OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

Feb 11, 2025

GENERIC DATA CALL-IN NOTICE

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachments 2 and 3 of this Notice to submit certain responses as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These responses are necessary for the Registration Review of your pesticide product(s) in its Registration Review case and to maintain the continued registration of your product(s) containing the active ingredient(s). Within 90 days after you receive this Notice, you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or,

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form, (see section III-B); or,

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice may be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

You may respond to this Generic Data Call-In Notice either electronically through the Central Data Exchange (CDX) or by mail as described in Attachment 1. When submission of responses is discussed throughout this Notice, either method can be used.

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended; sections 3(g)(2)(A) and (B) of FIFRA, as amended; and/or section 408(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This notice is issued as part of Registration Review and is also authorized by 40 CFR Part 155.40, et seq., which is the Agency's Registration Review regulations. Collection of this information is in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) as approved by the Office of Management and Budget (OMB) under Control Number 2070-0174.

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

The Attachments to this Notice are:

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data from the estrogen receptor (ER) and androgen receptor (AR) ToxCast Pathway Models for the active ingredient(s) identified in Attachments 2 and 3 of this Notice. The ToxCast ER and AR Pathway Models have been used to produce endocrine screening data for over 1,800 chemicals. These computational models can serve as alternatives to 4 of the 11 Tier 1 assays for the Endocrine Disruptor Screening Program (EDSP). ToxCast ER and AR Pathway Model data for the active ingredient(s) identified in Attachments 2 and 3 of this Notice show bioactivity that may provide evidence for a potential effect on estrogen, androgen, or both, indicating the need for additional data to evaluate the potential to interact with the estrogen, androgen, or both pathways. These responses are necessary to maintain the continued registration of products containing the subject active ingredient(s) and the continuation of any existing tolerances or tolerance exemptions for such active ingredient. This reevaluation conducted as part of Registration Review identified additional data necessary to assess the health and safety of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form, within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with protocols which meet the purpose of the test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established and which provide data of suitable quality and completeness as typified by the protocols cited in the guidelines.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Tel: 703-605- 6000) and on the

EPA's Chemical Safety and Pollution Prevention website (http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances).

Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices (40 CFR Part 160).

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) OR 4 DATA CALL-IN NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend (NOIS) their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt may be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: (1) voluntary cancellation, (2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice, (5) request a data waiver(s), or (6) other response options.

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option, or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained below and in Section III-C. A discussion of options relating to requests for data waivers is contained below and in Section III-D. A discussion of the other EDSP response options is contained in Section III-B-6.

There are two forms that accompany this Notice, and depending upon your response, one or both of those forms must be used in your response to the Agency. These forms are the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form and the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. The Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form must be submitted as part of every response to this Notice. Note that the company's authorized representative is required to sign the first page of the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form and the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, write or email EPA as indicated in Attachment 1.

You have several potential response actions from which to choose; each response option involves specific procedures that you must follow if you choose that response option:

1. Voluntary Cancellation of Products(s) - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form. If you choose this option, you do not need to complete Attachment 3, Generic Requirements Status and Registrant's Response Forms and

Instructions. You will be contacted about the need to submit a request for voluntary cancellation consistent with FIFRA section 6(f).

If you choose to voluntarily cancel your product, further sale and distribution of your product(s) after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - It may be possible for you to avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you are unsure what uses must be removed to avoid this Notice, please contact the Chemical Review Manager at green.tiffany@epa.gov . If you wish to amend your registration to delete uses, you must submit the Attachment 3, Generic Requirements Status and Registrant's *Response Forms and Instructions* Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. You must also complete an Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form by signing the certification, item number 8. For additional instructions on how to delete a use, please refer to the EPA webpage for "Voluntary Cancellation of a Pesticide Product or Use" at https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use. If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, please be aware that the further sale, distribution, or use of your product after one year from the due date of your 90-day response, must bear an amended label.

3. Generic Data Exemption Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). To qualify, all of the following requirements must be met:

    a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you;

    b. Every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

    c. You must have provided to EPA an accurate and current "Confidential Statement of Formula" (CSF) for each of your products to which this Notice applies.

    To apply for the Generic Data Exemption, you must submit a completed Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form and all supporting documentation. The Generic Data Exemption is item number 6a on the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form. If you claim a generic data exemption, you are not required to complete the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. Generic Data Exemption cannot be selected as an option for product specific data.

