TSCA Section 4(a)(2) Test Order for C.I Pigment Violet 29

Summary Information:

Order Name: TSCA Section 4(a)(2) Test Order for C.I. Pigment Violet 29
Company Subject to this Order: Sun Chemical Corporation
Order Effective Date: 5 days after signature date

Chemical Substance included in this Order:

Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone; C.I. Pigment Violet 29; 81-33-4[1]

Legal Requirements with Deadlines:

A. Initial Response; Deadline for Order Recipient's Initial Response (the recipient must choose one of the five responses below):

1) If the Initial Response is to Develop the Information, the Deadline to Inform EPA is **5 days after effective date.**

2) If the Initial Response is to Join a Consortium, the Deadline to Inform EPA is **5 days after effective date.** The deadline for Consortium's Initial Response is **10 days after effective date.**

3) If the Initial Response is to Request an Exemption from Testing, the Deadline to Request an Exemption is **5 days after effective date.**

4) If the Initial Response is Claiming that You Are Not Subject to the Order, the Deadline to Inform EPA is **5 days after effective date.**

5) If the Initial Response is to Cease Manufacture[2] of PV29, the Deadline to Cease Manufacture is **5 days after effective date.**

B. If the Initial Response was to Develop Information by an Order Recipient or via a Consortium:

1) the Deadline for Submission of the Study Plan(s) for EPA review is **15 days from effective date of order.**

2) the Deadline to submit the final EPA-approved Study Plan(s) and Initiate Testing is on or before **30 days from effective date of order.**

3) Deadlines for Submission of Final Test Reports for each Required Test are:

[1] For purposes of this order, this chemical substance will be referred to as PV29.
[2] For purposes of this order, manufacture includes import. See TSCA section 3(9).

a. Water Solubility: **90 days from effective date of order**
b. Octanol Solubility: **90 days from effective date of order**
c. Particulates Not Otherwise Regulated, Respirable: **120 days from effective date of order**

Order Recipients (Manufacturers (including importers) subject to this test order):

Company Name: Sun Chemical Corporation
Address: [redacted]

Contact Person: [redacted]
E-mail Address: [redacted]
Phone Number: [redacted]

Company Name: BASF Colors & Effects USA
Address: [redacted]

Contact Person: [redacted]
E-mail Address: [redacted]
Phone Number: [redacted]

This Order requires you and the other above-named manufacturer(s) of PV29 to develop and submit certain information for PV29, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "the EPA" or "the Agency").

Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of Section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614. Any person who violates TSCA shall be liable to the United States for penalties in accordance with Section 16 of TSCA, 15 U.S.C. § 2615.

This Order was sent to you via email and courier service and will be effective 5 calendar days after the signatory date of this Order. The Order and information supporting its requirements are available to the public in Docket Number EPA-HQ-OPPT-2020-0070 at www.regulations.gov. Each company subject to this Order will receive an email containing their unique Order ID number.

To prevent duplicative testing, the Agency encourages those companies subject to the same testing requirements for the same chemical(s) to form a consortium. By doing so, unnecessary, duplicative testing will be prevented, thereby reducing animal testing, and minimizing the total cost of testing. To facilitate the formation of consortia, this Order includes a table which lists the recipients of this Order; each listed company manufactures PV29.

If you know of another company that is not listed but should be subject to this Order because it manufactures PV29 as of the effective date, you are encouraged to inform the EPA as soon as possible so that the cost of testing can be equitably shared.

I. Purpose

The purpose of issuing this Order is to require manufacturers to develop and submit new information on PV29 (see Enclosure A) for the EPA to perform a risk evaluation under Section 6(b) of TSCA.

II. Statement of Need

Uncertainties were identified by the EPA and members of the Science Advisory Committee on Chemicals (SACC) for PV29 regarding reasonably available information characterizing PV29's solubility and occupational worker inhalation exposure. These uncertainties have resulted in the EPA requiring testing of PV29 to develop new information in order for the EPA to increase certainty in the final risk evaluation of PV29 under TSCA section 6(b). The basis for requiring the development of new information by this Order is described below. This statement of need includes 1) the need for the new information; 2) how information reasonably available to the Administrator was used to inform the decision to require new information; and 3) why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement.

