

Drinking Water (4607M), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 (e-mail: [kapadia.amit@epa.gov](mailto:kapadia.amit@epa.gov); Tel: 202-564-4879).

**SUPPLEMENTARY INFORMATION:** As part of the 2002 appropriations process, Congress directed EPA to "begin immediately to review the Agency's affordability criteria and how small system variance and exemption programs should be implemented for arsenic" (Conference Report 107-272, page 175). Congress further directed the Agency to prepare a report, which EPA submitted (Report to Congress: Small System Arsenic Implementation Issues: EPA 815-R-02-003), "on its review of the affordability criteria and the administrative actions undertaken or planned to be undertaken by the Agency, as well as potential funding mechanisms for small community compliance and other legislative actions, which, if taken by the Congress, would best achieve appropriate extensions of time for small communities while also guaranteeing maximum compliance." (Conference Report 107-272, page 175).

In evaluating treatment technologies for small systems, EPA currently uses an affordability threshold of 2.5% of median household income. EPA's national-level affordability criteria consist of two major components: an expenditure baseline and an affordability threshold. The expenditure baseline (derived from annual median household water bills) is subtracted from the affordability threshold (a share of median household income that EPA believes to be a reasonable upper limit for these water bills) to determine the expenditure margin (the maximum increase in household water bills that can be imposed by treatment and still be considered affordable). EPA compares the cost of treatment technologies against the available expenditure margin to determine if an affordable compliance technology can be identified. If EPA cannot identify an affordable compliance technology, then it attempts to identify a variance technology. Findings must be made at both the Federal and State level that compliance technologies are not affordable for small systems before a variance can be granted.

EPA is asking the NDWAC for advice on its national-level affordability criteria and the methodology used to establish these criteria. Taking into consideration the structure of the Safe Drinking Water Act and the limitations of readily available data and information sources, EPA is seeking the Council's opinion of

the national level affordability criteria, methodology for deriving the criteria, and approach to applying those criteria to NPDWRs.

As part of the Council's review of EPA's national-level affordability criteria, the Agency is seeking input on (1) the Agency's overall approach, (2) alternatives, if any, to the use of median household income as a metric, (3) alternatives, if any, to 2.5% as a metric, (4) alternatives, if any, to calculating the expenditure baseline, (5) the usefulness of a separate criteria for ground and surface water systems, (6) including an evaluation of the potential availability of financial assistance, and (7) the need for making affordability determinations on a regional basis. Other issue areas may also be discussed. The meeting is open to the public; statements from the public will be taken at the close of the meeting. EPA is not soliciting written comments and is not planning to formally respond to comments.

This will be the third, fourth, and fifth work group meetings on this topic. At the first meeting held on September 11-12, the work group was briefed by EPA on the approach to affordability taken by the Agency. At the first meeting, the work group also devised an approach to answer the Agency's charge questions. For the second work group meeting (to be held on October 21-22), other technical experts on financial assistance have been invited to speak. The purpose of these last three meetings is to continue the workgroup deliberations and to draft a report for the full National Drinking Water Advisory Council.

Dated: October 17, 2002.

**Cynthia C. Dougherty,**

*Director, Office of Ground Water and Drinking Water.*

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**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

**[OPP-2002-0275; FRL-7276-8]**

### **Hydrogenated Starch Hydrolysate; Notice of Filing a Pesticide Petition to Establish an Exemption From the Requirement of a Tolerance for a Certain Pesticide Chemical in or on Food**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain

pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2002-0275 must be received on or before November 22, 2002.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8373; e-mail address: [alston.treva@epa.gov](mailto:alston.treva@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

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

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2002-0275. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public

docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

#### *C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic

public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2002-0275. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2002-0275. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2002-0275.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2002-0275. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically

through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any 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 and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### **List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 9, 2002.

