

Prepublication Copy Notice:

The Director of the Chemical Control Division in the Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention signed the following *Federal Register* document on December 15, 2015:

Title: **Chlorinated Paraffins; Request for Available Information on PMN Risk Assessments**

FRL: 9940-13

Docket No.: **EPA-HQ-OPPT-2015-0789**

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Once the official version of the document publishes in the *Federal Register*, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2015-0789; FRL-9940-13]

Chlorinated Paraffins; Request for Available Information on PMN Risk

Assessments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is requesting new available data on certain chlorinated paraffins in different industries and for different uses, to inform the risk assessments for chlorinated paraffins submitted as Toxic Substances Control Act (TSCA) Premanufacture Notices (PMNs). The risk assessments have been placed in a public docket. Any comments on the assessments or data to inform the assessments will be placed in the docket subject to Confidential Business Information considerations.

DATES: Available data and/or comments must be received on or before [*insert date 60 days after date of publication in the **Federal Register***].

ADDRESSES: Submit your data and/or comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0789, 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:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 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.html>.

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: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, processors, or users of one or more subject chemical substances

(NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

B. What is the Agency's Authority for Taking this Action?

This action is issued under the authority in Section 5 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2604.

C. What Action Is the Agency Taking?

EPA is requesting new available data on the chlorinated paraffins, referenced in Unit II., in different industries and for different uses, to inform the risk assessments for chlorinated paraffins submitted as Toxic Substances Control Act (TSCA) Premanufacture Notices (PMNs). The risk assessments have been placed in a public docket. Any comments on the assessments or data to inform the assessments will be placed in the docket subject to Confidential Business Information considerations.

C. Why is EPA Taking this Action?

As a result of its TSCA new chemicals review, EPA preliminarily determined that the above mentioned chlorinated paraffin PMN substances may present an unreasonable risk to the environment for two independent reasons: (1) the PMN substances are expected to be persistent, bioaccumulative and toxic (PBT) chemicals; and (2) releases of the PMN substances may exceed concentrations of concern (COCs) to aquatic and sediment-dwelling organisms, even without taking into consideration the expected persistence and bioaccumulative properties of the PMN substances. EPA's assessments of the PMN substances have been placed in the docket.

1. The PMN substances are expected to be PBT chemicals based on the following lines of evidence:

(a) The available data on medium-chain chlorinated paraffins (MCCPs), sediment

core studies, environmental fate studies, and associated calculations, indicate transformation half-lives of months to years, depending on the environmental media. Even though there are limited data on the long-chain chlorinated paraffins (LCCPs), biodegradation data indicate increasing stability with increasing chain length. LCCPs are also expected to have transformation half-lives comparable to, or greater than, MCCPs. Therefore, the PMN substances are expected to be very persistent.

(b) The available data on MCCPs and LCCPs indicate that these substances have bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) that exceed 1,000 or 5,000 liters per kilogram wet weight of tissue (L/kg ww). Therefore, the PMN substances are expected to be very bioaccumulative.

(c) The available data on MCCPs and LCCPs indicate acute and chronic toxicity to aquatic organisms with effect levels below 10 milligrams per liter (mg/L) or 0.1 mg/L, depending on the species and MCCP or LCCP congener evaluated. Therefore, the PMN substances are expected to be toxic to aquatic organisms.

(d) EPA is concerned about PBT chemicals because even small releases may persist in environmental media, build up in the environment and concentrate/accumulate in organisms over time. These properties increase the potential for continual exposure, and thus risk.

(e) EPA expects there to be releases of the PMN substances to the environment resulting from distribution in commerce and during processing and all of the substances' intended uses.

2. Releases of the PMN substances may exceed concentrations of concern to aquatic and sediment-dwelling organisms, even without taking into consideration the

expected persistence and bioaccumulation of the PMN substances, based on the following evidence:

(a) Using estimated environmental concentrations, the PMN substances may present unreasonable acute and chronic risks to aquatic organisms because releases result in exceedances of COCs for aquatic organisms. Also, using the available measured concentrations of MCCPs in the environment as supporting information, the PMN substances are expected to partition to sediment and may partition to soil through land application of biosolids; and may be released to the environment resulting in levels at or above concentrations that are likely to exceed the COC. These concentrations may present acute and chronic risks to aquatic organisms.

