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CHAPTER 845

OREGON LIQUOR AND CANNABIS COMMISSION

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RULES:

845-025-1310, 845-026-0400, 845-026-0410

AMEND: 845-025-1310

RULE TITLE: Artificially Derived Cannabinoids

NOTICE FILED DATE: 03/27/2025

RULE SUMMARY: This rule details regulations for artificially derived cannabinoids.

RULE TEXT:

(1) A licensee may transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid, including an artificially derived cannabinoid created by a refinement process using a reactive material such as bleaching clay, or a marijuana or hemp item that contains an artificially derived cannabinoid if:

(a) The artificially derived cannabinoid:

(A) Is not a controlled substance under OAR chapter 855, division 80;

(B) Was manufactured in compliance with applicable laws relating to food safety;

(C) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the item; and

(D) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(b) The item is not intended for human inhalation; and

(c) The manufacturer of the artificially derived cannabinoid:

(A) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid and supplied a copy of that determination to the Commission;

(B) Has provided to the Commission a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(C) Has provided to the Commission an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

- (2) The Commission will notify the licensee of acceptance of documentation received under paragraph (1)(c)(A), (B) or (C) of this rule and may apply additional labeling and concentration limit rules.
- (3) Until January 2, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured before July 1, 2023 containing the artificially derived cannabinoid cannabiniol (CBN) if:
- (a) The item is not intended for human inhalation; and
 - (b) The CBN:
 - (A) Is not a controlled substance under OAR chapter 855, division 80; and
 - (B) Was manufactured in compliance with applicable laws relating to food safety.
- (4) Until July 1, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured on or after July 1, 2023 containing the artificially derived cannabinoid cannabiniol (CBN) if:
- (a) The item is not intended for human inhalation; and
 - (b) The CBN:
 - (A) Is not a controlled substance under OAR chapter 855, division 80;
 - (B) Was manufactured in compliance with applicable laws relating to food safety; and
 - (C) Was manufactured by a person with written approval from the Commission affirming that the manufacturer:
 - (i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;
 - (ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN and provided the Commission with a copy of the analysis; and
 - (iii) Has provided the Commission with copies of any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring a preventive control.
- (5) A manufacturer may request written approval as described in paragraph (4)(b)(C) of this rule in a form and manner prescribed by the Commission. The Commission:
- (a) Shall publish a list of manufacturers who obtain this written approval.
 - (b) May revoke this approval if the manufacturer no longer meets the requirements described in subsection (4)(b) of this rule. If the Commission revokes approval, the manufacturer has the right to a hearing under the procedures in ORS chapter 183.
 - (c) May consult with the Oregon Department of Agriculture for the purposes of reviewing the request.
- (6) If the Commission requires a manufacturer to submit or produce documents to the Commission that the manufacturer believes falls within the definition of a trade secret as defined in ORS 192.501, the manufacturer must mark each document "confidential" or "trade secret."
- (7) A licensee may not transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid or a marijuana or hemp item that contains an artificially derived cannabinoid other than as provided in this rule.
- (8) The Commission may reevaluate the regulation of artificially derived cannabinoids on an annual basis, including establishing purity standards.

STATUTORY/OTHER AUTHORITY: ORS 475C.017

STATUTES/OTHER IMPLEMENTED: ORS 475C.017

AMEND: 845-026-0400

RULE TITLE: Maximum Concentration and Serving Size Limits for Industrial Hemp Products: Definitions, Purpose, Scope and Effective Date

NOTICE FILED DATE: 03/27/2025

RULE SUMMARY: This rule sets the scope, definitions, purpose, and effective date for hemp item concentration and serving size limits pursuant to ORS 571.309.

RULE TEXT:

(1) Applicability.

(a) Except as provided in subsection (b) of this section, this rule applies to industrial hemp products that:

(A) Contain cannabinoids and are intended for human consumption or intended for human use; and

(B) Are offered for sale, transfer, or delivery to a consumer in Oregon or imported into Oregon for delivery to a consumer.

(b) This rule does not apply to hemp items, as that term is defined in OAR 845-025-1015, that are subject to the concentration and serving size limits in OAR 845-025-2760.

(2) An industrial hemp product meets the concentration limits permitted under this rule if:

(a) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent;

(b) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum concentration of THC permitted by more than 10 percent; and

(c) The testing done in accordance with ORS 571.330 or 571.339 was performed using a method with a LOQ sufficient to demonstrate that the total delta-9-THC does not exceed the maximum amount of THC permitted in a container by more than 10 percent.

(3) The maximum concentration and amount of total delta-9-THC permitted in a container and the maximum concentration or amount of total delta-9-THC permitted in a serving is listed in Table 3, incorporated by reference.

(4) An industrial hemp product may only contain an artificially derived cannabinoid if:

(a) Until July 1, 2025:

(A) The only artificially derived cannabinoid the industrial hemp product contains is cannabitol (CBN);

(B) The product is not intended for human inhalation; and

(C) The CBN:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety; and

(D) The manufacturer of the CBN:

(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;

(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN; and

(iii) Has documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control; or

(b) At any time:

(A) The artificially derived cannabinoid:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety;

(iii) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the product; and

(iv) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(B) The product is not intended for human inhalation; and

(C) The manufacturer of the artificially derived cannabinoid:

(i) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid;

(ii) Has received a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(iii) Has received an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

(5) Serving size is as determined by the manufacturer and must comply with applicable serving size limits.