**Debra Edwards,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was

prepared by the petitioner, and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### **Hydrogenated Starch Hydrolysate**

*PP 2E6503*

EPA has received a pesticide petition (2E6503) from Grain Processing Corporation, 1600 Oregon Street, Muscatine, Iowa 52761 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for hydrogenated starch hydrolysate (HSH) in or on growing crops or when applied to the raw agricultural commodity after harvest. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### *A. Residue Chemistry*

1. *Plant metabolism.* Like any other carbohydrate, HSH degrades readily in the soil and other substrates into carbon dioxide and water. HSH (CAS number 68425-17-2) is a carbohydrate polymer with a theoretical molecular weight (in amu) of 1,000-3,600. It can be supplied as a liquid syrup or white powder. The empirical formula of the components of HSH are:

Components	Formula
Sorbitol	$C_6H_{14}O_6$
Maltitol	$C_{12}H_{24}O_{11}$
Hydrogenated polysaccharides	$C_{12}H_{24}O_{11}$ plus $C_6H_{10}O_5$ for each additional glucose moiety in the chain

HSH is highly soluble in water. The aqueous solution has a pH range of 4.0-6.0. It hydrolyzes slowly to glucose and sorbitol. It combusts at 300 °C to carbon dioxide and water.

2. *Analytical method.* The qualitative analysis of HSH in the products to which it has been added may be accomplished by extraction of the sorbitol and maltitol moieties with appropriate solvents, followed by gas chromatography of the extracts. Similarly, the quantity of HSH occurring in food may be estimated by

determining the amount of maltitol recovered and applying an appropriate factor. Information on the sensitivity and reproducibility of the method has also been developed.

3. *Magnitude of residues.* HSH is readily degraded by microorganisms on leaf surfaces and in the soil. Due to the solubility of this carbohydrate, rain, or other water sources wash the carbohydrate into the soil where it is degraded by microorganisms into carbon dioxide and water. No harmful residues are produced.

#### *B. Toxicological Profile*

HSH has been widely used in foods since the early 1980s. It has been marketed extensively by Roquette, Lonza and SPI Polyols for years. Grain Processing Corporation produces HSH using a process that is equivalent to the process petitioned to the Food and Drug Administration by Lonza and Roquette Freres for GRAS (generally recognized as safe) affirmation. In support of the safety of our HSH, Grain Processing Corporation and SPI Polyols cites data

submitted by Roquette in its Lycasin® 80/55 petition regarding numerous studies relating to the safety of the ingredient, including reports on: Digestion, absorption, distribution and excretion; acute oral toxicity, subchronic toxicity, genotoxicity, reproduction, biological tolerance, human exposure, and laxation effects.

1. *Acute toxicity.* The acute oral toxicity of HSH has been evaluated. The acute oral lethal dose (LD<sub>50</sub>) of HSH is greater than 10 grams/kilogram (g/kg).

2. *Genotoxicity.* As stated in Roquette's GRAS submission of Lycasin® 80/55, HSH is nonmutagenic and nonclastogenic in short-term *in vivo*, and *in vitro* studies.

3. *Reproductive and developmental toxicity.* Again as noted in Roquette's GRAS submission of Lycasin® 80/55 HSH products, when administered to rats over 3-generations, produce no significant effects on reproduction.

4. *Subchronic toxicity.* In Roquette's GRAS submission for Lycasin® 80/55, it is noted that when administered orally to rats and dogs in amounts of 5 g/kg to 15 g/kg of body weight per day for 90 days, HSH produced no toxicologically meaningful effects which could not be accounted for by the presence of sorbitol. The possible treatment related effects are aggregates in the renal pelvis of some rats, diarrhea in most dogs, and minimal ectasia in the renule tubules of some dogs.

5. *Chronic toxicity.* HSH is used extensively in foods. Grain Processing Corporation is not aware of any chronic toxic effects associated with this product.

6. *Animal metabolism.* The GRAS submission for Lycasin® 80/55 developed by Roquette Freres states that over 96% of HSH (Lycasin® 80/55) is broken down by the mammalian digestive system into the GRAS substances, glucose and sorbitol, the remaining 4% is in the form of maltitol. One half of the maltitol is excreted in the feces and the majority of the remainder is excreted in the urine.

