uncertainty in the estimates for RfC spans an order of magnitude.

3.2.8 *lethal concentration 50 (LC_{50})*, *n*—a calculated air concentration of a substance for which inhalation is expected to cause the death of 50 % of an experimental animal population **(2)**.

3.2.9 *lethal concentration low (LCL_o)*, *n*—the lowest air concentration of a substance introduced by the inhalation route over any period of time that is reported to have caused death in humans or animals **(2)**.

3.2.10 *lowest-observed-adverse effect level (LOAEL)*, *n*—the lowest exposure at which there is a significant increase in an observable effect.

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 **(4, 5)**.

3.2.12 *no-observed-adverse-effect level (NOAEL)*, *n*—the highest concentration among all the available experimental studies at which no adverse health or toxic effect is observed **(2)**.

3.2.13 *permissible exposure limit (PEL)*, *n*—the OSHA-mandated time-weighted-average concentration of a chemical in air that must not be exceeded during any 8-h work shift or 40-h work-week **(2)**.

3.2.14 *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. It is calculated as the product of air concentration to which an individual is exposed times breathing rate times duration of exposure.

3.2.14.1 *Discussion*—The potential inhaled dose can be different from the dose actually absorbed by a target organ.

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

3.2.16 *short-term exposure limit (STEL)*, *n*—an American Conference of Governmental and Industrial Hygienists (ACGIH)-recommended 15-min time-weighted-average air concentration of a chemical that should not be exceeded at any time during a workday, even if the 8-h time-weighted-average level is within the threshold limit value (TLV) **(2)**.

3.2.17 *threshold limit value (TLV)*, *n*—established by ACGIH as the recommended time-weighted-average air concentration of a chemical for a normal 8-h workday and a 40-h work week, to which nearly all workers may be repeatedly exposed without adverse effects **(2)**.

3.2.18 *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 **(2)**.

3.2.19 *uncertainty factor*, *n*—a 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.

3.2.19.1 *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 to apply TLVs applicable to workers to a general population.

4. Summary of Guide

4.1 This guide presents guidance on conducting risk characterization of short-term exposures to volatile organic chemicals emitted from new bedding sets in a residential environment. The risk characterization discussed in this guide is limited to 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 **(6, 7)**. This guide addresses hazard assessment, evaluation of health effects data, and risk characterization. Companion documents (see Practices D 6177 and D 6178) 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 manufacture of bedding sets that should be further examined. Risk characterization also includes an assessment of potential odor problems for any individual chemical 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 E 943). 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/m^3-h. Dose is the quantity of chemical or physical agent that enters an organism or target organ (see Terminology E 609), 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 **(7)**. This is primarily because for cancer (a chronic toxic effect), a threshold for dose-response relationship does not exist, or if one does exist, it is very low and cannot 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 noncancer effects has been on chronic effects **(7)**. In recent years, however, researchers such as Berglund et al. **(8)** 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. MRLs are derived for acute exposure of 1 to 14 days **(4, 5)**. Other guidelines, such as AEGLs, being developed by the National Advisory Committee 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 RfCs are not for acute exposure but for subchronic exposures of less than seven years **(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 D 6177. A list of target chemicals included in the prior research on bedding sets is given in Table X1.1 **(2)**.

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

NOTE 1—In prior research, risk characterization of exposure to chemicals with concentrations below their detection limits was conducted by assuming that the respective air concentrations were one half of the detection limit **(2)**.

7.2 *Compilation of Inhalation Toxicity and Odor Thresholds*—Using data sources listed in 7.3, collect and compile the following information for each chemical:

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 experimental mammals, and

7.2.4 Human odor threshold values.

7.3 *Data Sources for Health Effect, Toxicity, and Odor Threshold Information*:

7.3.1 The major and primary source of published toxicity information is the National Library of Medicine's (NLM) TOXNET system. There are a number of other sources of compiled information, some of which are updated periodically. These databases and sources are summarized below in 7.3.2 through 7.3.4.

7.3.2 *TOXNET System*—The TOXNET system, easily accessible from NLM, consists of several cross-referenced individual databases of information that are periodically extracted from the toxicology literature.

7.3.2.1 *Hazardous Substances Data Bank (HSDB)*, a database that contains toxicology information on more than 4500 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.

7.3.2.2 *Agency for Toxic Substances and Disease Registry (ATSDR)*—Toxicological profiles for hazardous substances

provide an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations of hazardous substances.

7.3.2.3 *Registry of Toxic Effects of Chemical Substances (RTECS)*, maintained by the National Institute for Occupational Safety and Health, contains acute and chronic toxic-effects data on more than 111 000 chemicals.

7.3.2.4 *Integrated Risk Information System (IRIS)*, a database created by EPA, 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 information on carcinogenic and noncarcinogenic risk assessment values for oral and inhalation routes of exposure; unit-risk values for carcinogenic substances and reference doses for noncarcinogenic substances are given. In 1998, IRIS contained information on health effects of 500 specific chemical substances.

7.3.3 *Other Major Sources of Health Effect Information*:

7.3.3.1 *Health Effects Assessment Summary Tables (HEAST)*, a comprehensive listing of provisional risk assessment information concerning oral and inhalation routes of exposure for chemicals of interest to EPA. HEAST is updated annually if sufficient new data exist. 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 concensus information.

7.3.3.2 For potentially relevant information on current labeling requirements for various types of acceptable levels of regulated chemicals in certain types of consumer products, see 16 CFR 1500.

7.3.3.3 Check 29 CFR 1910 to obtain recent regulatory standards that may not have been reported in the HSDB.

7.3.3.4 *Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Values*, a report by the ACGIH, gives 8-h time-weighted-average occupational TLVs and 15-min STELs.

7.3.3.5 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) should 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).

7.3.4 *Major Sources of Information on Odor Thresholds*:

7.3.4.1 *American Industrial Hygiene Association's Odor Thresholds for Chemicals with Established Occupational Health Standards*, a peer-reviewed document that contains odor thresholds for a wide variety of chemicals.

7.3.4.2 See EPA 600/R 92/047, a guide for odor thresholds for hazardous air pollutants.

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 **(7)**.

8.2 Compile data for relevant parameters (such as RfC, MRL, and TLV) for each target chemical into a summary table, such as that shown in Fig. 1. The databases identified in 7.3 have reviewed a variety of health-effect studies, primarily toxicological studies. Acute toxicological end-points, such as

Chemical Name: **CAS No:**

Parameter	Value	Comments
Data Reported for Humans		
Human Regulatory Standards/ Guidelines		
Data Reported for Experimental Animals		

FIG. 1 Compilation of Summaries of Health Effects Data and Standards/Guidelines for Target Chemicals