

May 3, 2016

Via FedEx and Electronic Mail

Dr. Dennis Keefe
Director of the Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

**Re: Petition Seeking Amendment of Food Additive Regulation 21 C.F.R.
§172.515 to Remove the Clearance for Styrene Due to the Abandonment
of its Use as a Synthetic Flavoring Substance and Adjuvant in Food**

Dear Dr. Keefe:

The Styrene Information and Research Center (“SIRC” or “Petitioner”), by and through its Counsel, Keller and Heckman LLP, submits this Petition pursuant to Section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §171.130 (“Procedure for amending and repealing tolerances or exemptions from tolerances”). The Petitioner requests that the Food and Drug Administration (FDA) amend 21 C.F.R. §172.515 (“Synthetic flavoring substances and adjuvants”)¹ to remove the clearance for styrene on the basis that the use of styrene as a synthetic flavoring substance and adjuvant in food has been permanently abandoned.²

¹ Styrene is cleared in Section 172.515 when used as a synthetic flavoring substance and adjuvant in food at levels no greater than necessary to achieve its intended technical effect.

² This Petition does not address any of the clearances in FDA’s food additive regulations that permit the use of styrene in food-contact applications, nor does it address any Food Contact Notifications or Threshold of Regulation Exemptions that permit the use of styrene in food-contact applications.

I. Regulatory Basis for Abandonment

Under 21 C.F.R. §171.130, any interested person is permitted to file a petition to “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.”³ This 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.”⁴

II. Statement of Facts

The members of SIRC account for a substantial majority (over 95%) of the current North American styrene industry. With this in mind, the Petitioner has surveyed its membership to verify that they do not:

1. currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future; and
4. currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

Attached are signed surveys from Petitioner’s members verifying they do not engage in any of the aforementioned activities. These completed surveys confirm that industry has abandoned the use of styrene as a synthetic flavoring agent or adjuvant in food.

Petitioner also has confirmed with its foreign counterparts, including the Japan Styrene Industry Association and the European Chemical Industry Council, as well as contacts in China, that no foreign manufacturers appear to be using or marketing styrene for use as a synthetic flavoring agent or adjuvant in food. On these collective basis, Petitioner believes this

³ 21 C.F.R. §171.130(a).

⁴ §171.130(b).

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information convincingly demonstrates that styrene is no longer used a synthetic flavoring agent or adjuvant in food.

In further support of this proposed action, Petitioner has consulted with the Flavor and Extract Manufacturers Association of the United States (FEMA) to confirm that FEMA's membership is no longer using styrene as a synthetic flavoring agent or adjuvant in food.⁵ In this regard, FEMA informed Petitioner that it periodically surveyed its membership beginning in 1995 to determine the amount of styrene used by the U.S. flavor manufacturing industry in a given year, and that it participated in similar surveys conducted by the National Academy of Sciences under contract to the Food and Drug Administration for the years 1970, 1982, and 1987. The results of these survey data are presented in the table below.

Year	Amount of Styrene Sold (lbs)
1970	27
1982	14
1987	11
1995	4
2005	1
2010	0.3

These data clearly show styrene was never used in significant quantities pursuant to 21 C.F.R. § 172.515, and the poundage surveys show the progressively declining use of styrene as a synthetic flavoring agent and adjuvant in food. The FEMA Expert Panel conducts comprehensive cyclical reviews of all FEMA Generally Recognized as Safe (GRAS) flavoring substances, referred to as "GRAS reaffirmation", to assure that FEMA GRAS flavoring substances currently comply with the requirements for FEMA GRAS status, including the conditions of intended use as a flavoring substance. During the course of the Expert Panel's review of styrene for GRAS reaffirmation, the extremely small amount of styrene (0.3 lbs.) reported in the most recent FEMA poundage survey was not verified by the reporting company upon inquiry by FEMA. Thus, the Expert Panel determined that styrene is no longer used as a flavoring substance. Accordingly, styrene was determined to no longer be GRAS under its

⁵ The Flavor and Extract Manufacturers Association of the United States (FEMA) is comprised of flavor manufacturers, flavor users, flavor ingredient suppliers, and others with an interest in the U.S. flavor industry. Founded in 1909, it is the national association of the U.S. flavor industry.

