



Designation: D8588 – 24

Standard Practice for Approach to Calculating the Daily Inhalation Exposure Limit for a Non-cannabinoid Ingredient Intended for use in Cannabinoid Products for Vaporization¹

This standard is issued under the fixed designation D8588; 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 practice is not meant to classify the non-cannabinoid ingredient or final product as safe for inhalation. Inhaling anything other than clean air poses an inherent human health risk.

1.2 This practice shall outline the steps for calculating the acceptable daily inhalation limit from a point of departure (POD) for a non-cannabinoid ingredient intended for use in a cannabinoid product for vaporization.

NOTE 1—To use this practice, the user must have previously determined the POD for the non-cannabinoid ingredient under investigation and six uncertainty factors stated in this standard and correction factors.

1.3 This practice shall outline the steps for identifying the maximum allowable concentration limit of a non-cannabinoid ingredient that could be used in a proposed formulation from a POD or a defined TTC.

1.4 This practice shall outline the steps for comparing the concentration of a non-cannabinoid ingredient in an existing formulation to the calculated acceptable daily inhalation limit from a POD or a defined TTC of the non-cannabinoid ingredient under investigation.

1.5 This practice shall provide example scenarios to aid in the usage of the practice and understanding of how to perform the calculation.

1.6 This practice shall not define the means for calculating the acceptable daily inhalation limit from data generated *in vitro*.

1.7 This practice shall not define the means for calculating the acceptable daily inhalation limit from a lethal dose (for example, LC50 or LD50).

1.8 This practice shall not define the means for determining a POD or TTC for the non-cannabinoid ingredient under investigation.

1.8.1 A user must complete a toxicological risk based assessment to determine a POD or TTC for a non-cannabinoid ingredient under investigation. It is recommended to consult an experienced toxicologist when conducting the risk assessment.

1.9 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.10 *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

D8270 Terminology Relating to Cannabis

3. Terminology

3.1 *Definitions:*

3.1.1 *Related to Cannabis*—Definitions are in accordance with Terminology **D8270**, unless otherwise indicated.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *acceptable daily inhalation limit, mg/day, n—in reference to this practice*, is (1) the result of a calculation using a POD, or (2) a selected TTC.

3.2.2 *concentration, n*—the level of a substance of interest in a medium.

3.2.2.1 *Discussion*—Units may be expressed as %w/w, mg/L, mg/g, or mg/m³ of a medium, where the medium could include, but is not limited to, air, cell culture media, solvent, extract, or otherwise.

3.2.3 *corection factor, n—in acceptable daily inhalation limit calculations*, have units and are added to convert POD

¹ This practice is under the jurisdiction of ASTM Committee **D37** on Cannabis and is the direct responsibility of Subcommittee **D37.08** on Personal/Household-Use Cannabis Devices and Appliances.

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