

Chapter 1 : Indirect food additives and polymers: migration and toxicology.

The Food and Drug Administration (FDA or we) is amending the 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.

This includes component parts in machinery used for food processing, even covering such things as coffee machines and drink dispensers. Food contact materials and food contact substances FCS mean the same thing. During contact with a food or beverage, molecules from a material can migrate into the food or beverage. Because of this, most countries have food safety regulatory agencies that monitor materials for food safety. The FDA does not provide government inspection or certification of materials used for food contact use. Instead, the agency sets rules and guidelines regarding appropriate material composition, properties and uses. FDA standards also cover conditions of use like temperature, food type and whether that material is suitable for either single use or repeated contact. These need to be compliant with the appropriate sections of CFR Title 21. NSF is usually associated with standards for direct and indirect drinking water additives but it also plays a part in food safety. It primarily addresses physical properties of plastic components in piping and plumbing systems. Plastics piping system components and related materials complying with this standard are tested and approved by NSF for use in plumbing. While this standard typically applies to residential systems, the testing used makes it relevant for process filtration also. Materials must not contaminate food nor make food equipment difficult to clean and sanitize. This standard also applies to component parts used in food equipment. Fittings and tubes complying with this standard are tested and approved by NSF for contact with potable beverages and foodstuffs. Fittings and tubes complying with this standard are tested and approved by NSF for drinking water treatment systems. This standard only requires testing for materials safety, which looks for a wide variety of contaminants that may leach into the drinking water. It is most frequently associated with certification compliance regarding lead content. They must also be FDA food contact material compliant. USDA compliant products are documented as to their compliance with FDA food contact material standards by a written letter of guaranty from the manufacturer. Food Safe The international symbol for food safe materials is a stylized wine glass and fork. This indicates that the material used in the product is safe for food contact. This food safe indication is applicable to any product intended for food contact whether it is made of metals, ceramics, paper and paperboard, or plastics.

The Food and Drug Administration (FDA or the Agency) is amending the food additive regulations to no longer provide for the use of polycarbonate (PC) resins in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers.

FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time. The Food and Drug Administration FDA or we is amending the 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. This rule is effective May 4, Submit either electronic or written objections and requests for a hearing on the final rule by June 5, You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before June 5, VerDate Sep Electronic Submissions Submit electronic objections in the following way: Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to https: Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on https: All submissions received must include the Docket No. You should submit two copies total. Submit both copies to the Division of Dockets Management. These regulations further provide that any such petition must 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 submitted as a food additive petition must be furnished in the form specified in 21 CFR Such abandonment must be complete and permanent for any intended uses in the U. Instead, the amendment or revocation is based on the fact that regulatory authorization is no longer necessary because the use of the food additive has been permanently and completely abandoned. Abandonment may be based on the abandonment of certain authorized food additive uses for a substance e. If a petition seeks an VerDate Sep The present petition includes the following information to support the claim that the use of potassium perchlorate as a food additive in closure-sealing gaskets for food containers has been abandoned in the U. The petitioner surveyed the remaining three companies or their appropriate successor s in interest about their use of potassium perchlorate in closures with sealing gaskets for food containers and asked them to verify that they do not: The petition included signed letters from the three companies confirming agreement with these four points. Specifically, the petition included a signed letter from AMPAC stating that it does not manufacture, import, or maintain any inventory of potassium perchlorate for sale or distribution for use in closures with sealing gaskets for food containers in the United States. Third, the petition provided information to show that the major domestic manufacturers of gaskets do not use potassium perchlorate in the manufacture of their products. The petition stated that SPI conducted research to identify all major U. The petition further stated that SPI contacted each manufacturer identified by its research, and that each company confirmed to SPI that it does not use potassium perchlorate in the manufacture of gaskets for food contact materials, and that potassium perchlorate may never have been used for this purpose. According to the petition, these manufactures believe that they represent the substantial majority of gasket production, not only domestically, but globally as well. According to the petition, the FDCPMC companies represent the full range of the packing supply chain of plastic food-contact material manufacturers and their raw material suppliers, and they include international companies with affiliates throughout the world. Moreover, the petition stated that, in its effort to gather supporting information, the petitioner was unable to identify any company with memory of, or records indicating, that potassium perchlorate had ever been used commercially as a component of closures with sealing gaskets. Comments on the Filing Notification We provided 60 days for comments on the filing notification. We received two comments. Comment 1 The comment requested that we not make a final decision on the petition until after we make a final decision on the petition FAP 4B submitted in by Natural Resources Defense Council et al. FDAâ€™” â€™Fâ€™” , asking us to remove certain

