

Protocol for the Sampling and Analysis of Finished Marijuana Products and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers, and Colocated Marijuana Operations

Exhibit 7a. Concentration Limits for Residual Solvents

Exhibit 7b. Concentration Limits for Residual Levels of Propane, n-Butane, or Iso-Butane

Implemented March 11, 2021 and Revised July 13, 2021

This document is issued by the Cannabis Control Commission. The applicable Marijuana laws, which include M.G.L. c. 94I, 94G, 935 CMR 500.000 and 935 CMR 501.000, should be reviewed as they may provide or clarify the legal requirements related to this document. This protocol document should be checked periodically for revisions. Questions with regards to this document may be directed to <u>Commission@CCCMass.com</u>.

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Exhibit 7a. Concentration Limits for Residual Solvents

Solvent	Concentration Limit (mg/kg)	Solvent	Concentration Limit (mg/kg)
Acetic acid	5000	Heptane	5000
Acetone	5000	Hexane	290
Acetonitrile	410	Isobutyl acetate	5000
Anisole	5000	Isopropyl acetate	5000
1-Butanol	5000	Methanol	3000
2-Butanol	5000	2-Methoxyethanol	50
Butyl acetate	5000	Methyl acetate	5000
Tert-Butylmethyl ether	5000	3-Methyl-1-butanol	5000
Chlorobenzene	360	Methylbutylketone	50
Chloroform	60	Methylcyclohexane	1180
Cumene	70	Methylethyl ketone	5000

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Solvent	Concentration Limit (mg/kg)	Solvent	Concentration Limit (mg/kg)
Cyclohexane	3880	Methylisobutyl ketone	5000
1,2-Dichloroethene	1870	2-Methyl-1- propanol	5000
Dichloromethane	600	N- Methylpyrrolidone	530
1,2- Dimethoxyethane	100	Nitromethane	50
<i>N,N</i> - Dimethylacetamide	1090	Pentane	5000
<i>N,N</i> - Dimethylformamide	880	1-Pentanol	5000
Dimethyl sulfoxide	5000	1-Propanol	5000
1,4-Dioxane	380	2-Propanol	5000
Ethanol	5000	Propyl acetate	5000
2-Ethoxyethanol	160	Pyridine	200
Ethyl acetate	5000	Sulfolane	160

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Solvent	Concentration Limit (mg/kg)	Solvent	Concentration Limit (mg/kg)
Ethylene glycol	620	Tetrahydrofuran	720
Ethyl ether	5000	Tetralin	100
Ethyl formate	5000	Toluene	890
Formamide	220	1,1,2- Trichloroethylene	80
Formic acid	5000	Xylene	2170

Exhibit 7b. Concentration Limits for Residual Levels of Propane, n-Butane, or Iso-Butane

The Medical Use of Marijuana Program has amended the document *Protocol for the Sampling and Analysis of Finished Marijuana Products and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers, and Colocated Marijuana Operations* to reflect the addition of the hydrocarbon gases propane, butane and iso-butane to the list of approved solvents in Exhibit 7a.

Solvent*	Upper Limit (mg/kg)
Propane (CAS 74-98-6)	12
n-Butane (CAS 106-97-8)	12
Iso-Butane (CAS 75-28-5)	12

*The ingredients must be of purity suitable for use in food intended for human consumption. At a minimum, the solvent (gas) must be high-purity (>99%) of propane, n-butane, or iso- butane, or a blend these three hydrocarbon gases.

The upper limits are based on residual solvent recommendation by the Commission of the European Communities, Scientific Committee on Food (SCF, 1999). SCF has evaluated propane, n-butane and iso- butane as extraction solvents and determined that a residue level of 1mg of residual hydrocarbon per kg of food consumed is safe. The SCF evaluation suggests that these hydrocarbons are typically present in prepared foods in amounts less than 0.1 mg/kg. After careful review of the SCF assessment, MDPH has adopted a level of 1 mg/kg (or 10 times the background level of 0.1 mg/kg) as a health-protective residual solvent limit for cannabis oil.

Please note that these Protocols are continually evaluated and revised based upon new scientific and industry information.