**R66. Agriculture and Food, Specialized Products.**

**R66-52. Kratom Product Testing.**

**R66-52-1. Authority and Purpose.**

Pursuant to Section 4-45-107, this rule establishes the standards for kratom product potency testing and sets limits for foreign matter, microbial life, pesticides, residual solvents, heavy metals, mycotoxins, and other additives.

**R66-52-2. Definitions.**

(1) "7-OH level" means the concentration of 7-OH divided by the combined concentration of total kratom alkaloids.

(2) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:

(a) prohibited additives outlined in Section R66-52-11;

(b) pesticides;

(c) heavy metals;

(d) solvents;

(e) microbial life;

(f) mycotoxins; or

(g) foreign matter.

(3) "Alkaloid" means any class of nitrogenous organic compounds of plant origin which have pronounced physiological actions on humans

(4) "Analyte" means a substance or chemical component undergoing analysis.

(5) "Certificate of Analysis (COA)" means a certificate from a laboratory describing the results of the laboratory's analytical testing of a sample.

(6) "Extract" means:

(a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the alkaloid contained in the biomass; and

(b) any amount of a natural, derivative, or synthetic alkaloid in the synthetic alkaloid's purified state.

(7) "Foreign matter" means any matter that is present in a kratom:

(a) lot that is not a part of the kratom plant; or

(b) product that is not listed as an ingredient.

(8) "Kratom manufacturer" means an entity that holds, stores, packages, or labels a kratom product.

(9) "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.

(10) "Total alkaloid" means the sum of the determined amount of alkaloids from Mitragyna speciosa.

**R66-52-3. Required Kratom Product Tests.**

(1) Testing shall be performed on finished products identified with a lot or batch number.

(2) A kratom manufacturer may not register or sell a kratom product unless a third-party ISO/IEC 17025:2017 accredited testing laboratory has tested a representative sample of the kratom product to determine:

(a) the amount of any alkaloids present in the sample; and

(b) the presence of adulterants in the sample.

(3) Each batch or lot of kratom product shall include a certificate of analysis, in accordance with Section R66-51-5.

**R66-52-4. Foreign Matter Standards.**

A sample and related batch of kratom product fail quality assurance testing if:

(1) the sample contains foreign matter visible to the unaided human eye;

(2) 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

(3) foreign matter is found that is suspected to have been intentionally added to the sample to increase its visual appeal or market value.

**R66-52-5. Potency Testing and Standards.**

(1) At a minimum, the certificate of analysis for each batch of kratom product shall include the following test results, when applicable:

(a) the contents of mitragynine and 7-hydroxymitragynine in the kratom product certifying compliance with this rule and Subsection 4-45-104(1);

(i) the department may require testing of alkaloid content of a kratom product by the department lab for verification, at the cost of the registrant.

(b) the level of microbials in the kratom product that does not exceed the amounts listed in Table 1 when one gram or greater sample is tested;

(c) the levels of heavy metals in the kratom product that do not exceed the amounts listed in Table 2;

(d) the levels of pesticides in the kratom product do not exceed the amounts listed in Table 3;

(e) the levels of residual solvents in the kratom product that do not exceed the amounts listed in Table 4; and

(f) if required by the department, mycotoxin levels that are compliant with Section R66-52-10.

**R66-52-6. Microbial Standards.**

(1) A sample and related batch of kratom product fail quality assurance testing for microbiological contaminants if the results exceed the limits in Table 1.

|  |  |
| --- | --- |
| TABLE 1  Kratom Plant Matter | |
| Microbial | Microbial Limit Requirement |
| Total Aerobic Microbial Count | NMT ≤100,000 cfu/g |
| Total Combined Yeast and Mold | NMT ≤100,000 cfu/g |
| Salmonella spp.,  Shiga-toxin producing E. coli (STEC),  Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreusc | Not detected in 25g |
| Kratom Extract | |
| Microbial | Microbial Limit Requirement |
| Total Aerobic Microbial Count | NMT ≤10,000 cfu/g |
| Total Combined Yeast and Mold | NMT ≤1,000 cfu/g |
| Salmonella spp.,  Shiga-toxin producing E. coli (STEC) | Not Detected in 1g |
| Kratom Infused Edible | |
| Microbial | Microbial Limit Requirement |
| Total Aerobic Microbial Count | NMT ≤10,000 cfu/g |
| Total Combined Yeast and Mold | NMT ≤1,000 cfu/g |
| Salmonella spp.,  Shiga-toxin producing E. coli (STEC) | Not Detected in 1g |

**R66-52-7. Heavy Metal Standards.**

(1) A sample and related batch of kratom product fail quality assurance testing for heavy metals if the results exceed the limits in Table 2.

|  |  |
| --- | --- |
| TABLE 2  Heavy Metals | |
| Metals | Natural Health Products Acceptable Limits |
| Arsenic | <2 ppm |
| Cadmium | <0.82 ppm |
| Lead | <1.2 ppm |
| Mercury | <0.4 ppm |

**R66-52-8. Pesticide Standards.**

(1) A sample and related batch of kratom product fail quality assurance testing for pesticides if the results exceed the limits in Table 3.

|  |  |  |
| --- | --- | --- |
| TABLE 3  Kratom Plant Matter  Pesticide Analytes and Action Levels | | |
| Analyte | Chemical Abstract Service | Action Level |
|  | (CAS) Registry number | 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 | 0116-06-03 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-03 | 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 | 52315-07-08 | 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 | 80844-07-01 | 0.4 |
| Etoxazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-08 | 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 | 0732-11-6 | 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 the 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.

**R66-52-9. Residual Solvent Standards.**

(1) A sample and related batch of kratom product fail quality assurance testing for residual solvents if the results exceed the limits in Table 4, unless the solvent is:

(a) a component of the product formulation;

(b) listed as an ingredient; and

(c) generally considered to be safe for the intended form of use.

|  |  |  |
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| TABLE 4  Kratom Extract/Kratom Infused Edible  List of Solvents and Action Levels | | |
| Solvent | Chemical Abstract Service | Action Level |
|  | (CAS) Registry number | 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 | 290 | 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:

(a) 1,2-dimethylbenzene;

(b) 1,3-dimethylbenzene;

(c) 1,4-dimethylbenzene; and

(d) ethyl benzene.

**R66-52-10. Mycotoxin Standards.**

(1) Mycotoxin testing of a kratom product may be required if the department has reason to believe that mycotoxins may be present.

(2) A sample and related batch of kratom product fail quality assurance testing for mycotoxin if the results exceed the limits in Table 5.

|  |  |
| --- | --- |
| TABLE 5  Mycotoxin | |
| Test | Specification |
| The total of Aflatoxin B1, B2, G1 and G2 | <20 ppb of substance |
| Ochratoxin | <20 ppb of substance |

**R66-52-11. Additives.**

(1) A kratom product may not:

(a) contain additives that exceed the allowable limits in the following table:

|  |  |
| --- | --- |
| TABLE 6  Controlled Additives | |
| Additive | Limit per Serving |
| Ashwagandha | 250mg |
| Blue Lotus | 250mg |
| Caffeine | 100mg |
| California Poppy | 40mg |
| Corydalis Yanhuso | 500mg |
| Devil's Claw | 100mg |
| Guarana | 100mg |
| Kavalactones | 125mg |
| Valerian Root | 150mg |
| Yohimbe Bark | 9mg |

(b) contain any of the following:

(i) mushroom species that contain:

(A) psilocin;

(B) muscimol;

(C) ibotenic acid;or

(D) muscarine.

(ii) any cannabinoids.

**KEY: kratom, kratom processor, testing**

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