



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA-2016-F-1805]

Society of the Plastics Industry, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Keller and Heckman LLP on behalf of the Society of the Plastics Industry, Inc. (Petitioner or SPI), requesting that we amend our food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned.

DATES: The food additive petition was filed on May 11, 2016. Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/ Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-F-1805 for "Filing of Food Additive Petition: Society of the Plastics Industry, Inc." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions:** To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas C. Zebovitz, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1244.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 6B4816) submitted on behalf of the Society of the Plastics Industry, Inc. (Petitioner or SPI) by Keller and Heckman LLP, 1001 G Street, NW., suite 500 West, Washington, DC 20001. The petition proposes that we amend 21 CFR 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because the use has been intentionally and permanently abandoned.

II. Abandonment

Under section 409(i) of the FD&C Act, we "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." Our regulations specific to administrative actions for food additives provide that the Commissioner, on his own initiative or on the petition of any interested person, under 21 CFR part 10, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive (21 CFR 171.130(a)). These regulations further provide that any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are

available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (21 CFR 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary because the use of the food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The SPI petition includes the following information to support the claim that the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers has been abandoned in the U.S. market. The petition states that three of the four companies that filed the food additive petitions that resulted in the listing for potassium perchlorate in 21 CFR 177.1210 are still operating, and that the fourth company is no longer in business. The Petitioner polled the three companies about their use of potassium perchlorate in closure-sealing gaskets for food

containers asking them to verify that they do not: (1) Currently manufacture potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (2) currently import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (3) intend to manufacture or import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States in the future; or (4) currently maintain any inventory of potassium perchlorate for sale or distribution into commerce that is intended to be marketed for use as a component of closures with sealing gaskets for food containers in the United States. The petition includes signed letters from the three companies confirming agreement to these four points.

The petition also includes a signed letter from American Pacific Corporation, Western Electrochemical Company (AMPAC), which the Petitioner states is the sole domestic manufacturer of potassium perchlorate in the United States. The letter states that AMPAC does not manufacture, import, or maintain any inventory of potassium perchlorate for sale or distribution into commerce into the food-contact market for use in closure-sealing gaskets for food containers in the United States.

The petition also asserts that SPI surveyed the member companies that make up SPI's Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC). According to the petition, no FDCPMC member company responded that it had any knowledge or reason to believe that potassium perchlorate was being manufactured, used, distributed, or imported into the United States for use in the manufacture of closures with sealing gaskets for food-contact applications. The petition also states that SPI has been unable to identify any company with records indicating that potassium perchlorate was actually used as a component of closure-sealing gaskets for food containers.

A supplement to the petition, dated May 16, 2016, asserts that SPI contacted all known U.S.-based manufacturers of gaskets for food-contact applications, which the Petitioner asserts constitute the substantial majority, if not all of such manufacturers. The supplement asserts that each company indicated to SPI that it does not continue to use potassium perchlorate in the manufacture of gaskets for food-contact materials.

We expressly request comments on the Petitioner's request to amend 21 CFR 177.1210 of the food additive regulations to no longer permit the use of potassium perchlorate in closure-sealing gaskets used for food containers. As noted, the basis for the proposed amendment is that the use of potassium perchlorate in closure-sealing gaskets for food containers has been permanently and completely abandoned. Accordingly, we request comments that address whether this use of potassium perchlorate has been completely abandoned, such as information on whether closure-sealing gaskets containing potassium perchlorate are currently being introduced or delivered for introduction into the U.S. market. We are not aware of information that suggests continued use of potassium perchlorate as a component of closure-sealing gaskets in contact with food.

We are providing the public with 60 days to submit comments. We anticipate that some interested persons may wish to provide FDA with certain information they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to FDA as CCI or trade secret by clearly marking both the document and the specific information as "confidential." Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and our disclosure regulations (21 CFR part 20). For electronic submissions to <http://www.regulations.gov>, indicate in the

"comments" box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of the use of potassium perchlorate in closure-sealing gaskets for food containers because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing the safety of potassium perchlorate or containing safety information on this substance in our evaluation of this petition. In addition to our consideration of this petition, we are considering information on the safety of potassium perchlorate as an additive in closure-sealing gaskets for food containers as part of our consideration of a petition designated for reference as FAP 4B4808 (see 80 FR 13508 (March 16, 2015)). We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 24, 2016.

Dennis M. Keefe,
Director, Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.

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