(6) An industrial hemp product that does not fall within a category in Table 3 must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 3.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, 475C.405, ORS 571.309, 2024 OL Ch. 16 Sec. 9

STATUTES/OTHER IMPLEMENTED: ORS 571.309, 2024 OL Ch. 16 Sec. 9

OAR 845-026-0400**Table 3**

| INDUSTRIAL HEMP PRODUCT THC CONCENTRATION AND SERVING SIZE LIMITS | | | |
|--|---|---|--|
| Type of Industrial Hemp Product | Maximum Amount of Total Delta-9-THC Per Serving | Maximum Amount of Total Delta-9-THC per Container | Maximum Concentration of Total Delta-9-THC |
| Hemp Edibles | 2 mg | 20 mg | 0.3% |
| Hemp Topicals | N/A | N/A | 0.3% |
| Hemp Transdermal Patches | 2 mg | 20 mg | 0.3% |
| Hemp Tinctures | 2 mg | 100 mg | 0.3% |
| Usable Hemp | N/A | N/A | 0.3% |
| Industrial Hemp Concentrates or Extracts | N/A | N/A | 0.3% |
| Cannabinoid Hemp Products Other than Hemp Edibles, Topicals, Tinctures, or Transdermal Patches | 2 mg | 20 mg | 0.3% |

AMEND: 845-026-0410

RULE TITLE: Adult Use Cannabinoid Concentration Level for Industrial Hemp Commodities or Products Constituting Marijuana Items: Definitions, Purpose, Scope and Effective Date

NOTICE FILED DATE: 03/27/2025

RULE SUMMARY: This rule sets the scope, definitions, purpose, and effective date for hemp item concentration and serving size limits pursuant to ORS 475C.257.

RULE TEXT:

(1) Applicability.

(a) Except as provided in subsection (b) of this section, this rule applies to industrial hemp commodities or products that:

(A) Contain cannabinoids and are intended for consumption or use by humans or animals; and

(B) Are offered for sale or transfer to a consumer in Oregon or imported into Oregon for delivery to a consumer.

(b) Hemp items, as that term is defined in OAR 845-025-1015, subject to the concentration and serving size limits in OAR 845-025-2760 must also comply with the requirements in OAR 845-025-2760.

(2) An industrial hemp commodity or product does not exceed the concentration limits established under this rule if:

(a) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent;

(b) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum concentration of THC permitted by more than 10 percent; and

(c) The testing done in accordance with ORS 571.330 or 571.339 was performed using a method with a LOQ sufficient to demonstrate that the total delta-9-THC does not exceed the maximum amount of THC permitted in a container by more than 10 percent.

(3) Table 4, incorporated by reference, establishes the maximum concentration and amount of total delta-9-THC for a container and the maximum concentration or amount of total delta-9-THC for a serving.

(4) An industrial hemp commodity or product may contain an adult use cannabinoid that is an artificially derived cannabinoid only if:

(a) Until July 1, 2025:

(A) The only artificially derived cannabinoid the industrial hemp product contains is cannabidiol (CBD);

(B) The product is not intended for human inhalation; and

(C) The CBD:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety; and

(D) The manufacturer of the CBD:

(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;

(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBD; and

(iii) Has documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control; or

(b) At any time:

(A) The artificially derived cannabinoid:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety;

(iii) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the product; and

(iv) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(B) The product is not intended for human inhalation; and

(C) The manufacturer of the artificially derived cannabinoid:

- (i) Has made a “Generally Recognized as Safe” (GRAS) determination for the artificial cannabinoid;
 - (ii) Has received a Food and Drug Administration (FDA) letter responding to a “Generally Recognized as Safe” (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or
 - (iii) Has received an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.
- (5) Serving size is as determined by the manufacturer and must comply with applicable serving size limits.
- (6) An industrial hemp commodity or product that does not fall within a category in Table 4 must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 4.
- (7) Civil Penalties. The Commission may impose a civil penalty of no more than \$10,000 for each violation of ORS 475C.257 against a person other than a commission-licensed marijuana retailer for selling an industrial hemp commodity or product to a consumer that exceeds the concentration and serving size limits in this rule.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 475C.257, 2024 OL Ch. 16 Sec. 9

STATUTES/OTHER IMPLEMENTED: ORS 475C.257, 2024 OL Ch. 16 Sec. 9

OAR 845-026-0410

Table 4

| INDUSTRIAL HEMP PRODUCT THC CONCENTRATION AND SERVING SIZE LIMITS | | | |
|--|---|---|--|
| Type of Industrial Hemp Product | Maximum Amount of Total Delta-9-THC Per Serving | Maximum Amount of Total Delta-9-THC per Container | Maximum Concentration of Total Delta-9-THC |
| Hemp Edibles | 2 mg | 20 mg | 0.3% |
| Hemp Topicals | N/A | N/A | 0.3% |
| Hemp Transdermal Patches | 2 mg | 20 mg | 0.3% |
| Hemp Tinctures | 2 mg | 100 mg | 0.3% |
| Usable Hemp | N/A | N/A | 0.3% |
| Industrial Hemp Concentrates or Extracts | N/A | N/A | 0.3% |
| Cannabinoid Hemp Products Other than Hemp Edibles, Topicals, Tinctures, or Transdermal Patches | 2 mg | 20 mg | 0.3% |