

R68. Agriculture and Food, Plant Industry.

R68-37. Industrial Hemp Cannabinoid Product Testing.

R68-37-1. Authority and Purpose.

1) Pursuant to Subsection 4-41-204(2), this rule establishes the standards for industrial hemp cannabinoid product potency testing and sets limits for foreign matter, microbial life, pesticides, residual solvents, heavy metals, and mycotoxins.

R68-37-2. Definitions.

- 1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:
 - a) pesticides;
 - b) heavy metals;
 - c) solvents;
 - d) microbial life;
 - e) mycotoxins; or
 - f) foreign matter.
- 2) "Analyte" means a substance or chemical component that is undergoing analysis.
- 3) "Batch or lot" means a quantity of:
 - a) cannabinoid concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of industrial hemp are used; or
 - b) cannabinoid product produced on a particular date and time, following clean up until the next clean up during which industrial hemp concentrate is used.
- 4) "Cannabinoid" means any:
 - a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1); or
 - b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
- 5) "Cannabinoid concentrate" means:
 - a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass; and
 - b) any amount of a natural, derivative, or synthetic cannabinoid in the synthetic cannabinoid's purified state.
- 6) "Cannabinoid product" means the same as the term is defined in Subsection 4-41-102(1).
- 7) "CBD" means cannabidiol (CAS 13956-29-1).
- 8) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).
- 9) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the results for which that testing was performed.
- 10) "Department" means the Utah Department of Agriculture and Food.
- 11) "Final product" means a reasonably homogenous cannabinoid product in its final packaged form created using the same standard operating procedures and the same formulation.
- 12) "Foreign matter" means:
 - a) any matter that is present in a cannabis lot that is not a part of the cannabis plant; or
 - b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient.
- 13) "Industrial hemp" means a cannabis plant that contains less than 0.3% total THC by dry weight.
- 14) "Industrial hemp manufacturer" means an entity that holds, stores, packages, or labels an industrial hemp cannabinoid product.
- 15) "Pest" means:
 - a) any insect, rodent, nematode, fungus, weed; or
 - b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.
- 16) "Pesticide" means any:
 - a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;
 - b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and
 - c) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own used with a pesticide to aid in the application or effect of a pesticide.
- 17) "THC" means total composite tetrahydrocannabinol, including delta-9-tetrahydrocannabinol, tetrahydrocannabinolic acid, and any THC analogs as defined in Subsection 58-37-4(2)(a)(ii)(AA).
- 18) "THCA" means delta-9-tetrahydrocannabinolic acid (CAS 23978-85-0).
- 19) "Total CBD" means the sum of the determined amounts of CBD and CBDA, according to the formula: Total CBD = CBD + (CBDA x 0.877).
- 20) "Total THC" means the sum of the determined amounts of THC and THCA, according to the formula: Total THC = THC + (THCA x 0.877).
- 21) "Unit" means each individual portion of an individually packaged product.

R68-37-3. Required Cannabinoid Product Tests.

- 1) An industrial hemp manufacturer may not register or sell a cannabinoid product unless a third party testing laboratory has tested a representative sample of the cannabinoid product to determine:
- the amount of any THC analogs present in the sample; and
 - the presence of adulterants in the sample.
- 2) A certificate of analysis shall be included with each batch of cannabinoid product in accordance with Section R68-26-4.

R68-37-4. Foreign Matter Standards.

A sample and related batch of cannabinoid product fails quality assurance testing if:

- the sample contains foreign matter visible to the unaided human eye;
- the sample is found to contain microscopic foreign matter considered to be harmful or estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or
- foreign matter is found that is suspected to have been intentionally added to the sample to increase its visual appeal or market value.

R68-37-5. Potency Testing.

A batch of cannabinoid product shall have the quantity of any cannabinoid it is known to contain, including any THC analog, determined and listed on the COA.

R68-37-6. Microbial Standards.

A sample and related batch of cannabinoid product fails quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Table 2.

TABLE 2
Microbial Analytes and Action Levels

Material	Microbial Limit Requirement (cfu)
Concentrated oil	Total Aerobic Microbial Count ≤10,000
Tablet	Total Aerobic Microbial Count ≤10,000
Capsule	Total Combined Yeast and Mold Count ≤1,000
Liquid Suspension	Absence of E. Coli and Salmonella spp.
Gelatinous cube	Absence of Staph
Transdermal	Total Aerobic Microbial Count ≤100
	Total Yeast and Mold ≤100
	Absence of Pseudomonas
	Absence of Staph

R68-37-7. Pesticide Standards.

- A sample and related batch of cannabinoid product fails quality assurance testing for pesticides if the results exceed the limits as set forth in Table 3.

TABLE 3
Pesticide Analytes and Action Levels

Analyte	Chemical Abstract Service (CAS) Registry number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2

Etofenprox	80844-07-1	0.4
Etoazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
hexythiazox	78587-05-0	1
imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	143390-89-0	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

2) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

3) Pyrethrins should be measured as the cumulative residues of pyrethrin I (CAS 121-21-1), pyrethrin II (CAS 121-29-9), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2).

4) Abamectin is a composite of the amounts of avermectin B1a and avermectin B1b.

R68-37-8. Residual Solvent Standards.

1) A sample and related batch of cannabinoid product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 4 unless the solvent is:

- a component of the product formulation;
- listed as an ingredient; and
- generally considered to be safe for the intended form of use.

TABLE 4
List of Solvents and Action Levels

Solvent	Chemical Abstract Service (CAS)Registry number	Action level ppm
1,2 Dimethoxyethane	110-71-4	100
1,4 Dioxane	123-9	380
1-Butanol	71-36-3	5,000
1-Pentanol	71-41-0	5,000
1-Propanol	71-23-8	5,000
2-Butanol	78-92-2	5,000
2-Butanone	78-93-3	5,000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5,000
2-Propanol (IPA)	67-63-0	5,000
Acetone	67-64-1	5,000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5,000
Cumene	98-82-8	70
Cyclohexane	110-82-7	3,880
Dichloromethane	75-09-2	600

2,2-dimethylbutane	75-83-2	290
2,3-dimethylbutane	79-29-8	290
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5,000
Ethanol	64-17-5	5,000
Ethyl acetate	141-78-6	5,000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5,000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5,000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5,000
Methanol	67-56-1	3,000
Methylpropane	75-28-5	5,000
2-Methylpentane	107-83-5	290
3-Methylpentane	96-14-0	290
N,N-dimethylacetamide	127-19-5	1,090
N,N-dimethylformamide	68-12-2	880
Pentane	109-66-0	5,000
Propane	74-98-6	5,000
Pyridine	110-86-1	100
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes	1330-20-7	2,170

- 2) Xylenes is a combination of the following:
- 1,2-dimethylbenzene;
 - 1,3-dimethylbenzene;
 - 1,4-dimethylbenzene; and
 - ethyl benzene.

R68-37-9. Heavy Metal Standards.

A sample and related batch of cannabinoid product fails quality assurance testing for heavy metals if the results exceed the limits provided in Table 5.

TABLE 5
Heavy Metals

Metals	Natural Health Products Acceptable limits in parts per million
Arsenic	<2
Cadmium	<0.82
Lead	<1.2
Mercury	<0.4

R68-37-10. Mycotoxin Standards.

A sample and related batch of cannabinoid product fails quality assurance testing for mycotoxin if the results exceed the limits provided in Table 6.

TABLE 6
Mycotoxin

Test	Specification
The total of Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, and Aflatoxin G2	<20 ppb of substance
Ochratoxin A.	<20 ppb of substance

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