(b) EPA expects releases of the PMN substances to water during processing and all of the substances' intended uses to result in surface water concentrations that may present an unreasonable risk of adverse effects to aquatic and sediment-dwelling organisms. As described in EPA's risk assessment documents entitled "Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMN P-12-0282, P-12-0283) and Long-Chain Chlorinated Paraffins (PMN P-12-0284)", "Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMN P-12-0453) and Long-Chain Chlorinated Paraffins (PMN P-12-0433)", and "Standard Review Risk Assessment: Medium Chain Chlorinated Paraffins (PMNs P-14-0683/P-14-0684)", EPA reviewed a variety of sources to inform its assessment on the PMN substances, including: information provided in the PMNs, information on the environmental fate of MCCPs and LCCPs in different environmental compartments, the properties that control transport, and assessments performed by Canada and the European Union.

Given EPA's preliminary risk determinations, under section 5(e) of TSCA, EPA has informed the PMN submitters that it does not believe that manufacture of these PMN substances should commence (Qualice, LLC,) or continue (Dover Chemical and INOVYN Americas, Inc.) absent the development of sufficient information to permit a reasoned evaluation of the environmental effects of the substances, as described in a testing strategy shared with the PMN submitters. This testing strategy and the risk assessments for these three groups of PMNs are available in the public docket (EPA-HQ-OPPT-2015-0789).

While EPA used information provided by the submitters of the PMNs, EPA realizes that its assessment of some uses may be improved by more specific information on the chlorinated paraffins identified above. With this notice, EPA is requesting new, available information on chlorinated paraffins in different industries and for different uses to reduce the uncertainties in the risk assessments for the three groups of PMNs, submitted under TSCA by three companies. Such information may include whether there are uses for the PMN chlorinated paraffin substances that do not present the potential for direct or indirect release to water. In developing the risk assessments for these PMN substances, EPA used the information provided by the submitters of the PMNs and standard PMN models and scenarios. Processors and users of the PMN substances may have specific available data on such issues as treatment methods, environmental releases and other waste management practices, particularly for non-water based applications. EPA has received some information from the Independent Lubricant Manufacturers Association and would like to augment this information with specific data from other user sectors, particularly those sectors that formulate and use chlorinated paraffins as

plasticizers and flame retardants in adhesives, sealants and coatings.

II. What Chemicals are Subjects of this Notice?

This notice covers seven medium- and long-chain chlorinated paraffins (MCCPs and LCCPs). EPA is reviewing five PMNs as a result of settlements resolving violations of the TSCA premanufacture notice obligations for production and import of various chlorinated paraffins. As part of consent decrees between the Department of Justice (DOJ) and EPA and Dover Chemical (February 7, 2012) and separately between DOJ and EPA and INEOS Chlor Americas (now INOVYN Americas, Inc) (August 21, 2012) these companies were required to submit premanufacture notices under TSCA section 5 for all chlorinated paraffins domestically produced or imported. Also as part of the settlement, the companies were required to cease domestic manufacture and import of the closely-related short-chain chlorinated paraffins, which have persistent, bioaccumulative and toxic (PBT) characteristics.

On March 30, 2012, EPA received three PMNs: P-12-282 for the new chemical substance identified as Alkanes C14-16, chloro (no Chemical Abstract Service Registry Number (CASRN) assigned yet), P-12-283 for Tetradecane, chloro derivs. (no CASRN assigned yet), and Octadecane, chloro derivs. (no CASRN assigned yet). On October 28, 2015, the submitter, Dover Chemical Corporation, removed all prior assertions of CBI claims covering any or all of the information associated with these PMNs.

On June 27, 2012, EPA received PMN P-12-0433 for the new chemical substance identified as Alkanes, C18-20, chloro (CASRN 106232-85-3). On July 9, 2012, EPA received PMN P-12-0453 for the new chemical substance identified as Alkanes, C14-17, chloro (CASRN 85535-85-9). On August 13, 2012, EPA received PMN P-12-0453 for

the new chemical substance identified as Alkanes, C22-30, chloro (CASRN 288260-42-4). The submitter, INEOS Chlor Americas (now INOVYN Americas Inc.), claimed only production volume as CBI in these three PMN submissions.

On July 10, 2014, EPA received PMN P-14-0683 for the new chemical substance identified as Tetradecane, chloro derivs. (CASRN 198840-65-2) and P-14-0684 for the new chemical substance identified as Alkanes, C14-C16, chloro (CASRN 1372804-76-6). The submitter, Qualice, LLC, made no CBI claims in their PMN submissions.

As with all PMN submissions, EPA has followed the processes, procedures and statutory provisions of TSCA section 5 for the chlorinated paraffin PMNs, including EPA's Policy Statement on PBT New Chemical Substances in the **Federal Register** of November 4, 1999 (64 FR 60194)(FRL-6097-7).

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 15, 2015.

Maria J. Doa,
Director, Chemical Control Division, Office of Pollution Prevention and Toxics.