

6. *Prenatal and postnatal sensitivity.* The rationale for retaining the 10X FQPA safety factor is explained below:

i. There is evidence of increased susceptibility of offspring following *in utero* exposure to vinclozolin in the prenatal developmental toxicity study in rats.

ii. A developmental neurotoxicity study in rats with an expanded protocol is required for vinclozolin as a result of concern for the anti-androgenic properties of vinclozolin and its metabolites.

G. Conclusion

Based on the developmental and reproductive data for vinclozolin, EPA determined that an additional 10X safety factor for the protection of infants and children (as required by FQPA) should be retained.

1. *Acute risk.* No study with vinclozolin indicated that acute exposure to vinclozolin is likely to cause an adverse effect of concern on infants or children or the general public with the exception of the *in utero* effects on the developing fetus. Risks to the fetus are estimated by examining exposure to women of child-bearing age.

2. *Chronic risk.* Using the exposure assumptions described in this unit, it is concluded that aggregate exposure to vinclozolin from food will utilize 7% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Since the EEC's for residues of vinclozolin per se are lower than the chronic DWLOC's, aggregate exposure will not exceed 100% of the cPAD.

3. *Short- or intermediate-term risk.* The MOE is greater than or equal to 1,010 for aggregate risks to infants and children resulting from use of vinclozolin. Therefore, the risks do not exceed the Agency's LOC.

4. *Determination of safety.* Based on these risk assessments, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to vinclozolin residues.

H. International Tolerances

CODEX maximum residue limits (MRLs) for residues of vinclozolin and its metabolites containing the 3,5-DCA moiety have been established in common bean at 2 ppm, rape seed at 1 ppm (no limit for canola), cattle meat and milk at 0.5 ppm, and chicken meat and eggs at 0.05 ppm. No Canadian or Mexican tolerances have been

established for vinclozolin residues in succulent beans, rape, canola, meat, milk, poultry, or eggs.

The CODEX MRLs for canola (rapeseed), cattle meat, cattle milk, and poultry eggs are in harmony with the proposed tolerances associated with this petition. The chicken meat MRL (0.05 ppm) is not in harmony with the proposed tolerance in poultry meat (0.1 ppm) due to recovery discrepancies with the analytical method.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0324; FRL-7282-2]

Revised Final Health Effects Test Guideline; Skin Sensitization; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this notice, EPA is announcing the availability of the revised final test guideline for Series 870-Health Effects Test Guidelines, OPPTS 870.2600 Skin Sensitization. EPA has established a unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These test guidelines represent an Agency effort that began in 1991 to harmonize the test guidelines within OPPTS, as well as to harmonize the OPPTS test guidelines with those of the Organization for Economic Cooperation and Development (OECD). The process for developing and amending these test guidelines includes public participation and the extensive involvement of the scientific community, as warranted, including peer review by the Scientific Advisory Panel (SAP), the Scientific Advisory Board (SAB) and other expert scientific organizations, as well as determination of validation status by the Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM).

FOR FURTHER INFORMATION CONTACT: For general information contact: TSCA information contact: TSCA Hotline at TAIS/7408, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone

number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

FIFRA information contact:

Communications Services Branch (7506C), Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5017; fax number: (703) 305-5558.

For FIFRA technical information contact: Deborah McCall, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7109 e-mail address: mccall.deborah@epa.gov.

For TSCA technical information contact: Ronald Ward, Ph.D., Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8926; e-mail address: ward.ron@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under TSCA, FFDCA, or FIFRA, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Copies of This Document and Other Related Information?

A. Docket

EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0324. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is