    If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice. These options are covered by Items 6a, 7a, and 7b in the Generic Data Call-In Response Forms and Instructions Form (Attachment 2) and Item 9, Options 1-6 in the Generic Requirements Status and

Registrant's Response Forms and Instructions Form (Attachment 3). If you choose Items 6b or 7a-7b in the Generic Data Call-In Response Forms and Instructions Form (Attachment 2), you must submit both forms as well as any other information/data pertaining to the option(s) chosen to address the data requirement. The options are:

a. I will generate and submit data within the specified time frame (Developing Data),

b. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

c. I have made offers to cost-share (Offers to Cost Share),

d. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

e. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

f. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

5. Request for Data Waivers - Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

6. Other Response Options for EDSP assays - As part of your Initial Response, you may also ask EPA to reconsider some or all of the testing specified in this Notice if:

a. You can demonstrate (supported by appropriate data) that the chemical causes adverse effects to the estrogen, androgen and/or thyroid pathway in humans and that additional screening or testing under the EDSP is unnecessary for the pathways for which adverse effects were observed.

b. You can demonstrate (supported by appropriate data) that the chemical meets the standard for an exemption under FFDCA section 408(p)(4) (i.e., “that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogen”).

The Agency intends to make a determination on any claim under this Section III.B.6 and to respond to you in writing within 90 days of receipt. If EPA does not agree with your assertion(s), the original requirements and deadlines in this Notice remain. If your claim is verified, EPA will consider your response to be satisfaction of the Notice and will close out this Notice

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Attachment 2 *Generic Data Call-In Response Forms and Instructions* Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form related to data production for each data requirement. Your option selection is to be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data –

If you choose to develop the required data, then it must be submitted in conformance with the Agency's deadlines and other requirements that are referenced herein and in the attachments. All data generated and submitted must comply with Good Laboratory Practice (GLP) standards (40 CFR Part 160), be conducted in accordance with the Pesticide Assessment Guidelines (PAG), be in conformance with Pesticide Registration Notice (PRN) 2011-3 entitled "Standard Format for Data Submitted Under FIFRA and Certain Provisions of FFDCA" (http://www.epa.gov/pesticide-registration/pesticide-registration-notices-year), and, as applicable, comply with 40 CFR Part 26, "Protection of Human Subjects." In addition, certain studies should follow an Agency-approved test protocols. Those studies for which an approved protocol should be followed have been identified in the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you should submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may determine that use of a protocol not specified in Section II-C is unlikely to produce data acceptable to EPA. If the Agency requests changes to your protocol, you will be notified in writing; however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data. Any data generated using an unapproved protocol may not satisfy the requirements of this DCI. EPA may determine that such data is unacceptable and may initiate appropriate action as described in Section IV, below.

A progress report should be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report should be submitted for all studies. This 90-day progress report should include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratories or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports should be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study should be included as well as a full description of any problems encountered since the last progress report.

The time frames in the *Generic Requirements Status and Registrant's Response Forms and Instructions* Form (Attachment 3) are those allowed by the Agency for the submission of completed study reports or protocols. The noted deadlines begin from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s) and the affected tolerances or tolerance exemptions are subject to revocation.

If you cannot submit the data to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a written request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request for additional time,

the original deadline to submit data remains. The Agency will respond to your request in writing. If EPA does not grant your request, then the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data –

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. FIFRA section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement, they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development –

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, where the other registrant(s) developing the data has refused to accept the offer.

To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, *Certification of Offer to Cost Share in the Development of Data* (see Attachment 5). In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant(s) must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a *Generic Data Call-In Response Forms and Instructions* Form (Attachment 2) and a *Generic Requirements Status and Registrant's Response Forms and Instructions* Form (Attachment 3) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study –

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency. Existing studies are studies which predate

issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

If you choose to submit an existing study in response to this Notice (including other scientifically relevant information), your Initial Response must include either the data or a reference to the data for each test that is required, along with a rationale that explains how the study you cited or submitted satisfies part or all of this Notice. In order to be accepted as satisfying the requirements imposed in this Notice, the Agency expects that any such hazard-related data would be of high quality and achieves the objective of the required data to provide reasonable assurance that a chemical does or does not have the potential to interact with the estrogen, androgen, or thyroid systems. EPA's decisions about whether the data submitted satisfies part or all of the DCI will be based on the weight of evidence from all relevant information available to the Agency.