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conditions of intended use as a synthetic flavoring substance or adjuvant in food, and it was removed from the “FEMA GRAS list.”⁶

III. Proposed Amendment

On the basis of the foregoing, the Petitioner respectfully requests that FDA amend 21 C.F.R. §172.515 to remove the clearance for styrene as a synthetic flavoring substance and adjuvant in food because its use has been abandoned. This amendment would have the effect of precluding the use of styrene as a synthetic flavoring substance and adjuvant in food in the future, and would appropriately reflect the purposeful abandonment of such use by industry.

IV. Environmental Impact

Petitioner hereby claims a categorical exclusion from the need to prepare an environmental assessment for this action pursuant to 21 C.F.R. §25.32(m) (“Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics”). The claim complies with the categorical exclusion criteria, and to the Petitioner’s knowledge, there are no extraordinary circumstances that would otherwise warrant the preparation of an environmental assessment.

Sincerely,



Devon Wm. Hill

Enclosures:

Attachment 1 – March 17, 2016 Survey Response from Total Petrochemicals & Refining USA, Inc.

Attachment 2 – March 21, 2016 Survey Response from Dart Container Corporation

Attachment 3 – March 23, 2016 Survey Response from Lyondell Chemical Company

Attachment 4 – March 29, 2016 Survey Response from Ashland, Inc.

⁶ Cohen S.M., Fukushima S., Gooderham N.J., Hecht S.S., Marnett L.J., Rietjens I.M.C.M., Smith R.L., Bastaki M., McGowan M.M., Harman C., and Taylor S.V. GRAS flavoring substances 27. *Food Technology*. 69(8), 40. 2015.

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Attachment 5 – March 31, 2016 Survey Response from Americas Styrenics

Attachment 6 – April 27, 2016 Survey Response from SABIC Petrochemicals Holding US, Inc.

Attachment 7 – May 2, 2016 Survey Response from INEOS Styrolution America LLC

Attachment 1



TOTAL
COMMITTED TO BETTER ENERGY

Total Petrochemicals & Refining USA, Inc.
Corporate Headquarters

Styrene Information and Research Center
910 17th St., NW, 5th Floor
Washington, D.C. 20006

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT IN FOOD

Name of Company: Total Petrochemicals & Refining USA, Inc.
Address: 1201 Louisiana St, Suite 1800
Houston, TX 77494
Name of Authorized Agent/Representative: Paul Bradley
Title: Manager, Product Stewardship
Telephone: (713) 483 - 5633
E-Mail Address: Paul.Bradley@total.com

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? No Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

Comments: See Section II

SECTION II

With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:

Paul Bradley

Signature of Authorized Agent/Representative

3/17/2016
Date

Attachment 2



DART CONTAINER CORPORATION

MASON, MICHIGAN 48854 • TELEPHONE (517) 676-3803

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT IN FOOD

Name of Company: Dart Container Corporation

Address: 500 Hogsback Road
Mason, Michigan 48854

Name of Authorized Agent/Representative: Harry J. Kopp

Title: Manager Engineering

Telephone: (517) 244-2931

E-Mail Address: harry.kopp@dart.biz

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? No X Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

Comments: _____



SECTION II

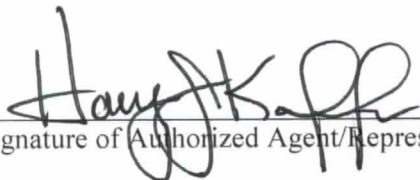
- Michigan • Pennsylvania • Illinois • Georgia • California • Florida • Washington • Texas • Kentucky • Mississippi • North Carolina • Canada • Mexico • United Kingdom • Australia • Argentina



With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:



Signature of Authorized Agent/Representative

21 MARCH 2016

Date

Attachment 3



**Styrene Information and Research Center
910 17th St., NW, 5th Floor
Washington, D.C. 20006**

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT IN FOOD

Name of Company: Lyondell Chemical Company

Address: LyondellBasell Tower
1221 McKinney Street, Suite 300
Houston, TX 77010

Name of Authorized Agent/Representative: J. Stephen Bass, Ph.D.

Title: Senior Product Steward

Telephone: (713) 309-4375

E-Mail Address: Stephen.Bass@lyondellbasell.com

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? No Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

Comments: _____



SECTION II

With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:

March 23, 2016

Signature of Authorized Agent/Representative

Date

Attachment 4



Scott Sieber, MS
Toxicologist, EH&S

Ashland Inc.
5200 Blazer Pkwy
Dublin, Ohio 43017

Styrene Information and Research Center
910 17th St, NW, 5th Floor
Washington, DC. 2006

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND
ADJUVANT IN FOOD

Name of Company: Ashland, Inc

Address: 5200 Blazer Parkway

Dublin, Ohio 43017

Name of Authorized Agent/Representative: Scott Sieber

Title: Toxicologist

Telephone: (614) 790-3197 x

E-Mail Address: SSieber@ashland.com

SECTION I

Styrene (CAS Reg. No.100-42-5) is permitted for use as a synthetic: flavoring substance and adjuvant in food pursuant to 21C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? **No** Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21C.F.R. § 172.515 that you believe may be relevant.

