



Reassessed Inert Ingredients

Background

The National Organic Program (NOP) regulations currently allow use of inert ingredients which appear on the Environmental Protection Agency (EPA) *List 4A – Minimal Risk Inert Ingredients* and *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* – in a variety of applications, primarily as pesticides in organic production operations. These lists are maintained and managed by EPA.

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. EPA completed their reassessments in 2006.

EPA reassessments resulted in the revocation of a few List 4 inert ingredients, and are therefore prohibited under NOP. List 4 inert ingredients that have been revoked for use in pesticide formulations and are now prohibited under NOP are as follows:

- 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 methylacrylate 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 tetrastearate 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.

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.

EPA has informed USDA that the “Inerts List” system may no longer be effective or available for the NOP to reference in the Regulations. Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations. As a result, the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA. NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations.



Policy

Parties reviewing pesticide product ingredients for compliance with the NOP are advised to use EPA's August 2004 lists of approved List 4 inert ingredients, minus the revoked inert ingredients. Links to the aforementioned lists are as follows:

- List 4A - http://www.epa.gov/opprd001/inerts/inerts_list4Aname.pdf
- List 4B - http://www.epa.gov/opprd001/inerts/inerts_list4Bname.pdf

The NOSB has requested that inert ingredients reassessed by EPA, but not previously authorized for use under the NOP remain prohibited in organic agriculture. Until the NOP and NOSB can determine the best course to take in response to EPA's reassessment decisions, NOP will concur with the NOSB's request and grant that use of such ingredients must be petitioned. A petition may be submitted to the NOSB using the [National List petition procedures](#). Petitioned substances must be recommended by the NOSB and added to the National List through notice and comment rulemaking before use in organic agriculture.

This policy will remain in effect until superseded by regulatory changes or new guidance. Certifiers and other affected parties should consult the NOP Document Control Masterlist for the most current guidance on this topic.