Ohio Department of Commerce
Medical Marijuana Control Program

Residual Solvent Threshold Guidance

This communication is intended to provide guidance on thresholds for residual solvents that may be present in medical marijuana products manufactured by processors licensed under the Ohio Medical Marijuana Control Program.

Processors are permitted by OAC 3796:3-2-01(C) to employ extraction methods utilizing ethanol, propane, isobutane, N-butane, heptane, or other solvents exhibiting minimal toxicity with the approval of the department. OAC 3796:4-2-04 requires testing laboratories to analyze samples for the presence of residual solvents. Based on International Conference for Harmonization (ICH) Guideline Q3C on Impurities: Guidelines for Residual Solvents, which had been further reviewed by a public health toxicologist, MMCP has developed a list outlining the thresholds for residual solvents in manufactured medical marijuana products. A sample analyzed by a testing laboratory will be deemed to have passed if residual solvent levels do not exceed the following:

Solvent	Parts-per-million (ppm)
Propane	5000
N-butane	5000
Isobutane	5000
Heptane	5000
Ethanol	5000
Other solvents	Per ICH Guideline Q3C on Impurities

The Department is **NOT** approving additional solvents for use in the manufacture of medical marijuana products at this time. However, in the event that solvent contaminants other than N-butane, isobutane, heptane, propane, or ethanol be detected in laboratory analysis, the levels may not exceed human protective thresholds identified in the ICH Guideline Q3C on Impurities: Guidelines for Residual Solvents. Laboratories detecting significant and/or frequent presence of solvents other than N-butane, isobutane, heptane, propane, or ethanol should report the matter to MMCP staff immediately.

Please send any questions about this guidance document to your compliance agent or to MMCPcompliance@com.ohio.gov.