The submitted study must have been conducted in accordance with accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (see http://www.epa.gov/oppts and select "Test Methods and Guidelines"). Deviations from the protocols validated for the Tier 1 assays must be identified, along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol used should still be considered as providing an accepted scientific methodology or protocol, demonstrating that the data generated is sufficient to satisfy the requirement, and any other information you think the Agency should consider in deciding whether to accept the data in satisfaction of this Notice.

You should be aware that if the Agency determines that the existing study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

EPA will review any existing study submitted in response to this Notice to determine whether the study is acceptable and whether the study satisfies the requirements of this Notice. The Agency will notify you in writing of its determination. If the Agency determines that the study is acceptable, the Initial Response Form is the only response you are required to complete to satisfy this Notice and EPA will notify you in writing that the Notice is satisfied. If, however, EPA determines that the study is not acceptable, you must still satisfy the requirements of this Notice. You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required due date for submission of the data. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following four criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) standards of 40 CFR Part 160. As stated in 40 CFR Part 160.3(7) "*raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR Part 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40

CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR Part 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. You must identify each deviation from the PAG and you need to explain and justify why the study should be accepted notwithstanding such deviation(s). It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

d. If any existing study involves testing subject to 40 CFR Part 26, you must comply with all applicable requirements in EPA's regulations at 40 CFR Part 26 entitled "Protection of Human Subjects."

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as per PRN 2011-3.

Option 5, Upgrading a Study –

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, write or email EPA as indicated in Attachment 1. If you submit data to upgrade an existing study, you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and be in conformance with PRN 2011-3.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to

upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies –

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Do not cite data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded. With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you choose to cite an existing study in response to this Notice (including data previously submitted to the Agency and/or other scientifically relevant information), your Initial Response must include either the data or a reference to the data for each test that is required, along with a rationale that explains how the study you cited or submitted satisfies part or all of this Notice. Existing studies are studies that predate issuance of this Notice. In order to be accepted as satisfaction of the requirements imposed in this Notice, the Agency expects that any such hazard-related data would be of high quality and achieves the objective of the required data to provide reasonable assurance that a chemical does or does not have the potential to interact with the estrogen or androgen, or thyroid systems. EPA's decisions about whether the data cited or submitted satisfies part or all of the DCI will be based on the weight of evidence from all relevant information available to the Agency.

The cited study must have been conducted in accordance with accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (see http://www.epa.gov/oppts and select "Test Methods and Guidelines"). Deviations from the protocols validated for the Tier 1 assays must be identified, along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol used should still be considered as providing an accepted scientific methodology or protocol, and any other information you think the Agency should consider in deciding whether to accept the data in satisfaction of this Notice.

If EPA has previously reviewed a protocol for a study you are citing, you must identify any action taken by the Agency on the protocol and must indicate the manner in which all Agency comments, concerns or issues were addressed in the final protocol and study.

EPA will review any existing study cited in response to this Notice to determine whether the study is acceptable and whether the study satisfies the requirements of this Notice. The Agency will notify you in writing of its determination. If the Agency determines that the study is acceptable, the Initial Response Form is the only response you are required to complete to satisfy this Notice and EPA will notify you in writing that the Notice is satisfied. If, however, EPA determines that the study is not acceptable, you must still satisfy the requirements of this Notice. You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required due date for submission of the data. The Agency may determine at any time that a study is not valid and needs to be repeated.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PRN 2011-3) EPA Form 8570-34.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver (Option 8 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form) Section 3(c)(2)(E) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In

implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(a) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management,

(b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives,

(c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and

(d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver. Low volume minor use waivers may not be available for data required for continuation of tolerances or exemptions.

2. Request for Waiver of Data (Option 9 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered and no tolerance or tolerance exemption exists or that the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file, you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to FIFRA section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a different method of meeting the requirements of this Notice within the time frame provided by this Notice. In most instances, EPA will not review successive requests to waive a DCI data requirement for which a waiver request was previously denied. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form indicating the option chosen.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND REGISTRATION/ORDER REVOKING OR MODIFYING TOLERANCE OR EXEMPTION

The Agency may issue a Notice of Intent to Suspend products subject to this Notice or an order revoking or modifying associated tolerances or tolerance exemptions due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B) or FFDCA section 408(f), respectively. Events which may be the basis for issuance of a Notice of Intent to Suspend or of an order revoking or modifying associated tolerances or exemptions include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit acceptable data on the required schedule as required by this Notice.

3. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

4. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

5. Withdrawal of an offer to share in the cost of developing required data.

6. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. Inform EPA of intent to develop and submit the data required by this Notice on an Attachment 2, Generic Data Call-In Response Forms and Instructions Form and an Attachment 3, Generic Requirements Status and Registrant's Response Forms and Instructions Form; or,

   b. Fulfill the commitment to develop and submit the data as required by this Notice; or,

   c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

7. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend or an order revoking or modifying a tolerance or tolerance exemption. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice and that set forth in PRN 2011-3. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

3. Requirements, as applicable, set forth in 40 CFR Part 26 entitled “Protection of Human Subjects.”

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of FIFRA.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a FIFRA section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most

circumstances, one year from the date your 90-day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90-day response period required by this Notice will not result in the Agency granting any additional time to sell distribute or use existing stocks beyond a year from the date the 90-day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if, at any time after a pesticide is registered, a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies regarding unreasonable adverse effects on human health or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, contact EPA as listed in Attachment 1, the *Data Call-In Chemical Status Sheet*.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form and a completed Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and any other documents required by this Notice, and must be submitted either electronically through CDX or by mail as identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Attachment 2, *Generic Data Call-In Response Forms and Instructions* Form need be submitted.

Sincerely,

Name: TBD
Title: TBD
Division: TBD
Office: TBD
Agency: TBD
Feb 11, 2025 01:23:31

Attachment 1. Data Call-In Data Chemical Status Sheet

DATA CALL-IN CHEMICAL STATUS SHEET

Submit all responses to the GDCI using the information below. To expedite processing, include the GDCI identification number (e.g., GDCI-555555-5555) in the Subject line of all DCI-related correspondence.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have specific questions or need assistance responding to the GDCI, contact the Chemical Review Manager: Tiffany Green at : 202-566-2224 or at: green.tiffany@epa.gov.
All responses to this notice for the GDCI data requirements are to be submitted electronically through the Central Data Exchange (CDX) or by mail as described below.

If You Choose to Respond through the Central Data Exchange (CDX):

The DCI receipt acknowledgement, 90-day response, and data can be submitted through CDX via the DCI application of the Pesticide Submission Portal (PSP). If you have a CDX account with access to the PSP, you may follow the link below to sign in, acknowledge receipt, and access your DCI(s): https://cdx.epa.gov/.

A user guide is available for instructions on what to do if you do not have a CDX account (page 16 in the link below) or if you need to add PSP to your account (page 51 in the link below): https://cdx.epa.gov/content/documents/PSP/OPP_CDX_Pesticide_Submission_PortalRegistration_UserGuidev1.0p.pdf

If You Choose to Respond by Mail:*

By US mail, express or courier service:
Document Processing Desk (DCI/OPP)
Attn: Tiffany Green
US EPA (7504M)
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

*NOTE: If this DCI was sent to you via email, you may acknowledge receipt via email.

Attachment 2. Generic Data Call-In Response Form and Instructions

United States Environmental Protection Agency
Washington D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
Expiration Date 12/31/2025
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
ZSCHEM USA, INC. 4110 136TH STREET CT., NW GIG HARBOR, Washington 98332	7203 - Clomazone Chemical # and Name: 125401 Clomazone	11-Feb-2025 GENERIC ID #GDCI-125401-5627

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
93653-6				N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company

11. Phone Number

INSTRUCTIONS: DATA CALL-IN RESPONSE FORM

These instructions apply to the form titled “Data Call-In Response” and are to be used to respond to generic Data Call-Ins issued as part of EPA's Registration Review Program under the Federal Insecticide, Fungicide, and Rodenticide Act. Read these instructions carefully before filling out the forms.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The respondent burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This is a mandatory collection under 40 CFR 158. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 2070-0174. Please send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information Engagement Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Item #	GENERIC DATA CALL-IN RESPONSE Information
Item 1.	This item identifies your company name, number and address.
Item 2.	This item identifies the case number, case name, EPA chemical number and chemical name.
Item 3.	This item identifies the type of Data Call-In. The date of issuance is date stamped.
Item 4.	This item identifies the EPA product registrations relevant to the data call-in. Note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
Item 5.	Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-in requires both generic and product specific data, you must complete item 5 on both Data Call-In response form. You do not need to complete any item on the Generic Requirements Status and Registrant's Response Forms and Instructions Form.
Item #	DATA CALL-IN RESPONSE Information
Item 6a.	Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice. If you are eligible for or claim a Generic Data Exemption, enter the EPA Registration Number of each registered source of that active ingredient that you use in your product. Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item

Item 6b.	Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the "Generic Requirements Status and Registrant's Response Forms and Instructions" Form that indicates how you will satisfy those requirements. Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, supply all relevant details so that EPA can ensure that its records are correct.
Item 7a.	Not Applicable
Item 7b.	Not Applicable
Item 8.	This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.
Items 9, 10, 11.	Provide date of signature, name of company, and telephone number.

