

toxicological endpoint for short-term dermal risks is the NOEL of 100 mg/kg/day from a 21-day dermal toxicity study in rabbits. No acute oral hazard has been identified following an acute exposure to S-metolachlor and, therefore, no nondietary assessment is needed.

The short-term dermal post-application risks for adults and children are acceptable, ranging from 520 to 870. These risk estimates exceed the EPA's level of concern for S-metolachlor (all MOEs are greater than 100).

Aggregate exposure. (Drinking Water and Dietary Exposure). Using the total MOE equation for the determination of aggregate chronic exposure (food and drinking water only) resulted in an aggregate MOET of >4,000 for the most sensitive subpopulation, non-nursing infants. For this particular subpopulation, there are no non-dietary exposure contributions to the MOET aggregate value.

D. Cumulative Effects

EPA has examined the common mechanism potential for S-metolachlor and has concluded that S-metolachlor should not be included with some pesticides that comprise the class of chloroacetanilides included in a "Common Mechanism Group." Therefore, a cumulative assessment is not necessary for S-metolachlor.

E. Safety Determination

1. *U.S. population.* Based on the aggregate assessment described above and the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to S-metolachlor (including the proposed uses) in food will utilize less than 0.1 percent of the cRfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to S-metolachlor in drinking water and from non-dietary, non-occupational exposures, the assessment presented above demonstrates that the high levels of safety exist for current and proposed uses of S-metolachlor; it is not expected that aggregate exposure from all sources will exceed 100% of the RfD. Therefore, one can conclude there is a reasonable certainty that no harm will result from aggregate exposure to S-metolachlor.

2. *Infants and children.* [FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness

of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. A full consideration of the available reproductive toxicity data supporting S-metolachlor demonstrates no increased sensitivity to infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that the cRfD at 0.1 mg/kg/day is appropriate for assessing aggregate risk to infants and children from use of S-metolachlor.

Based on the aggregate assessment described above, the percent of the cRfD that will be utilized by aggregate exposure to residues of S-metolachlor is less than 0.7 percent for all children subpopulations. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to S-metolachlor in drinking water and from non-dietary, non-occupational exposure, the assessment described above demonstrates that it is not expected that aggregate exposure from all sources provides for a large margin of safety and will exceed 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the exposure assessment, it is concluded there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to S-metolachlor residues.

F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRL's) established for residues of S-metolachlor in or on raw agricultural commodities.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0271; FRL-7322-6]

Etoazole; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain

pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0271, must be received on or before September 12, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7546; e-mail address: kenny.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)]

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0271. 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