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 coolant fluid of the internal active thermal control system of the International Space Station to control aerobic/microaerophilic bacteria in the aqueous coolant. The applicant proposes the use of a new chemical which has not been registered by EPA. Therefore, in accordance with the Code of Federal Regulations (CFR), EPA is soliciting public comment before making the decision whether to grant the exemption.

DATES: Comments must be received on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2019-0322, by one of the following methods:

- Federal eRulemaking Portal: https://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),
• **Hand Delivery**: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at [https://www.epa.gov/dockets/where-send-comments-epa-dockets](https://www.epa.gov/dockets/where-send-comments-epa-dockets).

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at [https://www.epa.gov/dockets](https://www.epa.gov/dockets).

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

**SUPPLEMENTARY INFORMATION:**

In accordance with the regulations at 40 CFR section 166.24(a)(1), EPA is soliciting public comment before making the decision whether to grant the exemption.

**I. General Information**

**A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are a pesticide manufacturer (North American Industrial Classification System (NAICS) Code 32532) or involved with the International Space Station. This listing is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Other types of entities not listed could also be affected.

**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 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 preparing and submitting your comments, see the commenting tips at https://www.epa.gov/dockets/commenting-epa-dockets.

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 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 EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. NASA has requested the EPA Administrator to issue a specific exemption for the use of ortho-phthalaldehyde (OPA) in the coolant of the internal active thermal control system (IATCS) of the International Space Station (ISS) to
control aerobic/microaerophilic bacteria in the aqueous coolant. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant stated that it has considered the registered biocide alternatives and has concluded that OPA is the most effective biocide which meets the requisite 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. The ISS would not have an adequate long-term solution for controlling the micro-organisms in the IATCS coolant without the use of OPA. The OPA is incorporated into a porous resin material contained in a stainless-steel canister. The canister containing the OPA-incorporated resin is inserted into a coolant system loop, using flexible hose and quick disconnects, and is placed in-line for 8 hours to deliver the OPA into the fluid. As the coolant fluid flows through the canister, the OPA elutes from the resin material into the coolant fluid. The total volume of the circulatory loops of the IATCS is 829 liters. The maximum concentration would be 500 milligrams (mg) of OPA per liter of coolant fluid. A total of 414,500 mg of OPA would be needed for the entire system. The OPA is incorporated into the resin at 210 mg OPA per cm$^3$ resin, resulting in a potential total use of 1,974 cm$^3$ of the OPA-containing resin. The level of OPA in the coolant is monitored periodically, and because OPA degrades over time, the concentration decreases to a level that is no longer effective in about 1 to 2 years. At this point, replenishment with new OPA-containing canisters is required. EPA has authorized similar emergency exemptions for this use since 2011. With the decision to extend the mission of the ISS to 2024, the need for this use is expected to continue for the duration.

This notice does not constitute a decision by EPA on the application itself. The
regulations governing FIFRA section 18 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.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by NASA.

Authority: 7 U.S.C. 136 et seq.

Dated: June 3, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

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