1) *The need for the new information.* Information is needed to address uncertainties raised by the EPA's scientists and the TSCA SACC regarding PV29's water and octanol solubility studies submitted by European chemical companies (see EPA-HQ-OPPT-2018-0604-0036). A log Kow estimation was provided for PV29 in one of the studies along with a characterization of other physical-chemical properties. The EPA found this study unacceptable because log P (or log Kow) is not a relevant property for an insoluble chemical such as PV29. For an insoluble chemical, the octanol and water solubility should be considered separately to give a useful indication of its bioavailability. Furthermore, the study authors did not strictly follow the OECD 105 guideline (flask method) nor did they explain the rationale for deviations from the guideline.

Currently, numerous conclusions in the draft risk evaluation regarding potential exposures to human health and the environment are based on the low solubility of PV29. However, without a high-quality experimental estimate of water and octanol solubility data, the EPA cannot dismiss the potential for PV29 to absorb and/or bioaccumulate in tissues. The SACC recommended that the EPA improve the risk evaluation with respect to absorption via oral, dermal and inhalation routes. The SACC proposed that the Agency obtain high-quality data for log Kow or fat solubility to solidify the argument that PV29 is not bioavailable or likely to be absorbed into organisms or tissues (see EPA-HQ-OPPT-2018-0604-0088).

Another public comment presented during the June 2019 SACC meeting (EPA-HQ-OPPT-2018-0604-0088) indicated PV29 exhibits low insolubility in all solvents at room temperature except 96% sulfuric acid. This would support the EPA's position in the draft risk evaluation that absorption of PV29 via oral, dermal and inhalation routes would be negligible.

The EPA requires follow-up testing on water and octanol solubility with specific enhancements to accommodate the known physical chemical properties of PV29. The Agency hypothesizes that the results will confirm the preliminary conclusion of low water and octanol solubility for PV29. These data would address the specific comment from the SACC, which recommended that the Agency obtain additional data to better characterize the solubility of PV29 in order to support the numerous conclusions in the draft risk evaluation regarding potential exposures to human health and the environment that are based on the low solubility of the chemical.

Additionally, information is needed to address uncertainties raised by the EPA's scientists and the SACC regarding workplace air concentrations of PV29 resulting from PV29 production and use in the sole manufacturing facility in the U.S. (Bushy Park, S.C.) in order to better characterize the occupational exposures of PV29. The draft risk evaluation of PV29 relied on particle size information to estimate potential worker exposure to respirable dust. It used single point estimates, provided by the Color Pigments Manufacturers' Association (CPMA), of the total air concentration results associated with PV29 production activities. To validate the reliability of the submitted single point data, after the June SACC, the EPA requested additional characterization of the workplace air concentration, including a particle size distribution. On November 7, 2019, Sun Chemical provided, via CPMA, additional workplace air concentration data, as well as particle size distribution data. This data indicates that the mean weight diameter of the particles is 43 nanometers (nm), or 1000 times smaller, than the particle size reported in the BASF study report upon which the EPA had based its particle size estimate in the draft risk evaluation (EPA-HQ-OPPT-2018-0604-0036). Two additional clarification emails were sent from CPMA on November 19, 2019 and January 6, 2020. These clarifications provided by Sun Chemical explained that PV29 can be present as a particle as well as an agglomerate, which results in a range of potential particle diameters. These explanations did not address uncertainties regarding the potential for workers to be exposed to these finer particles as respirable dust.

Particle size data is integral to the EPA's assumptions about the potential risks of occupational exposure to PV29 dust during manufacturing, processing, and downstream use in the draft risk evaluation. However, the lack of information on what portion of the workplace air borne dust is respirable creates uncertainties about the validity of the preliminary determination that risks are not expected for workers at the manufacturing site.

