



Designation: D8587 – 24

Standard Guide for Determining a Point of Departure (POD) or Assigning a Threshold of Toxicological Concern (TTC), if needed, for Use in a Toxicological Risk Assessment of a Non- Cannabinoid Ingredient Intended for Use in Cannabinoid Products for Vaporization¹

This standard is issued under the fixed designation D8587; 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 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 guide shall cover all formulated (manufactured) cannabinoid-containing products intended for vaporization regardless of the method of obtention (source) of the cannabinoids used in the product.

1.3 This guide shall cover all formulated (manufactured) cannabinoid-containing products intended for vaporization regardless of whether the cannabinoids can be classified as intoxicating.

1.4 This guide shall cover all formulated (manufactured) cannabinoid-containing products intended for vaporization regardless of the regulatory classification of the consumer product.

1.5 This guide shall cover all non-cannabinoid ingredients, regardless of the method of obtention (source), used in formulated (manufactured) cannabinoid-containing products intended for vaporization.

1.5.1 Because naturally-derived and synthetic compounds produce comparable biological effects, so long as their chemical structure and spatial orientation are identical, the method of obtention (source) of the compound is irrelevant to the need to conduct a toxicological risk assessment of the non-cannabinoid ingredients.

1.6 This guide includes considerations for thermal breakdown products of the non-cannabinoid ingredient through the process of aerosolization via vaporization device usage.

1.7 This guide excludes formulated (manufactured) cannabinoid-containing products intended for combustion as well as dry herbal materials and inhalers (for example, dry powder and metered-dose).

1.8 This guide excludes the cannabinoids themselves.

1.8.1 Exclusion does not mean risk assessment of cannabinoids is unnecessary or that they are risk-free, only that they are beyond the scope of this standard. Investigation into these areas is encouraged to expand knowledge and safety of cannabinoid-containing products.

1.9 This guide excludes impurities and contaminants within the non-cannabinoid ingredients that are otherwise regulated. It is the responsibility of the user of this standard to know the impurities and contaminants and action limits set by the AHJ.

1.10 This guide excludes interactions between the compounds in the cannabinoid-containing product intended for vaporization. Interaction may include chemical interactions between two or more substances that might form new substances. Interactions may also include biological interactions such as a terpene altering cannabinoid binding to a receptor or other types of pharmacokinetic or pharmacodynamic or toxicokinetic or toxicodynamic interactions.

1.10.1 Exclusion does not mean risk assessment of interactions between compounds in the cannabinoid-containing product intended for vaporization are unnecessary or that they are risk-free, only that they are beyond the scope of this standard. Investigation into these areas is encouraged to expand knowledge and safety of cannabinoid-containing products.

1.11 *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.*

1.12 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the*

¹ This guide 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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