

EPA Phosalone Facts

EPA has assessed the dietary risks of phosalone and prepared a “Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision” for this organophosphate (OP) pesticide. Phosalone fits into its own “risk cup”-- its individual risks are within acceptable levels.

Phosalone has no U.S. registrations and nine import tolerances, on almond (hulls), almonds, apples, apricots, cherries, grapes, peaches, pears, and plums (fresh prunes). Phosalone treated crops do not pose risk concerns, and no risk mitigation is necessary at this time.

EPA’s next step under the Food Quality Protection Act (FQPA) is to complete a cumulative risk assessment and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on phosalone cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be warranted at that time.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs need decisions about their eligibility for reregistration under FIFRA. OPs with residues in food, drinking water, and other non-occupational exposures also must be reassessed to make sure they meet the new FQPA safety standard.

The phosalone interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA’s development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in this interim decision document, which concludes the OP pilot process for phosalone.

The OP Pilot Public Participation Process

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA’s highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA’s web site, www.epa.gov/pesticides/op.)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides, and will make final decisions through a cumulative OP assessment.

Uses

- An insecticide/acaricide, phosalone is used to control various insect species in/on almonds, apples, apricots, cherries, grapes, peaches, pears, and plums in Algeria, Austria, Belgium, Canada, Croatia, Czech Republic, France, Greece, Hungary, Iraq, Italy, Japan, Kuwait, Morocco, Poland, Portugal, Russia, Slovak Republic, Spain, Switzerland, Taiwan, Tunisia, Turkey, and Ukraine. It is not registered under FIFRA and may not be sold, distributed, or used in the U.S.
- Nine import tolerances are established for residues of phosaone in/on imported almonds, apples, apricots, cherries, grapes, peaches, pears, and plums. It is estimated that less than 1.5% of the apples (fresh and dried), 0.1% of pears, 0.05% of peaches, and 0.2% of plums available in the U.S. are imported from countries with phosalone registrations. Total imports treated with phosalone is approximately 13.0 %; 6.0 % of which is from apple juice.

Health Effects

- Phosalone can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

Risks

- Dietary exposures from eating food crops treated with phosalone are below the level of concern for the entire U.S. population, including infants and children. Dietary exposure through drinking water is not expected because there is no domestic usage.

Risk Mitigation

- Dietary risk from exposure to phosalone does not exceed EPA's level of concern. Therefore, no mitigation is necessary and no further actions are warranted at this time.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The phosalone IRED therefore is issued in final (see www.epa.gov/REDS/ or www.epa.gov/pesticides/op), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.
- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for phosalone and may request further risk mitigation measures. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.