

Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

Richard P. Keigwin, Jr., Pesticide Re-evaluation Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-8000; fax number: (703) 308-8005; email address: [keigwin.richard@epa.gov](mailto:keigwin.richard@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. What action is the Agency taking?**

EPA is taking public comment on a document entitled, "Proposal for Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives," a copy of which is available in the docket at <http://www.regulations.gov> under docket ID number EPA-HQ-OPP-2012-0442. The document describes proposed changes to EPA's pesticide registration review program and how it conducts consultation with the Services under Section 7 of the ESA.

**II. Why is the Agency taking this action?**

In an effort to be responsive to stakeholders' desires for a mechanism to get information into the registration review process as early as possible, EPA proposes to hold "Focus" meetings at the start of registration review for each active ingredient. In response to stakeholders' desires for a more open, reliable, and transparent pesticide consultation process, EPA proposes to initiate any needed formal ESA consultations at a later stage in the review process. Consulting later in the registration review process allows EPA to develop more refined ecological risk assessments and to engage affected stakeholders in discussions that should result in more focused consultation packages inclusive of mitigation for listed species. There is an emerging consensus that EPA and the Services should engage informally and early in the consultation process, but that formal consultation should be reserved until EPA's ecological risk assessment and

proposed decision are more fully formed. This approach has the potential to maximize the opportunity to effect changes that provide protections for species and their designated critical habitat, lessen the impacts on agriculture, and narrow the scope of the Federal action.

Additionally, the proposal describes EPA's plans to reach out to pesticide users potentially affected to discuss the technological and economic feasibility of "Reasonable and Prudent Alternatives" (RPAs) intended to avoid jeopardy to threatened and/or endangered species. The USDA's relationships with the agricultural community provide a critical link between EPA's expertise on pesticides and the Services' expertise on listed species' locations, status and biology.

Finally, the proposal describes the process by which public comments received on RPAs will be summarized and organized by EPA and provided to the Services, who will prepare a document to be included in the administrative record of the consultation explaining how comments were considered, and if appropriate, how the final biological opinion was modified to address the comments. The Services will provide the document to EPA, and both the Services and EPA will make the document available to the public upon request. These process changes are intended to provide clarity and transparency to the ESA Section 7 consultation process for pesticides.

EPA and the departments of Agriculture, Commerce, and Interior are taking this action because many stakeholders have expressed concerns regarding the apparent lack of transparency surrounding ESA consultations on pesticide registration review decisions, and the need for increased access to the decision-making process by states and other stakeholders for the purpose of providing relevant data for consideration during registration review and accompanying ESA consultation. Increasing public participation opportunities during both the registration review and accompanying ESA consultation processes, and improving clarity and transparency during these processes are important goals of this action.

In the interest of facilitating discussion and providing clarification on the process changes described in the proposal, EPA and the departments of Agriculture, Commerce, and Interior are willing to meet with affected stakeholders. Individuals and/or organizations wanting to meet with the agencies to discuss this proposal should submit a request to the docket.

**List of Subjects**

Environmental protection, Endangered species, Pesticides and pests, Threatened species.

Dated: August 3, 2012.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

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**ENVIRONMENTAL PROTECTION AGENCY**

[EPA-HQ-OPP-2012-0570; FRL-9358-4]

**Ortho-Phthalaldehyde; Receipt of Application for Emergency Exemption, Solicitation of Public Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has received a specific exemption request from the National Aeronautics and Space Administration (NASA) to use the pesticide ortho-phthalaldehyde (OPA) (CAS No. 643-79-8) to treat the International Space Station internal active thermal control system (IATCS) coolant to control *Cupriavidus metallidurans*, *Variovorax paradoxus*, *Acidovorax sp.*, *Sphingomonas parapaucimobilis*, *Stenotrophomonas maltophilia*, *Methylobacterium extorquens*, and unidentified gram negative rods. This emergency exemption involves the use of a chemical which has not been registered by the EPA. EPA is soliciting public comment on the exemption.

**DATES:** Comments must be received on or before September 4, 2012.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0570, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

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information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

Debra Rate, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 306-0309; fax number: (703) 605-0781; email address: [rate.debra@epa.gov](mailto:rate.debra@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 a pesticide manufacturer (NAICS code 32532) or involved with the International Space Station. 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. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through [www.regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a

Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

**II. What action is the agency taking?**

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the Administrator determines that emergency conditions exist which require the exemption. NASA has requested the Administrator to issue a specific exemption for the use of OPA in the International Space Station IATCS coolant to control *Cupriavidus metallidurans*, *Variovorax paradoxus*, *Acidovorax sp.*, *Sphingomonas parapaucimobilis*, *Stenotrophomonas maltophilia*, *Methylobacterium extorquens*, and unidentified gram negative rods. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that OPA is the most effective biocide which meets the requisite IATCS criteria, including: the need for safe, non-intrusive implementation and operation in a functioning system; the

ability to control existing planktonic and biofilm residing micro-organisms; a negligible impact on system-wetted materials of construction; and a negligible reactivity with existing coolant additives. Non-use of OPA in the requested manner would leave NASA's International Space Station without an adequate long-term solution for controlling the micro-organisms in the coolant systems.

The Applicant proposes to make no more than one application of OPA per module in the International Space Station IATCS coolant including the U.S. Laboratory, the Japanese Experiment Module, the Columbus and Node with a total treated coolant volume not to exceed 829 Liters with a maximum of 1,974 cubic centimeters (cm<sup>3</sup>) OPA resin.

The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient) which has not been registered by EPA. The notice provides an opportunity for public comment on the application. Owing to the long lead time necessary for sending products to the International Space Station, EPA has evaluated NASA's application in advance of seeking public comment, and has concluded that the emergency exemption should be approved. Although EPA has approved this emergency exemption, EPA still welcomes public comment. EPA's regulations provide that an emergency exemption may be modified or revoked if, among other things, additional information indicates that the product may cause unreasonable adverse effects or may not be effective at controlling the target pests. Accordingly, the Agency will review and consider all comments received during the comment period in determining whether the specific exemption should be modified or revoked.

**List of Subjects**

Environmental protection, Pesticides and pests.

Dated: August 3, 2012.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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