authorizations, including the use of potassium perchlorate that is the subject of this petition. The comment stated that if we make a decision on the petition based on abandonment before making a decision on FAP 4B based on safety, a company may conclude that the use of potassium perchlorate in closures with sealing gaskets for food containers is generally recognized as safe GRAS without notifying us. The comment also stated that making a decision on the abandonment petition first encourages industry to only consider whether a use of a food additive has been abandoned in order to preempt a safety decision. We are not required to make a final decision on FAP 4B before the current petition. With regard to the assertion that FDA is required to make a safety determination, FDA has numerous responsibilities related to food additives. Each year, FDA receives and responds to hundreds of submissions under the various petition and notification programs it administers. Therefore, if the use of a food additive is no longer authorized in response to an abandonment petition, FDA may determine that it is neither necessary nor an efficient use of its VerDate Sep Prior approval as a food additive does not necessarily mean that the use of a substance is GRAS see 81 FR at , August 17, FDA encourages firms to seek our evaluation of any conclusion of GRAS status before they introduce the substance into the market. With regard to the assertion that an abandonment petition could be used by industry to preempt a safety determination by FDA, we have the discretion to make a safety determination regardless of whether there is an abandonment petition. Comment 2 The comment stated that SPI has not considered overseas use and manufacturing of potassium perchlorate in closures with sealing gaskets for food containers. The comment indicated that SPI had not provided sufficient assurances that the uses of potassium perchlorate had been abandoned. According to the petition, SPI gathered information about the use of potassium perchlorate used in closures with sealing gaskets for food containers from its member companies, which include international companies with affiliates throughout the world, and from major domestic manufacturers of gaskets, and these manufacturers believe that they represent the substantial majority of gasket production, not only domestically, but globally as well. None of the companies surveyed reported that they had any reason to believe that potassium perchlorate is used to make closures with sealing gaskets for food containers. We note that the comment PO Frm Fmt Sfnt did not provide information to show that this use has not been abandoned. The WTO contact point for each country distributes the notices to the relevant regulatory agencies and industry bodies within that country. We did not receive any comments to the WTO notice on the filing of this petition. Conclusion We reviewed the data and information in the petition and other available relevant material to determine whether the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers has been permanently and completely abandoned. Based on the available information, we conclude that the use of potassium perchlorate has been abandoned for use as an additive in closure-sealing gaskets for food containers. Therefore, we are amending part as set forth in this document to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers. We stated that we had determined, under 21 CFR We have not received any new information or comments that would affect our previous determination. The authority citation for part continues to read as follows: Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of is not required. You must separately number each objection, and within each numbered objection you must specify with particularity the provision s to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a. This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program NFIP that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency FEMA receives documentation that the community has adopted the required floodplain management measures prior to the

effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the Federal Register on a subsequent date. The CSB is available at <https://www.csb.gov>. The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 67. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the Federal Register. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act. The petition proposed to amend Sec. 181.101 of the Code of Federal Regulations. Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive. Sec. 181.101. 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. First, the petition provided information to show that the original petitioners who filed the food additive petitions that resulted in the listing of potassium perchlorate in Sec. 181.101. The petition stated that three of the original four companies that filed the food additive petitions that resulted in the listing for potassium perchlorate in Sec. 181.101, asking us to remove certain authorizations, including the use of potassium perchlorate that is the subject of this petition. Therefore, if the use of a food additive is no longer authorized in response to an abandonment petition, FDA may determine that it is neither necessary nor an efficient use of its limited resources to address safety arguments related to an abandoned use. In the event that, after the authorization in Sec. 181.101. We note that the comment did not provide information to show that this use has not been abandoned. The WTO provides notice of the potential action in this case, the removal of authorization for potassium perchlorate in Sec. 181.101. Based on the available information, we conclude that the use of potassium perchlorate has been abandoned for use as an additive in closure- sealing gaskets for food containers. Because the authorization for this intended use has been removed from Sec. 181.101. Public Disclosure In accordance with Sec. 181.101. As provided in Sec. 181.101. Paperwork Reduction Act of 1995. This final rule contains no collection of information.

Chapter 3 : Indirect Food Additives and Polymers: Migration and Toxicology - CRC Press Book

The List of 'Indirect' Additives Used in Food Contact Substances contains information on substances mentioned in Title 21 of the U.S. Code of Federal Regulations (21CFR) Parts 170, 175, 177, and 181.

Chapter 4 : Code of Federal Regulations > Title 21 > Chapter I > Part - INDIRECT FOOD ADDITIVES: POLYMERS

International in scope, the Handbook of Indirect Polymeric Additives in Food and Water: Migration and Toxicology offers comprehensive data on the toxic effects of polymeric materials and their ingredients.

Chapter 5 : Food Safety | HACCP | In House Dry Age, Dry Cure Meat | DryAgePro

Indirect Food Additives and Polymers: Migration and Toxicology studies the potential hazards of indirect additives for human health and develops recommendations for their safe manufacture and use.

Chapter 6 : CFR Testing | Food Contact Testing

DOWNLOAD PDF INDIRECT FOOD ADDITIVES AND POLYMERS

part - food additives permitted for direct addition to food for human consumption.

Chapter 7 : Indirect Food Additives and Polymers: Migration and Toxicology - Victor O. Sheftel - Google Bo

This is a list of United States Code sections, Statutes at Large, Public Laws, and Presidential Documents, which provide rulemaking authority for this CFR Part.. This list is taken from the Parallel Table of Authorities and Rules provided by GPO [Government Printing Office].

Chapter 8 : Food Contact Materials | Industrial Specialties Mfg. and IS Med Specialties (ISM)

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part is amended as follows: PART INDIRECT FOOD ADDITIVES: POLYMERS 0 1.