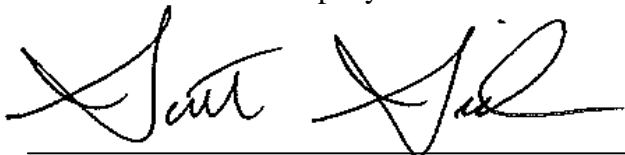
Comments: _____

SECTION II

With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:



Signature of Authorized Agent/Representative

3-29-16

Date

Attachment 5

Styrene Information and Research Center
910 17th St., NW, 5th Floor
Washington, D.C. 20006

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT
IN FOOD

Name of Company: Americas Styrenics

Address: 24 Waterway Avenue
Suite 1200
The Woodlands, TX 77380

Name of Authorized Agent/Representative: Randall Pogue

Title: Senior Vice President, Styrene and Corporate Services

Telephone: (832) 616 - 7800 x

E-Mail Address: RPogue@AmSty.com

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? No Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

Comments: _____

SECTION II

With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:



Signature of Authorized Agent/Representative

3/31/14

Date

Attachment 6

Styrene Information and Research Center
 910 17th St., NW, 5th Floor
 Washington, D.C. 20006

**SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT
 IN FOOD**

Name of Company: SABIC

Address: 1 Loran Lane
Mount Vernon, IN 47620

Name of Authorized Agent/Representative: Paul Roscoe

Title: Commercial Manager, USA Styrene Monomers

Telephone: (812) 423-5753 x BUSINESS

E-Mail Address: Paul.Roscoe@Sabic.com

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise market styrene for use as a synthetic flavoring substance and adjuvant in food? No Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

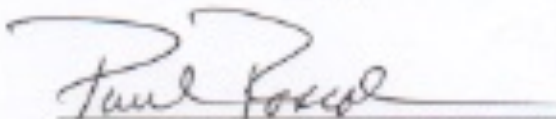
Comments: _____

SECTION II

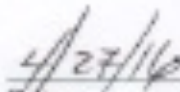
With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not currently import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
3. The Company does not intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future;
4. The Company does not currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

On behalf of the Company:



Signature of Authorized Agent/Representative



Date

Attachment 7

Styrene Information and Research Center
910 17th St., NW, 5th Floor
Washington, D.C. 20006

SURVEY REGARDING USE OF STYRENE AS SYNTHETIC FLAVORANT AND ADJUVANT IN FOOD

Name of Company: INEOS Styrolution America LLC
Address: 12222 Port Road
Pasadena, Texas 77507
Name of Authorized Agent/Representative: Arndt Kotyczka
Title: Vice President, Styrene Monomer Americas
Telephone: 281-474-1681
E-Mail Address: arndt.kotyczka@styrolution.com

SECTION I

Styrene (CAS Reg. No. 100-42-5) is permitted for use as a synthetic flavoring substance and adjuvant in food pursuant to 21 C.F.R. § 172.515.

Does your company currently manufacture, import, or otherwise use styrene as a synthetic flavoring substance and adjuvant in food? No Yes

If you answered no to the above question, please proceed to Section II of this survey. If you answered yes, please provide any additional information about your current use of styrene pursuant to 21 C.F.R. § 172.515 that you believe may be relevant.

Comments None

SECTION II

With respect to styrene (CAS Reg. No. 100-42-5), the Company hereby confirms that:

1. The Company does not currently use styrene (whether domestically produced or imported) as a synthetic flavoring substance and adjuvant in food in the United States;
2. The Company does not intend to use styrene (whether domestically produced or imported) as a synthetic flavoring substance and adjuvant in food in the United States in the future; and
3. The Company does not currently maintain any inventory of styrene to use in its own manufacturing as a synthetic flavoring substance and adjuvant in food in the United States.

Sincerely yours,

INEOS STYROLUTION AMERICA LLC

By: A. Kotyczka / May 2, 2016
Arndt Kotyczka, Vice President,
Styrene Monomer Americas