Attachment 3. Generic Requirements Status and Registrant's Response Form and Instructions

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
Expiration Date 12/31/2025

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
ZSCHEM USA, INC. 4110 136TH STREET CT., NW GIG HARBOR, Washington 98332	7203 - Clomazone Chemical # and Name: 125401 Clomazone	11-Feb-2025 GENERIC ID #GDCI-125401-5627

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
870.3800	Reproduction and fertility effects (1) (2)	N				A, C		48	
890.1200	Aromatase (Human Recombinant)	N				A, C		6	
890.1400	Hershberger (Rat)	N				A, C		9	
890.1450	Female Pubertal (Rat)	N				A, C		15	
890.1500	Male Pubertal (Rat)	N				A, C		15	
890.1550	Steroidogenesis (Human Cell Line- H295R)	N				A, C		6	

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative

11. Date

12. Name of Company

13. Phone Number

United States Environmental Protection Agency
Washington D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 7203 - Clomazone
DCI Number: GDCI-125401-5627

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood
Use Categories Key:

A - Terrestrial food crop
C - Terrestrial nonfood crop

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

1	This study requirement may also be fulfilled by conducting an extended one-generation reproductive toxicity study according to OECD (2018), Test No. 443: Extended One-Generation Reproductive Toxicity Study, OECD Guidelines for the Testing of Chemicals, Section 4, OECD Publishing, Paris, available at the following link: https://doi.org/10.1787/9789264185371-en.
2	This is an EDSP Tier 2 study if conducted according to the current (1998) 870.3800 test guideline. The need for this study will be determined based on the results of the five lower-tiered studies submitted to comply with this DCI. Alternatively, this Tier 2 study may be conducted in lieu of the five lower-tiered required in this DCI to address the estrogen and androgen pathways.

INSTRUCTIONS: REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

These instructions apply to the form titled "Requirements Status and Registrant's Response" and are to be used to respond to generic Data Call-Ins issued as part of EPA's Registration Review program under the Federal Insecticide, Fungicide, and Rodenticide Act.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency. You may provide additional information that does not fit on the form in a signed letter that accompanies this response. For example, you may wish to report that your product has already been transferred to another company or that the product has already been voluntarily cancelled.

The respondent burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This is a mandatory collection under 40 CFR 158. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 2070-0174. Please send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information Engagement Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Item #	DATA CALL-IN RESPONSE Information
1	This item completed by the Agency provides identifying information for the company subject to the Data Call-In.
2	This item completed by the Agency identifies the case number, case name, EPA chemical number and chemical name.
3	This item completed by the Agency identifies the type of Data Call-In. The date of issuance is date stamped. Note the unique identification number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.
4	This item completed by the Agency identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note: For required studies for which no guideline exists (i.e., "special studies), registrants are generally required to submit a protocol for EPA review prior to initiating the study.
5	This item completed by the Agency identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies. If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Generic Requirements Status and Registrant's Response Forms and Instructions Form.

Item #	DATA CALL-IN RESPONSE Information
6	This item completed by the Agency identifies the code associated with the use pattern of the pesticide. A brief description of each code follows: A Terrestrial food B Terrestrial feed C Terrestrial non-food D Aquatic food E Aquatic non-food outdoor F Aquatic non-food industrial G Aquatic non-food residential H Greenhouse food I Greenhouse non-food crop J Forestry K Residential L Indoor food M Indoor non-food N Indoor medical O Indoor residential P Aquatic non-food crop Q Residential outdoor R Agricultural premises and equipment S Food handling/storage establishments, premises, & equipment T Commercial, institutional & industrial premises, & equipment U Residential and public access premises V Medical premises and equipment W Human drinking water systems X Materials preservatives Y Industrial processes and water systems – once through Z Industrial processes and water systems – not once through AA Antifouling coatings BB Wood preservatives CC Swimming pools DD Aquatic areas EE Indoor use FF High exposure antimicrobial GG Low exposure antimicrobial HH Occupational use conventional chemical II Residential use conventional chemical

