All registrants of the pesticide product containing the active ingredient listed in this document have been sent the appropriate RED, and must respond to labeling requirements and product-specific data requirements (if applicable) within 8 months of receipt. Products also containing other pesticide active ingredients will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing the RED as a final document with a 60–day comment period. Although the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. If any comment significantly affects a RED, EPA will amend the RED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for the RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 2, 2004.

Debra Edwards,

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

[FR Doc. 04–25944 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0296; FRL–7685–3]

Captan; Cancer Reclassification; Amendment of ReregistrationEligibility Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's modification of certain provisions of the 1999 Reregistration Eligibility Decision (RED) for the pesticide captan, and opens a public comment period on these changes. EPA is amending the captan RED in response to public comments received. EPA has made certain modifications to the captan RED which are discussed in the ''Amendment to the 1999 Captan RED'' document, which is available in the captan docket and e-docket. This notice also opens the public comment period announcing the results of the Agency's reevaluation of captan's cancer classification. The Captan Task Force voluntarily pursued a process to reclassify captan's initial cancer classification, as a probable human carcinogen, by supporting a third-party review of data to support a mode of action determination for captan. Based on the third-party review and subsequent Agency review, EPA has determined that captan acts through a non-genotoxic threshold mode of action. Although the Agency is issuing a single FR to announce both the amendment to the RED and the reevaluation of the cancer classification, the change in cancer classification does not change the risk management conclusions nor amend the 1999 Captan RED, and is not considered a reregistration action.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0296, must be received on or before January 24, 2005.

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: *For questions regarding the cancer reclassification*: Susan Jennings, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (706) 355–8574; e-mail address: *jennings.susan@epa.gov*.

For questions regarding the ''Amendment to the 1999 Captan RED'' document: Cathryn O'Connell, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0136; e-mail address:*oconnell.cathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may 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 sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any 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–2004–0296. 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, 1801 S. Bell St., 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. 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.1. 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–2004–0296. 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*, Attention: Docket ID Number OPP–2004–0296. 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–2004–0296.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0296. 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. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

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. Background

A. What Action is the Agency Taking?

The Agency is issuing an ''Amendment to the 1999 Captan RED'' document for public comment. In addition, this notice announces the results of the Agency's reevaluation of captan's cancer classification. This reevaluation does not change the conclusions of the RED and does not amend the Captan RED.

i. *Amendment to the 1999 Captan RED*. In 1999, EPA issued a RED for captan under section 4(g)(2)(A) of FIFRA. EPA has modified certain captan label requirements including: Double notification for all agricultural uses of captan; verbal notification of eye concerns associated with captan for 7 days following application; wettable powders applied aerially to be formulated in water soluble packages; reductions in the dichondra ornamental grass use rate; establishing a Re-Entry Interval for ornamentals, blackberries, blueberries, dewberries, raspberries, and grapes of 48 hours; removing the dust/mist respirator requirement for handling bags of treated seed.

ii. *Cancer reclassification*. When the RED was issued, captan retained its previous classification as a B2 chemical carcinogen (probable human carcinogen). Cancer risk from captan was quantified using the Agency's default approach described in the Agency's 1986 Cancer Risk Assessment Guidelines. When much uncertainty exists regarding the mode of carcinogenic action, EPA assumes the tumor dose response from a cancer study is linear. In the absence of adequate information to the contrary, the linearized multistage procedure is applied to the tumor response data to calculate the cancer unit risk (Q1*), which is the upper confidence limit (95th percentile) of the dose response curve. This linear low dose approach used to estimate cancer risk is believed to be conservative.

Although the Captan Task Force (CTF) had submitted several mechanism studies for captan, the Agency determined that they did not contribute sufficient additional information to the mode of action nor have a significant bearing on the cancer risk assessment. In the RED, the Agency reaffirmed its decision that the linear low dose extrapolation model should continue to be used for risk assessment and determined that a reconsideration for captan according to the 1996 Draft Cancer Risk Assessment guidelines was not required.

In February of 2000, the CTF petitioned the Agency to reevaluate the cancer risk assessment for captan using a threshold approach rather than the traditional linear low dose (Q1*) approach. They submitted additional data, including data on thiophosgene, and stated that they strongly believed that captan should be regulated as a threshold carcinogen. Their comments were bolstered by portions of the RED, which stated that ''the carcinogenic process is thought to be triggered by the highly reactive but short-lived metabolite thiophosgene.''

When the Agency reviewed this petition and additional data, it concluded that the information might be sufficient to warrant a cancer reclassification. However, the Agency also concluded that the resources required to conduct a thorough reclassification effort would not be available in the short-term. Since the reclassification would not change the conclusions of the RED, namely that the risk of cancer from exposure to captan was below the Agency's level of concern, the Agency determined that reevaluating captan's cancer classification was not a priority action at that time and was not necessary to reregister end-use products containing captan.