2) *How information reasonably available to the Administrator was used to inform the decision to require new information.* The Agency has conducted a literature review, collected reasonably available information, and obtained information from European chemical companies. The reasonably available information about solubility of PV29 in water and octanol and PV29's occupational worker inhalation exposure has significant uncertainties, as identified by the EPA scientists and the SACC. The uncertainties in regard to water and octanol solubility studies are listed below:

a. The water and octanol solubility studies received as a single study report from BASF are presented in summary format and do not represent a full study report with enough details about the study methodology.
b. The choice of study methodology is not explained or justified in the studies.
c. The analytical methods are insufficiently justified in the studies. The UV/vis method may not be sufficiently sensitive, given that there are potentially more

sensitive analytical methods (e.g., mass spectrometry). Adequate justification for this technique should have been provided.

d. Chemical purity was not definitively reported, but rather it was described as a range and impurities were not discussed. In addition, study authors did not describe the sample preparation or discuss the pulverization process as recommended in the guideline.
e. The limit of detection, reported to be 0.07 mg/L in the octanol solubility test and undescribed in the water solubility test, is inconsistent with reported water solubility values in the results as low as 0.006 mg/L. This is an order of magnitude discrepancy that adds to the uncertainty in the reported results.
f. Use of filtration for the complete removal of undissolved solids is not justified and a determination that no undissolved particles remained in the test material was not reported. The method reported in the study report may not be enough to ensure that particles were completely removed. Furthermore, the decision to not use centrifugation was not explained.
g. The study reports contain no discussion about how saturation conditions of the water and octanol were achieved.
h. Flask method requires the reporting of pH throughout the test; pH in the test was reported in the study report, but no justification was presented for using a pH of 6.0. Although this is not a specific recommendation in the guideline, a justification would serve to reduce uncertainties as discussed in the SACC report regarding solubility as a function of pH.

The uncertainties in regard to PV29's occupational worker inhalation exposure include:

a. The background information describing the sampling strategy lacks necessary detail (e.g., how samples were taken, how employees were chosen, what work they were doing, and why the samples were taken).
b. There are too few sample results, mainly from one day, and only one work shift. This is far less than the number of samples needed to be able to assess worker (~10-12 samples) and occupational non-user exposures (~6-10 samples)[3].
c. It is not clear if these measurements were taken during the handling of PV29 or solids other than PV29.
d. The sample collection and analysis method used (NIOSH 0500) is not the correct method. This method should be used for general nuisance dust sampling. NIOSH 0500 is not the correct method for assessing respirable dust (particle size ranges below 100 microns) which is needed to characterize worker occupational exposures at Sun Chemical's Bushy Park facility.

As a result of the uncertainties identified regarding the solubility of PV29 and occupational worker inhalation exposure, and considering the critical importance of such information to the overall risk conclusions for human health and the environment in the draft risk evaluation for

[3] Ignacio J. S. & Bullock W. H. (Editors). *A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed.* AIHA Press. 2006.

PV29, the Agency needs additional testing of water and octanol solubility (with specific modifications) and monitoring of worker occupational inhalation exposure to be carried out.

3) *Why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement.* The EPA is using its order authority under TSCA section 4(a)(2) to meet its statutory obligations under TSCA section 6(b).. Use of this TSCA section 4(a)(2) authority will obtain the needed information more quickly than if the EPA were to issue a section 4 rulemaking or enforceable consent agreement.

III. The Authorities for this Order and Information Collection

The Agency is issuing this Order under the authority of TSCA Section 4(a)(2) to require PV29 manufacturers to develop and submit information. The Order applies to only two companies and therefore is not subject to the information collection requirements enforced by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

IV. Information Required by this Order

This section applies to Options V.A.1. and V.A.3. of this order.

IV.A. Required Tests

This Order requires the testing of PV29. The test substance must have a purity of 99% or greater. The tests required hy this Order are listed in Table 1 in the column titled "Test Names."

Table 1: Required Tests, Protocols/Methodologies

Test Names	Protocols/ Methodologies
Water Solubility	OECD 105 with EPA modifications
Octanol Solubility	OECD 105 with EPA modifications
Particulates Not Otherwise Regulated, Respirable	NIOSH 0600

IV.B. Required Protocols/ Methodologies and Study Plans

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. You may not modify the required protocols/methodologies unless you first consult with the Agency and obtain Agency approval of any planned modification.

