



Reassessed Inert Ingredients

1. Purpose

This guidance provides information to OCal certifying agents, cultivators and distributors regarding the allowance of inert ingredients, primarily used in pesticide products.

2. OCal Regulations, Title 3 California Code of Regulations (3 CCR)

3 CCR § 10000. Definitions.

3 CCR § 10105. Allowed and prohibited substances and methods in OCal production.

3. Background

The OCal regulations allow and prohibit substances for use in OCal production according to the National List of Allowed and Prohibited Substances (National List), at § 205.601 and § 205.602 in title 7 of the Code of Federal Regulations (CFR). The National List allows use of inert ingredients in a variety of applications, primarily as pesticides, and refers to lists maintained and managed by Environmental Protection Agency (EPA):

List 4A – Minimal Risk Inert Ingredients

List 4B – Other Ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect the public health or the environment.

The EPA has been reassessing exemptions from tolerances for inert ingredients in pesticide products to ensure that they meet the safety standard established by the Food Quality Protection Act (FQPA). FQPA requires the reassessment of inert ingredient tolerances and tolerance exemptions that were in place prior to August 3, 1996. The EPA completed their reassessment in 2006 and certain List 4 inert ingredients were revoked (below).

List 4 inert ingredients now prohibited under the OCal Program are:

- Acetylated lanolin alcohol (CAS Reg. No. 91994-94-4); Revoked in 70 FR 31401, June 1, 2005.
- Acrylic acid methyl ester, polymer with acrylonitrile and 1,3-butadiene



- (CAS Reg. No. 27012-62-0); Revoked in 71 FR 14411, March 22, 2006; the tolerance exemption is called “Nitrile rubber modified acrylonitrile methyl acrylate conforming to 21 CFR 177.1480.
- Coumarone – indene resin (CAS Reg. No. 63393-89-5); Revoked in 71 FR 14411, March 22, 2006.
- Manganous oxide (CAS Reg. No. 1344-43-0); Revoked in 71 FR 45415, August 9, 2006.
- Pentaerythritol monostearate (CAS Reg. No. 78–23–9); Revoked in 71 FR 14411, March 22, 2006.
- Pentaerythritol tetra stearate CAS Reg. No. 115–83–3); Revoked in 71 FR 14411, March 22, 2006.
- **Polyglyceryl phthalate ester of coconut oil fatty acid (CAS Reg. No. 66070-87-9); Revoked in 71 FR 45415, August 9, 2006.**
- **Sodium fluoride (CAS Reg. No. 7681-49-4); Revoked in 70 FR 31401, June 1, 2005.**

The EPA has also reclassified a number of List 3 inert ingredients (inerts of unknown toxicity) as List 4 inert ingredients. Those materials have not been added to EPA’s published List 4 documents but appear through individual approvals issued by EPA and posted on their website.

The EPA has informed the USDA NOP that it may not issue an updated List 4. The NOP plans to amend the National List of Allowed and Prohibited Substances, 7 CFR § 205.601 – § 205.606, to accommodate this change. The OCal Program will notify certifiers and certified operations when the National List has been amended that affects OCal operations.

4. Policy

Parties reviewing pesticide product ingredients for compliance with the OCal Program are advised to use the EPA’s List 4, published on the EPA Website, minus the revoked inert ingredients above, to verify allowed inert ingredients. This policy will remain in effect until superseded by regulatory changes or new guidance.

5. References

National Organic Program Regulations, Title 7 Code of Federal Regulations (7 CFR part 205)

7 CFR § 205.601. Synthetic substances allowed for use in organic crop production.



Other Laws and Regulations

EPA List 4, <https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists>

United States. Cong. Food Quality Protection Act of 1996. 104th Cong. Washington: GPO, 1996. Print.