In 2001, based on a request from the CTF, EPA agreed to consider a re-evaluation of captan's cancer classification by a third party. It was envisioned that an organization, separate from the CTF, would manage an expert scientific peer review of the cancer information, and generate the supporting documentation and proposed conclusion from the third party. The Agency would then review the work of the third party and make its own decision regarding captan's cancer reclassification. The Agency was available for consultation, but did not manage or approve any portion of these proceedings. Records of interactions between the Agency and the CTF regarding this process are available in the public docket.

The CTF chose Toxicology Excellence for Risk Assessment (TERA) to recruit and manage the process of reviewing the captan cancer mode of action data. On September 3 and 4, 2003, a third party of outside experts in various fields and affiliations reviewed the captan cancer mode of action data. This Peer Review Panel concluded that captan acted through a non-genotoxic threshold mode of action.

In 2004, the CTF submitted the results of the Peer Review Panel meeting to the EPA for review. EPA reviewed this information and determined that the weight of evidence indicates that captan's carcinogenicity is limited to a single tumor type (adenomas and adenocarcinomas in the small intestine, primarily the proximal portion of the duodenum) in both sexes of a single species (mouse). EPA agreed that the results of the rat bioassays provide no evidence that captan is associated with kidney tumors in male rats or uterine tumors in female rats, and, therefore, these tumors do not add to the weight-of-evidence considerations for the carcinogenicity of captan.

The Agency accepts the proposed mode of action as set forth by the CTF that suggests that ''captan induces adenomas and adenocarcinomas in the duodenum of the mouse by a non-genotoxic mode of action involving cytotoxicity and regenerative cell hyperplasia that exhibits a clear dose threshold. These responses are reversible following cessation of captan exposure. There is a strong causal association (dose-response, temporality) indicating that tumor formation is secondary to cytotoxicity and hyperplasia and that the latter is a key event in the sequential cascade of events leading to cancer.''

In September 2004, the Agency, in accordance with the EPA 1999 Proposed Guidelines for Carcinogen Risk Assessment, classified captan as ''not likely to be a human carcinogen at dose levels that do not cause cytotoxicity and regenerative cell hyperplasia'' and ''likely to be carcinogenic to humans following prolonged, high-level exposures causing cytotoxicity and regenerative cell hyperplasia.''

The new cancer classification considers captan to be a potential carcinogen at prolonged high doses that cause cytotoxicity and regenerative cell hyperplasia. These high doses of captan are many orders of magnitude above those likely to be consumed in the diet, or encountered by individuals in occupational or residential settings.

Therefore, captan is not likely to be a human carcinogen nor pose cancer risks of concern when used in accordance with approved product labels.

For further information and discussion about the cancer reclassification see the September 22, 2004 report, ''CAPTAN: Fourth Report of the Cancer Assessment Review Committee.'' In addition, the ''Reader's Guide to the Captan E-Docket'' provides an organized list to help readers navigate the documents in the docket, including scientific supporting documents and registrant and third-party submissions.

All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. Comments and proposals will become part of the Agency Docket for captan. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. EPA will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and electronic EDOCKET. If any comment significantly affects the document, EPA also will publish an amendment to the RED in the **Federal Register**. In the absence of substantive comments requiring changes, the captan RED will be implemented as it is now presented.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA, as amended, directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products and either reregistering products or taking other ''appropriate regulatory action.''

Section 408(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 12, 2004.

Debra Edwards,

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

[FR Doc. 04–26083 Filed 11–24–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0234; FRL–7370–8]

Cycloate; Availability of Reregistration Eligibility Decision Document for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces availability and starts a 60–day public comment period on the Reregistration Eligibility Decision (RED) document for the pesticide active ingredient cycloate (*S*-ethyl cyclohexyl(ethyl)thiocarbamate). The RED represents EPA's formal regulatory assessment of the health and environmental data base of the subject chemical and presents the Agency's determination regarding which pesticidal uses are eligible for reregistration.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0234, must be received on or before January 24, 2005.

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: Carmen Rodia, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–306–0327; e-mail address: *rodia.carmen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any 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–2004–0234. 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), Room 119, Crystal Mall #2, 1801 S. Bell Street, Arlington, VA 22202–4501. 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/*. To access RED documents and RED fact sheets electronically, go directly to the REDs table on the EPA Office of Pesticide Programs Home Page, at *http://www.epa.gov/pesticides/reregistration/status.htm*.

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. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's 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 Dockets. EPA's policy is that copyrighted material will not be placed in EPA Dockets but will