7	This item completed by the Agency identifies the code assigned to the substance that must be used for testing. A brief description of each code follows: MP: Manufacturing-Use Product **EUP:** End-Use Product **MP:** Manufacturing-Use Product **MP/TGAI:** Manufacturing-Use Product and Technical Grade Active Ingredient **PAI:** Pure Active Ingredient **PAI/M:** Pure Active Ingredient and Metabolites **PAI/PAIRA:** Pure Active Ingredient or Pure Active Ingredient Radiolabeled **PAIRA:** Pure Active Ingredient Radiolabeled **PAIRA/M:** Pure Active Ingredient Radiolabeled and Metabolites **PAIRA/PM:** Pure Active Ingredient Radiolabeled and Plant Metabolites **TEP:**Typical End-Use Product, Percent Active Ingredient Specified **TEP__%:** Typical End-Use Product, Percent Active Ingredient Specified **TEP/MET:** Typical End-Use Product and Metabolites **TEP/PAI/M:** Typical End-Use Product or Pure Active Ingredient and Metabolites **TGAI:**Technical Grade Active Ingredient **TGAI/PAIRA:** Technical Grade Active Ingredient or Pure Active Ingredient Radiolabeled **TGAI/TEP:** Technical Grade Active Ingredient or Typical End-Use Product **MET:** Metabolites **IMP:** Impurities **DEGR:** Degradates
8	This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5. The time frame runs from the date of your receipt of the Data Call-In notice.

Item #	DATA CALL-IN RESPONSE Information
9	Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options. 1. **Developing Data:** I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above. 2. **Agreement to Cost Share:** I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice. 3. **Offer to Cost Share:** I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well. 4. **Submitting Existing Data:** I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response. 5. **Upgrading a Study:** I will submit or cite by the specified due date, data to-upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By- indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade. 6. **Citing a Study:** I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study. 7. **Deleting Uses:** I am attaching an application to amend my product’s (or products’) labeling to delete the uses for which the data are required. 8. **Low Volume/Minor Use Waiver Request:** I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that unless the Agency provides a written response waiving the requirement to submit data, the data remain required and are to be submitted according to the timelines specified in the Data Call-In Notice. 9. **Request for Waiver of Data:** I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that unless the Agency provides a written response waiving the requirement to submit data, the data remain required and are to be submitted according to the timelines specified in the Data Call-In Notice.

Attachment 4. List of All Registrants Sent this Data Call-In Notice

United States Environmental Protection Agency
Washington D.C. 20460

OMB Control No.
2070-0174

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 7203 - Clomazone

DCI Number: GDCI-125401-5627

Co. Nr.	Company Name	Agent For Company	Address	City	State	Zip
93653	ZSCHEM USA, INC.		4110 136TH STREET CT., NW	GIG HARBOR	Washington	98332

Attachment 5. Additional Documents and Information

LINKS TO FORMS:

The pesticide registration forms that are listed below can be found at:
http://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtai

Link to Confidential Statement of Formula and Instructions (Form # 8570-4):
http://www.epa.gov/sites/production/files/2013-07/documents/8570-4_0.pdf

Certification of Attempt to Enter Into an Agreement With Registrants for Development of Data (Form # 8570-32):
http://www.epa.gov/sites/production/files/2015-10/documents/8570-32.pdf

Certification With Respect to Citation of Data (Form # 8570-34):
http://www.epa.gov/sites/production/files/2013-08/documents/8570-34.pdf

ATTENTION DCI RESPONDENTS:

The supporting statement for the Information Collection Request (ICR) covering this DCI request is entitled
"Pesticides Data Call-In Program" (OMB No. 2070-0174; EPA No. 2288).
For more information about the Agency's burden estimates, please go to the following RegInfo.gov website produced by the office of Management and Budget (OMB):
http://www.reginfo.gov/public/do/PRAMain .

From this site location, under the "Information Collection Review" heading, submit a search by the agency name, or, in the blue bar area at top right of the page, select "ICR" and in the search window nearby type the OMB control number (2070-0174), then click on the "Go" button at the right of the search window.

Specifically the ICR associated with the DCI request is located at:
http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0174 .