You must also request the EPA's approval if you wish to use a protocol/methodology not listed in this Order. You must submit a detailed description of the protocol/methodology you are requesting to use and your reason(s) for wishing to use it. Also indicate whether the requested protocol/methodology has been scientifically validated or whether its deviations from the

protocol/methodology required by this Order are such that they could alter the validity of the study. If the EPA has concerns about the requested protocol/methodology or any of your requested modifications of the required protocol/methodology, the Agency will so inform you through CDX with a rejection status of the study plan and rationale for the rejection which will include concerns that must be addressed before the EPA will approve your request. Testing to be conducted according to a requested protocol/methodology or requested modifications must not be initiated until the EPA approves the requested protocol/methodology and any requested modifications.

The EPA has identified the protocols/methodologies that must be followed to perform each required test. They are listed in Table 1 and include protocols/methodologies (also known as test guidelines) from OECD. The protocols/methodologies are available via the Internet. When OECD protocols are required by the EPA, your final test report must be submitted using the appropriate OECD harmonized template format which can be located at https://www.oecd.org/ehs/templates/harmonised-templates.htm.

If a protocol/methodology listed in Table 1 is noted to be "with EPA modifications," the Agency has attached a copy of the modified protocol/methodology to this Order.

Within 15 calendar days of the effective date of this Order, you, as the developer of information, or a person designated by a consortium must submit Study Plans to the EPA for each test to be conducted. The Study Plan must contain the following information:

1) The Test Order number.
2) Name of test to be covered by the test protocol.
3) The name of the protocol/methodology identified by the Order which you intend to follow, or a copy of the identified protocol/methodology with your modifications that the EPA has approved, or a copy of the protocol/methodology you requested to use which the EPA has approved. If approval for the identified protocol/methodology with your modifications or the use of a protocol/methodology you requested to use is not granted by the EPA in time to be included in the study plan, they must be referenced as "submitted and pending approval" and submitted later, once approved, in final form in an amended study plan.
4) The rationale for any modification of the identified protocol/methodology that the EPA has approved or the use of a requested protocol/methodology that the EPA has approved. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant protocols/methodologies.
5) The identity and supporting data on the chemical substance to be tested including physical constants, spectral data, chemical analysis, and stability under test and storage conditions required by the protocol.
6) The rationale for any combination of protocols/methodologies; the rationale for species/strain selection, dose selection (and supporting data), and route or method of exposure; description of diet to be used and its source (including nutrients and contaminants and their concentration); for in vitro test systems, a description of culture

medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

7) The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.
8) The name, mailing address, phone numbers, and e-mail address of the appropriate individual(s) for the EPA to contact concerning the planned test.
9) The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol is in compliance with appropriate quality assurance and quality control procedures.

If you are not aware of a need to request a modification of an identified protocol/ methodology or a need to request the use of a different protocol/methodology until after the test plan has been submitted or until testing is underway, the test sponsor may submit the request at a later time, but must still meet the deadline set out in Table 2 for the relevant test or request an extension for a study plan, if needed.

For purposes of satisfying the requirements of this Order, you are required to follow the Good Laboratory Practice (GLP) standards described in 40 CFR part 792 as specified in the Code of Federal Regulations on the day this order is signed. You are also required to provide a statement of compliance with these standards when submitting information to the EPA pursuant to this Order.

In selecting the identified protocols/methodologies, the EPA considered certain aspects of testing pursuant to TSCA Section 4(h)(1) and TSCA Section 4(h) (see Enclosure B, "Considerations in Selecting Protocols/Methodologies and Reducing Vertebrate Testing").

IV.C. Deadlines for Submission of Test Reports

If you choose to respond to the Order by developing the required information, you must submit the information developed by each test to the EPA no later than the deadlines indicated on pages 1-2 of this Order and in Table 1 in Unit IV.A.

Pursuant to TSCA Section 4(b)(1)(C), the Agency considers these deadlines to be reasonable because they are based on estimates the EPA obtained from nine testing laboratories for the time needed by the laboratories to complete tests according to the required test protocols and to analyze results. Additionally, the EPA has been in communication with companies subject to this Order regarding the required testing and study plans.

