

119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP-2002-0346. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the proposed rule or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response.

You may also provide the name, date, and **Federal Register** citation.

II. Background and Statutory Findings

In the **Federal Register** of February 12, 1997 (62 FR 6228) (FRL-5583-9), EPA issued a notice under section 408 of the FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 6F4770) by Nayfa Industries, Inc., c/o 1625 K St., N.W., Suite 501, Washington, D.C. 20006. The petition requested that 40 CFR 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide propionic acid, also known as propanoic acid (CAS Reg. No. 79-09-4) in or on the raw agricultural commodities sugarbeets, potatoes, and sweet potatoes. This notice included a summary of the petition prepared by Nayfa Industries, Inc., the petitioner. There were no comments received in response to the notice of filing. The Agency has not yet issued a final rule for this petition, and has, in fact, determined to issue a proposed rule.

The Agency is now issuing this rule as a proposal for two reasons: First, the calcium and sodium salt forms of propanoic acid are being added to the existing exemptions from the requirement of a tolerance of propanoic acid (40 CFR 180.1023). Second, based on a review and evaluation of the available data, the Agency believes that a broader use than what was requested by the petitioner is appropriate. The Agency is proposing to remove the existing tolerance exemptions for propionic acid and sodium propionate in 40 CFR 180.1001(c). These exemptions from the requirement of a tolerance will be covered by the proposed revisions to 40 CFR 180.1023. No uses would be lost as a result of these actions. Since the 1997 publication of the Notice of Filing, the Agency has completed the Tolerance Reassessment process for propanoic acid. Based on the results of that reassessment, EPA on its own initiative, under section 408(e) of the FFDCA, 21 U.S.C. 346a, is proposing to establish an unlimited exemption from the requirement of a tolerance for residues of propanoic acid (CAS Reg. No. 79-09-4); propanoic acid, calcium salt (CAS Reg. No. 4075-81-4); and propanoic acid, sodium salt (CAS Reg. No. 187-40-6), when used as either an active or inert ingredient in pesticide formulations that are applied to growing crops or raw agricultural commodities and in pesticide formulations that are applied to animals.

The data used by the Agency to make the safety determination for propanoic

acid included data that was generated using the sodium and calcium salts of propanoic acid. Often, when conducting animal tests using an acid, such as propanoic acid, as the test substance, the acid must be neutralized (converted to a salt - in this case the calcium and sodium salt) to conduct the tests. Therefore, the Agency is proposing that these two salts of propanoic acid also be included in the tolerance exemption expression.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure.

Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for the establishment of an exemption from the requirement of a tolerance for residues of propanoic acid and its calcium and sodium salts. EPA's assessment of exposures and risks associated with establishing the exemption from the requirement of a tolerance follows.

III. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the