

DC 20460-0001, Attention: Docket ID number OPP-2003-0055.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0055. 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. Make sure to submit your comments by the deadline in this notice.

7. 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. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 28, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The summary of the petition announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Holliday Pigments Limited

PP 3E6549

EPA has received a pesticide petition (3E6549) from Holliday Pigments Limited, Morley Street, Hull, East Yorkshire, England HU8 8DN proposing, pursuant to section 408(d) of

the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180. to establish an exemption from the requirement of a tolerance for ultramarine (sodium aluminosilicate) when used as an inert ingredient as a dye in seed coatings. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Ultramarine is a synthetic form of the naturally occurring semi-precious mineral Lapis Lazuli, which has been mined, processed and used for decorative purposes for thousands of years. It is a zeolitic mineral and is totally insoluble in water. As such, it is not metabolized by plants. It is stable in neutral and alkaline soils. Under acidic conditions it decomposes to give hydrogen sulphide, which is evolved as a gas together with an insoluble, inert clay-like residue, which will not be metabolized by plants.

2. *Analytical method.* Since this petition is for an exemption from the requirement of a tolerance, an analytical method is not required.

3. *Magnitude of residues.* The proposed use for ultramarine is as a seed coating to impart color for identification. It will not be metabolized and will remain in the soil. There will therefore, be no residues on the crop produced.

B. Toxicological Profile

The last of the following tests described was completed in 1981. Holliday Pigments no longer carries out tests of any of their products on animals nor do they subscribe to any form of animal testing.

1. *Acute toxicity—i. Skin irritation.* Albino rabbits were used for a study of irritation produced by ultramarine contact with abraded and intact skin. No irritation was found and no reactions were observed throughout the study.

ii. *Skin sensitization.* Skin sensitization in the guinea pig was studied using the maximization test of Magnusson and Kligman. No visible reaction was exhibited by any animal in the test or control group throughout the trials. The report concluded that there was no evidence that ultramarine acts as a sensitizer in the guinea pig.

2. *Genotoxicity.* Bacterial toxicity and mutagenicity were studied using two