IV.D. Extension of Deadlines

If you believe you cannot submit the required information to the Agency by the deadlines specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through the EPA's CDX portal as soon as you know you may

need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis. Normally, extensions will be granted only in cases of extraordinary testing problems beyond the expectation or control of the manufacturer(s). Extensions will not be considered if the request for the extension is not made in a timely manner, i.e. as soon as it is suspected that the deadline cannot be met. In no event shall an extension request be considered if it is submitted on or after the test submission deadline.

IV.E. Fees for Submitting

See 40 CFR § 700.45 for information concerning, when applicable, the requirement to pay a fee when submitting information under TSCA Section 4.

V. Responding to the Order

Within calendar 5 days of the effective date of this Order, you are required to respond to the Order through the EPA's CDX portal informing the Agency which of five options you have chosen to comply with the Order. **Follow the instructions in Enclosure E for its submission to the EPA.**

You must comply with this Order by the deadlines applicable to you on pages 1 and 2 of this Order (and Table 1).

V.A. Five Options for Responding to the Order

You have five options from which to choose to comply with the Order.

V.A.1. Option 1: Develop the Information

If you choose to develop information by testing in response to this Order, you must state that in your Initial Response to the EPA in the CDX portal. You must indicate every test you intend to develop information for to comply with the Order. Information on the required tests, required protocols/methodologies, and deadlines for submission of test reports is presented in Units IV.A through C.

Once the EPA has completed its review of the submitted test reports and accepts the information as complying with your testing obligations under the Order, the EPA will notify you of your compliance through CDX correspondence.

In considering whether to choose this option to comply with the Order, you should be aware that if other companies, subject to the same Order for the same chemical(s), requested exemptions from testing and those requests were granted due to your intention to test, those companies are responsible for reimbursing you for their share of the final tests costs. See Unit V.A.4. (Request an Exemption) and Enclosure D (Cost Sharing).

V.A.2. Option 2: Form a Consortium or Offer to Join a Consortium

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other participants of the consortium) must individually submit an Initial Response to the EPA through the CDX portal within 5 days of the effective date of this Order, stating your intention to participate in a testing consortium for each specific chemical and specific test.

The designated lead for the consortium must then submit an Initial Response to the EPA through CDX for the consortium within 10 days of the effective date of this Order. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by listing each specific test. The letter must also include contact information for the designated lead of the consortium, who must be domiciled in the U.S. The designated lead for the consortium must submit the Initial Response and required information on behalf of the consortium and its member companies by the deadlines listed on pages 1 and 2 (and Table 2 in Unit V.B.). Submissions made on behalf of the consortium must be in accordance with instructions in Enclosure E. When the results of the last required test of the Order is submitted and the EPA accepts the information as complying with the Order, the EPA will provide notification of compliance with the Order to the Order Recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with the Order and is individually liable in the event of any failure to comply with the Order. If the consortium fails to submit the information or meet the requirements of the Order, you will be in violation of the Order unless you submit the required information.

The Agency has provided a list describing each of the non-confidential manufacturers that have received this Order. This table can be used to help Order Recipients identify other Order Recipients subject to the same testing requirements for the same chemical with whom they could form a consortium to jointly develop information and share the cost of testing. Information on cost sharing is provided in Enclosure D.

V.A.3. Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA 4(c)(1)).

The Administrator will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1) Information on an equivalent chemical has been submitted in accordance with a rule, Order, or consent agreement under TSCA Section 4(a), or is being developed in accordance with such rule, Order, or consent agreement, and

2) Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, Order, or consent agreement.

See Enclosure C for what the EPA considers satisfactory equivalence data.

