Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries

Exhibit 7 (a). Concentration Limits for Residual Solvents

This document was issued originally by the Department of Public Health (DPH). As part of the transfer of the medical-use of marijuana program on or before December 31, 2018, the Commission adopted this document. We suggest that before you rely on the contents of this document, you check the applicable medical-use marijuana laws, which include M.G.L. c. 94I and 935 CMR 501.000, as they may provide or clarify the legal requirements related to this document. We also suggest that you periodically check for revisions to this document. Questions with regards to this document may be directed to Commission@CCCMass.com.

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
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
N,N - Dimethylacetamide	1090	Pentane	5000
N,N - 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
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 7 (b). Concentration Limits for Residual Levels of Propane, n-Butane, or Iso- Butane

Interim – Not Final

As a standard is not available from USP, DPH developed interim guidance for the use of butane in marijuana extractions that is based on measured levels in prepared food (see DPH Circular Letter DHCQ 15-08-638, available at mass.gov/medicalmarijuana).

The Medical Use of Marijuana Program has amended the document "Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries" to reflect the addition of the hydrocarbon gases propane, butane and iso-butane to the list of approved solvents in Exhibit 7. Analysis Requirements for Residual Solvents in Cannabis Oil.

Solvent*	Upper Limit (mg/kg)
Propane (CAS 74-98-6)	1
n-Butane (CAS 106-97-8)	1
Iso-Butane (CAS 75-28-5)	1

** 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.

Source: MDPH August 17, 2015 Circular Letter: DHCQ 15-08-638
http://www.mass.gov/eohhs/docs/dph/quality/medical-marijuana/dph-hydrocarbons.pdf

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