Within the first 2 hours after oral administration of HSH (Lycasin® 80/55), virtually all of the glucose to glucose bonds are broken down in the digestive system, producing a resulting mixture of glucose, sorbitol, and maltitol. Within 7 hours, 95% of the total maltitol, is broken down into glucose and sorbitol. Of the remaining 5% of maltitol, 2% is found in the digestive tube and fecal contents, less than 1% is found in the plasma, and approximately 1% is excreted in the urine.

There is no accumulation of maltitol in the plasma, liver, kidneys, or spleen

of rats fed 13.5 g/kg/day of Lycasin® 80/55 for 10 days irrespective of whether measurements are made 12 hours or 10 days after cessation of dosing.

Lycasin® 80/55 at the dose levels tested, 30 to 180 grams per day, produces no significant variations in the clinical chemical, hematological or urinary profile of humans with the exception of glucose and insulin peaks which are less than 50% of those produced by equivalent amounts of glucose, and 50 to 90% of those produced by sucrose. The only significant clinical effects are flatulence and diarrhea, which can be accounted for by the presence of free and bound sorbitol. The mean laxative threshold in adult males is approximately 180 grams per day, while in females the threshold is approximately 100 grams per day. In children, the threshold is approximately 60 grams per day, about half that of adults.

7. *Metabolite toxicology.* None of the metabolites of HSH are considered to be of toxicological significance for the use of this product as a pesticide inert ingredient.

8. *Endocrine disruption.* Grain Processing Corporation is not aware of any endocrine disruption with the use of this product.

#### C. Aggregate Exposure

1. *Dietary exposure.* This product is already used extensively in foods. Studies have shown that it is safe even when consumed at levels of up to 100 g/day.

i. *Food.* As a pesticide inert ingredient HSH will not result in any harmful exposure. The proposed use will not result in any dietary exposure beyond what is currently present in commonly consumed foods.

ii. *Drinking water.* There is no anticipated human exposure to HSH through drinking water. HSH is expected to be degraded by soil microorganisms to carbon dioxide and water before it reaches surface or ground water. Moreover, in water, HSH hydrolyses to glucose and sorbitol.

2. *Non-dietary exposure.* No significant non-dietary human exposure to HSH is anticipated.

#### D. Cumulative Effects

HSH is a widely used food ingredient, is readily digested by humans, and there are no cumulative effects. Except for possible occupational exposure of the pesticide mixer/loader/applicator, the proposed use of HSH will not result in the exposure of other persons.

#### E. Safety Determination

1. *U.S. population.* The proposed use of HSH does not pose a safety concern for the U.S. population due to the non-toxic nature of the compound and the absence of exposure.

2. *Infants and children.* Infants and children will not be exposed to HSH from its proposed use as a pesticide inert ingredient.

#### F. International Tolerances

Grain Processing Corporation is unaware of any international tolerances for this product. HSH was developed by a Swedish company in the 1960's and has been widely used by the food industry for many years, especially in confectionery products. Roquette's petition indicates that Roquette's Lycasin® products have been approved for use in food in Europe since 1963, as indicated below.

Country	Year of Approval
Sweden	1963 (reaffirmed in 1975)
Switzerland	1968
Norway	1975
Finland	1975 (reaffirmed in 1980)
Denmark	1976

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#### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0188; FRL-7199-7]

#### Availability of the Risk Assessments on FQPA Tolerance Reassessment Progress and Tolerance Reassessment Decision (TRED) for Hexazinone

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's tolerance reassessment decision and related documents for hexazinone including the *Hexazinone Overview, Hexazinone Summary, Hexazinone Decision Document (TRED)*, and supporting risk assessment documents. EPA has reassessed the 25 tolerances, or legal limits, for residues of hexazinone in or on raw agricultural commodities. These tolerances are now considered safe under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by