

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO INDOXACARB

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02	30	3.7	0.02	490
All infants less than 1 year old	0.02	29	3.7	0.02	140
Children 1 to 2	0.02	79	3.7	0.02	43

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* There is no evidence for mutagenicity and there is no evidence of carcinogenicity in either the rat or mouse. Indoxacarb has been classified as "not likely to be carcinogenic in humans" by the Agency; therefore, Indoxacarb is not expected to pose carcinogenic risk when used as directed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to Indoxacarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography HPLC/UV Method AMR 2712-93) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of indoxacarb; therefore, international harmonization is not an issue at this time.

V. Conclusion

A 15-day comment period is being allowed for this proposed rule because of the speed of growth and the pest pressure, and the Agency's desire to be supportive of efforts by peach growers and researchers to find alternatives to organophosphates for control of oriental fruit moth and plum curculio in peaches. Additionally, the Agency feels that there is strong evidence in support of the safety of this proposed action.

Therefore, a temporary tolerance for 3 years is proposed for combined residues of Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[methoxy carbonyl] 4-(trifluoromethoxy)phenyl] amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate + its R-enantiomer] (R)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl] 4-(trifluoromethoxy)phenyl] amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate in peaches at 10.0 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule is establishing a tolerance under section 408(d) of the FFDCA. EPA is proposing this regulation in cooperation with Research Extension Specialists at the University of Georgia, Rutgers University, Clemson University, Pennsylvania State University, Michigan State University, University of West Virginia, and DuPont de Nemours and Company. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211,

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this proposed rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is