UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 15, 2017

Mr. Martijn Schoonenberg
SCGBV Weesp - Legal
Sun Chemical Group Coöperatief U.A.
Leeuwenveldseweg 3
1382 LV Weesp
The Netherlands

Email: [redacted]

Dear Mr. Schoonenberg:

I am requesting your cooperation to provide certain scientific studies on Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone (CASRN 81-33-4), also known as Pigment Violet 29, to the U.S. Environmental Protection Agency (EPA). Under the authority of section 6 of the Toxic Substances Control Act (TSCA), EPA is conducting a risk evaluation of Pigment Violet 29 and requires the full study reports to ensure the adequacy of data used to assess the potential unreasonable risk this chemical may present to human health and the environment.

EPA is aware from the European Chemicals Agency (ECHA) database of the registration dossier under the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) that there are study reports of certain studies on Pigment Violet 29, possibly in the possession of Sun Chemical Group Coöperatief U.A., The Netherlands. EPA is requesting cooperation from Sun Chemical Group Coöperatief U.A. to obtain full study reports because Sun Chemical Corporation is a manufacturer of Pigment Violet 29 in the United States according to EPA's Chemical Data Reporting information and comments to the Pigment Violet 29 Docket (EPA-HQ-OPPT-2016-0725).

In comments submitted to the Pigment Violet 29 Docket (EPA-HQ-OPPT-2016-0725-0006), and during a meeting with the EPA on February 13th, 2017, members of the Color Pigments Manufacturers Association (CPMA) questioned the necessity of providing the EPA with full study reports. EPA acknowledges CPMA's comments; however, summary study results do not provide sufficient information upon which the hazard(s) and risk(s) from manufacture, distribution in commerce, processing, use, or disposal of this substance or any combination of such activities on health or the environment can reasonably be determined or predicted. As such, EPA is requesting the full study reports of endpoints as deemed necessary.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA, was signed into law. The new law includes statutory deadlines for actions related to conducting risk evaluation of existing chemicals. In order to meet the statutory deadline, set forth in TSCA § 6(b)(4)(G)(i) for completion of the risk evaluation, the EPA is seeking to obtain all known scientific data as soon as possible. The current step in risk evaluation of Pigment Violet 29 is the "Problem Formulation" phase which will finish in December 2017.

The thoroughness of EPAs risk evaluation depends on timely access to full study reports for Pigment Violet 29. I therefore ask that you assist EPA by providing the full study reports for each of the studies known to have been submitted as part of the REACH Dossier, identified in the Table 1 of the Enclosure. EPA's review of the robust summaries for the aforementioned studies suggest to EPA that results are negative and/or that hazards of Pigment Violet 29 are low. However, EPA needs to review the full study reports to confirm the information in the summaries meets the scientific standards set forth in TSCA section 26.

Please see the Enclosure for our information request and more details. If you have any questions, please contact me or Hannah Braun of my staff at +[redacted] or at [redacted].

Sincerely,

Maria J. Doa, Ph.D.
Director
Chemical Control Division

Enclosure

cc: Dr. Robert Mott
Email: [redacted]

ENCLOSURE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY INFORMATION REQUEST

The U.S. Environmental Protection Agency ("EPA" or "Agency") is conducting a risk evaluation to determine the potential risk to human health and the environment of Pigment Violet 29.

TSCA § 6(b)(4) requires U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Pigment Violet 29 was one of these chemicals. EPA requests your cooperation in providing information to support the risk evaluation.

To help EPA evaluate the potential unreasonable risk of Pigment Violet 29 to human health and the environment, EPA requests that you provide full and complete information in response to the tests set forth in this enclosure. **We respectfully request that you provide the information within fifteen (15) calendar days of receipt of this request.**

All submissions should be addressed to:

Maria J. Doa, Ph.D.
Director, Chemical Control Division
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
USEPA/OCSPP/OPPT/CCD
1200 Pennsylvania Avenue, N.W., 7401M
Washington, DC 20460 [redacted]
Email: [redacted]

Additionally, we respectfully request that within five (5) calendar days of receipt of this request, you kindly provide notice as to whether or not you will submit all of the information requested. Please notify Hannah Braun regarding your decision about whether or not you will submit all of the information requested at braun.hannah@epa.gov.

EPA is requesting that you provide this information voluntarily. Data/full study reports voluntarily provided (as per Table 1 of the Enclosure) in response to this request may be claimed as Confidential Business Information (CBI), and information covered by such a claim will not be disclosed by EPA except to the extent, and by means of the procedures, set forth in EPA confidentiality regulations at 40 Code of Federal Regulations (CFR) Part 2, Subpart B. All responses which contain information claimed as CBI must be clearly marked as such. Persons submitting information, any portion of which they believe is entitled to treatment as CBI by EPA, must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

Please read this enclosure carefully and follow the directions provided. Your response is respectfully requested within fifteen (15) calendar days of receipt of this letter. Directions for properly submitting information responsive to this request and for claiming CBI are included in the enclosure. Depending on the information you may provide in response to this request, EPA may follow up with a request for your voluntary submittal of additional information.

EPA requests that the information you submit be verified by, and submitted under an authorized signature by, a responsible corporate officer,[1] with the following certification:

> I certify that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, I certify that the information submitted is, to the best of my knowledge and belief, true, accurate, and complete.

[1] The term "responsible corporate officer," as used herein, means a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation.

As referenced above, requests for confidential treatment of documents must be made when information or access to records is provided and in accordance with the instructions provided below.

INSTRUCTIONS

EPA requests that you kindly try to follow the instructions below in developing and submitting responses to this information request:

A. Respond to Each Request Completely. The U.S. EPA is requesting the full study reports for each test. Test summaries are available to our scientists through the European Chemicals Agency (ECHA), but EPA needs to review the full test for adequacy and quality before relying on the results to make conclusions about the risk of the chemical.