As explained in Appendix E on Cost Sharing, persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of the EPA. However, if agreement cannot be reached on the amount or method of reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA 4(c)(3)(A). An exemption request must be submitted through the CDX portal and contain the following:

1) The Test Order number, the chemical identity, and the CAS No. of the test substance on which the application is based.
2) The specific testing requirement(s) from which an exemption is sought.
3) The basis for the exemption request must be provided when, for example "another company(ies) has submitted the required information for an equivalent chemical pursuant to a TSCA Section 4(a) rule, order, or consent agreement." Your request must identify the company(ies).
4) The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.
5) The equivalence data specified in Enclosure C.
6) The name, mailing address, telephone number, and e-mail address of applicant.
7) The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.
8) A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:
"I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

The EPA's granting of an exemption from testing is conditional upon the proper completion of the required tests. Pursuant to TSCA Section 4(c)(4)(B), if any exemption is granted on the basis that a person or consortium has submitted or is developing information for a chemical under Section 4(a), and, if later the Agency determines that no such person or consortium (or individual members of the consortium) has complied with that rule, order, or consent agreement, the Agency would, after providing notice through CDX to the person who holds such exemption and an opportunity for a hearing, by order terminate the exemption, and notify in writing such person of the requirements of the order with respect to which such exemption was granted and terminated. That person whose conditional exemption is terminated must, within 10 calendar days of receipt of the EPA's notice terminating the exemption, re-

submit the initial response in accordance with one of Options 1, 2, 4, or 5 of this Unit V.A, including as applicable the information required under Unit IV.B., or be found in violation of this Order (TSCA Section 15(1)). If the exemption is based on testing pursuant to this Order, then the person or consortium and individual member of the consortium that failed in their commitment to complete the required testing would also be found in violation of this Order (TSCA Section 15(1)).

V.A.4. Option 4: Claim that You Are Not Subject to the Order

You may claim that you are not subject to this Order if you do not manufacture the chemical identified on page 1 of this Order or you believe the Order was otherwise sent to you in error. An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your Initial Response in the CDX portal so that the EPA can evaluate the claim. If the EPA cannot verify your claim, the original requirements and deadlines in this Order remain. If your claim is approved, the EPA will notify you that you are not subject to this Order through CDX correspondence.

V.A.5. Option 5: Cease the Manufacture of the Chemical

If, within 90 days of the effective date of the Order, you cease the manufacture of the chemical(s) for which you are required by this Order to submit information, you may satisfy the Order by informing the Agency in your Initial Response in the CDX portal that you have ceased manufacture. Your letter must include the following certifying statement: "I certify that the statements made in this letter 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." The letter must be signed by an authorized representative of the company and include the representative's title/position in the company.

If you choose to respond to the Order by ceasing manufacture, you may not resume manufacture of the chemical until the sunset date has been reached. A standard sunset date is calculated according to TSCA 4(c)(3) by adding 5 years to the receipt date of the last test report submitted under this Order and can be located on the Agency's website here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/sunset-dates-chemicals-subject-final-tsca-Section-4-test.

V.B. Schedule for Responding to the Order

Table 2 presents the deadlines in chronological order for completing the required actions under this Order and will apply to you based on the response option you choose. Response options are discussed in Unit V.A.1. through V.A.5. of this Order.

Table 2: Deadlines for Responding to the Order Depending on Chosen Response Option

Deadline	Option 1: Develop the Information by Testing	Option 2: Form or Join a Consortium
5 days after effective date of order	Submit Initial Response	Submit Initial Response
10 days after effective date of order	N/A	Designated lead of consortium submits Initial Consortium Response
15 days after effective date order	Submit study plan for tests to be conducted	Designated lead of consortium submits study plan for tests to be conducted
30 days after effective date of order	Initiate tests to be conducted	Initiate tests to be conducted
90 days after effective date of order	Submit test report for water and octanol solubility	Designated lead of consortium submits final test report for water and octanol solubility
120 days after effective date of order	Submit test report for particulates not otherwise regulated, respirable	Designated lead of consortium submits final test report for particulates not otherwise regulated, respirable

V.C. Confidentiality

Under TSCA Section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which testing is required under Section 4 or notification is required under Section 5. However, Section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for confidential treatment.

Information submitted under TSCA that you wish to have the EPA protect as confidential business information (CBI) must he clearly identified as such when submitted. When claiming and certifying information to be CBI, you must state the following:

> "I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;
(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA 14(c)(2). Guidance for substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission .

Failure to follow the statutory requirements for asserting a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA Section 14 is approved by the EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if the submitter wishes to maintain the CBI claim. In certain cases, the EPA may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA Section 14(d), the EPA may disclose information approved as CBI to appropriate persons including Federal and State authorities, health and environmental professionals, poison control centers, emergency responders, and other appropriate persons.

