

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

the Food Quality Protection Act (FQPA) of 1996.

**DATES:** Comments on the tolerance reassessment decision for hexazinone, must be received by EPA on or before November 22, 2002. In the absence of substantive comments, the tolerance reassessment decision will be considered final. Comments on the human health and ecological effects risk assessments for hexazinone, must be received by EPA on or before November 22, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in the **SUPPLEMENTARY INFORMATION** section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0188 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Dirk V. Helder, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-4610; e-mail address: [helder.dirk@epa.gov](mailto:helder.dirk@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

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

This action is directed to the public in general, but will be of interest to a wide range of stakeholders, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides. The Agency has not attempted to describe all the persons or entities who may be interested in or affected by this action. If you have questions in this regard, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

You can obtain copies of the TRED and related documents discussed in this notice on EPA's website at <http://www.epa.gov/pesticides/reregistration/status.htm>. Information on pesticide reregistration and tolerance reassessment, including the purpose and status of Agency programs to complete Reregistration Eligibility Decisions (REDs), Interim REDs, and Tolerance Reassessment Decisions (TREDs), is available at <http://www.epa.gov/pesticides/reregistration>. General information is available on the Office of Pesticide Programs' home page, <http://www.epa.gov/pesticides/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0188. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

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

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0188 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from

8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0188. Electronic comments may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record 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. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.

8. 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 reassessed the risks associated with current food uses of the pesticide hexazinone, reassessed 25 existing tolerances, and reached a tolerance reassessment and risk management decision. The Agency is issuing for comment the resulting report on FQPA tolerance reassessment progress, including the *Hexazinone Overview, Hexazinone Summary, Hexazinone Decision Document (TRED)*, and supporting risk assessment documents.

EPA must review tolerances and tolerance exemptions that were in effect when FQPA was enacted in August 1996, to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard established by the new law. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA has reviewed and made the requisite safety finding for the tolerances and exemptions included in this notice. EPA completed the hexazinone Reregistration Eligibility Decision (RED) prior to the 1996 enactment of the FQPA; therefore, while no reregistration decision is required at present, risks from non-occupational exposure to hexazinone through food, drinking water, and residential uses must be reassessed. There are no residential uses of hexazinone. The Agency has reassessed the 25 tolerances for hexazinone and determined that residues in food and drinking water are not expected to pose risk concerns. Because existing data were inadequate to calculate residue estimates for pasture and rangeland grass and grass hay, EPA constructed the maximum theoretical dietary burden (MTDB) of hexazinone to livestock using protective assumptions for the contributions of other hexazinone treated feed items. Thus, tolerances for meats and milk can be reassessed. Additional field trial data for grass forage and grass hay, as well as rotational crop studies for corn and wheat are required. Because of the relatively low volume of use on pasture and rangeland, data from these confirmatory studies are not expected to significantly change current dietary risk estimates. Some tolerances may be revised once additional data has been submitted to and reviewed by the Agency. The current tolerance

expression for hexazinone in 40 CFR 180.396 is for "combined residues of the herbicide hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1H,3H)-dione) and its metabolites, calculated as hexazinone." The tolerance expression should be modified to include specific metabolites A, B, C, D, and E, identified by the appropriate chemical name. Final tolerances are being proposed as part of this Tolerance Reassessment Decision (TRED). In addition, occupational and ecological risk management decisions were made as part of the 1994 hexazinone RED.

EPA works with affected parties to reach the tolerance reassessment decisions. The Agency therefore is issuing the hexazinone decision as a final decision with a public comment period. All comments received during the public comment period will be considered by the Agency. If any comment significantly affects the Agency's decision, EPA will publish an amendment to the decision in the **Federal Register**. In the absence of substantive comments, the tolerance reassessment decisions reflected here will be considered final.

### List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: October 4, 2002.

**Betty Shackelford,**

*Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0223; FRL-7274-1]

### Availability of the Report on FQPA Tolerance Reassessment Progress and Risk Management Decision (TRED) for Metolachlor

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of the report on the Food Quality Protection Act (FQPA) tolerance reassessment progress and Risk Management Decision (TRED) for metolachlor for public comment. EPA has reassessed the 81 tolerances, or legal limits, established for residues of metolachlor in/on raw agricultural commodities (RACs). These tolerances are now considered safe under the Federal Food, Drug, and Cosmetic Act

(FFDCA), as amended by the FQPA of 1996.

**DATES:** Comments, identified by docket ID number OPP-2002-0223, must be received on or before November 22, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0223 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Anne Overstreet, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8068; fax number: (703) 308-8005; e-mail address: overstreet.anne@epa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

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

This action is directed to the public in general, but will be of interest to a wide range of stakeholders, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides. The Agency has not attempted to describe all the persons or entities who may be interested in or affected by this action. If you have questions in this regard, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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