VI. Consequences of Failure to Comply with this Order

Failure to comply with any of the requirements in this Order is a violation of TSCA and could subject you to civil and/or criminal penalties under TSCA as modified by the Inflationary Adjustment Act. Each day a violation continues constitutes a separate violation. TSCA Section 16.

VII. Signature

Under the authority in TSCA Section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order, to take effect on the date of my signature.

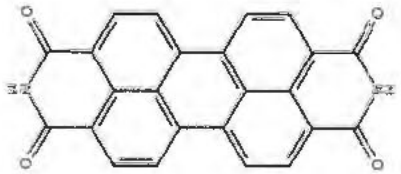
Date: FEB 28 2020

Signature: 

Andrew R. Wheeler, Administrator

U.S. Environmental Protection Agency

Chemical Names and Structures for Acronyms used in this Order

Acronym Used in Order	Acronym Stands for	Chemical Name CASRN	Chemical Structure
PV29	C.I. Pigment Violet 29	Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone 81-33-4	

Enclosure B

Considerations in Reducing Vertebrate Testing

Consistent with the mandate under TSCA Section 4(h) to reduce and replace the use of vertebrate animals in chemical testing, the tests required under the Order do not involve any vertebrate testing.

The EPA encourages exemption requests and the formation of consortia to avoid the possibility of duplicative testing. When several companies have the same testing responsibilities, forming a consortium to administer a single testing program should save its members time and resources as well as avoid unnecessary, duplicative testing, thereby reducing the number of animals needed for testing. This is also accomplished when an Order Recipient requests an exemption from testing when it is known that another Order Recipient or consortium plans to develop the information.

Enclosure C

Equivalence Data

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent". Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR 790.3.

If testing under TSCA Section 4(a) is required of two test substances which are forms of the same chemical, the EPA may consider them equivalent and grant an exemption from testing to the manufacturer of one substance if the information required under TSCA Section 4(a) is submitted or is being developed on the other, and the manufacturer submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in the test order which may bear on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured prior to use or distribution in commerce by the applicant.

Cost Sharing

Not every person subject to this Order must individually conduct testing. The EPA encourages all recipients of an Order that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in the Order. They are forming or joining a consortium, discussed in Unit V.A.2, or requesting an exemption, discussed in Unit V.A.3.

Persons that form or join a consortium will most likely sign an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate. The details of the agreement would be decided by the companies involved.

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is to be negotiated between the companies involved. The EPA has promulgated regulations that explain how the EPA views fair and equitable reimbursement in the context of Section 4(a) test rules. In general, those regulations (40 CFR 791.40 through 791.52) provide that each person's share of the test costs shall be in proportion to its share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations are not binding for a Section 4 test order, you may wish to consider them as you decide how to share the costs.

If persons subject to a test order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA 4(c)(3)(A).

Information collected by the Agency and Recordkeeping

Test Reports

1. Each test report submitted to the EPA must include the following:
    a. A title page including the following information:
        - The title of the study, including identification of the substance(s) tested and the required test addressed by the study.
        - The author(s) of the study.
        - The date the study was completed.
        - If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.
        - If the report is a commentary on or supplement to another previously submitted report, full identification of the other report with which it should be associated in review.

    b. The final test report and underlying data.
    c. If the report is claimed to be CBI, the report must be accompanied by a signed and dated document containing the appropriate statement(s) regarding confidentiality in Unit V.B. and a sanitized version of the report only removing the CBI content must be submitted.
    d. A statement of compliance with respect to GLP standards as set forth in 40 CFR part 792 and applicable to this Order.

Submission Instructions

The Initial Response, study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to the EPA as follows:

1. Submit to the EPA's Central Data Exchange (CDX) system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is http:www.epa.gov/cdx/ which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting Section 4 Order information. To access the instructions, select "Report electronically" on the EPA Internet homepage at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data.

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

Recordkeeping

Retain copies of all information documenting your compliance with this Order for ten years. This includes your Initial Response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.