B. Source(s) of Response. Include with each narrative response, the name, position, and title of each person(s) who provided information responsive to the request.

C. Electronic Submittal. You should submit your responses as one or more electronic files on a CD, similar media storage device or attachment in email in a form that allows EPA to readily retrieve and utilize the information using commercially available software. Your electronic files should be accompanied by a letter that identifies the file software and version, file name(s), size(s), date(s), and time(s) of creation. Your electronic files should include any documents you relied on in preparing your responses.

D. Submission of Documents. Label each document submitted with the requested test's title to which it corresponds. Date stamp each document you submit. If anything is deleted from a document produced in response to this request, state the reason for and the subject matter of the deletion.

E. Documents Responsive to More than One Request. If a document you submit is responsive to more than one test, please provide one copy of the document and identify all the test titles, by title, to which it corresponds.

F. Provide the Best Information Available. Unless otherwise specified, we are not requesting that you create new data or information. However, you should provide responses to the best of your ability, even if the information sought was never put down in writing or if the written documents are no longer available. You should seek responsive information from current and former employees and/or agents. If you cannot provide a precise answer to any questions, please approximate and state the reason for your inability to be specific.

G. Unavailability of Records. If you are unable to respond to a request in a detailed and complete manner, or if you are unable to provide any of the information requested, indicate the reason for your inability to do so. If a record(s) responsive to a request is not in your possession, custody, or control and is not available to you through your parent company and you have reason to believe that another person may be able to provide it, state the reasons for your belief and provide the person's name, address, telephone number, and any information available (i.e., author, date, or subject matter) about the record(s).

H. Provide and/or Correct Information on a Continuing Basis. If any records responsive to a request are not known or are not available to you at the time you submitted your response, but later become known or available to you, you should submit the new information as a supplement to your response. If at any time after submission of your response you learn that any portion is or becomes false, incomplete, or misrepresents the facts, you should notify EPA of this fact as soon as possible and provide a corrected response.

I. Indicate Objections to Requests. While you may indicate that you object to certain requests contained in this information request, EPA requests that you provide responsive information notwithstanding those objections.

J. Claims of Privilege. If you claim that an entire document responsive to this information request is a communication for which you assert that a privilege exists, identify the document and provide the basis for asserting the privilege. For any document for which you assert that a privilege exists for a portion of it, provide the portion of the document for which you are not asserting a privilege; identify the portion of the document for which you are asserting the privilege; and provide the basis for such an assertion. Please note that regardless of the assertion of any privilege, any facts contained in the document which are responsive to this information request should be disclosed in your response.

K. Confidential Business Information. You should provide the information requested even though you consider it confidential information or trade secrets. You must assert a business confidentiality claim for part or all of the information requested, as described below and set forth in 40 C.F.R. Part 2, Subpart B. Information covered by such a claim will not be disclosed by EPA except to the extent and only by the procedures set forth in 40 CFR. Part 2, Subpart B. If no confidentiality claim accompanies the information when EPA receives it, the information may be made available to the public by EPA without further notice to you.

If you wish EPA to treat any information or response as "confidential," you must advise EPA and comply with the following procedures. Place on or attach to the information at the time it is submitted to EPA a cover sheet, stamped or typed legend, or other suitable form of notice employing such language as *trade secret, proprietary,* or *company confidential.* You must clearly identify allegedly confidential portions of otherwise non-confidential documents, and you may want to submit these separately to facilitate identification and handling by EPA. EPA may ask you to substantiate each claim of confidential business information by separate letter in accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B.

DEFINITIONS

Please use the following definitions for purposes of responding to the questions set forth below:

A. The term "any," as in "any documents," for example, shall mean "any and all."

B. The term "full study report" shall mean the original report which includes abstract, introduction, methods, results, discussion, conclusion and is signed by the laboratory technician. A full study report is a complete and comprehensive description of the study performed to generate data and information, including deviation(s) from the study.

Table 1: List of Full Study Reports

1. OECD Guideline 401: Acute Oral Toxicity [2, 3]
2. Acute Toxicity: Intraperitoneal [4, 5]
3. Acute Toxicity: Inhalation [6, 7]
4. OECD Guideline 404: Acute Dermal Irritation/Corrosion [8, 9]
5. OECD Guideline 429: Skin Sensitisation: Local Lymph Node Assay [10]
6. OECD Guideline 405: Acute Eye Irritation/Corrosion [11, 12]
7. OECD Guideline 476: *In vitro* Mammalian Cell Gene Mutation Test [13]
8. OECD Guideline 421: Reproduction / Developmental Toxicity Screening Test [14]
9. OECD Guideline 203: Fish, Acute Toxicity Test [15]
10. OECD Guideline 202: Daphnia sp. Acute Immobilisation Test [16]
11. OECD Guideline 221: Lemna sp. Growth Inhibition test [17]
12. OECD Guideline 209: Activated Sludge, Respiration Inhibition Test [18]
13. OECD Guideline 301 F: Ready Biodegradability: Manometric Respirometry Test[19]
14. Bioaccumulation in aquatic sediment[20]
15. Solubility in organic solvents/fat solubility [21]
16. OECD Guideline 102: Melting point/Melting Range [22]

---

[2] OECD Guideline 401: Acute Oral Toxicity, gavage, Sprague-Dawley rats, result: LD50 >10,000 mg/kg bw, 1978.
[3] OECD Guideline 401: Acute Oral Toxicity, gavage, Sprague-Dawley rats, result: LD50 >10,000 mg/kg bw, 1976.
[4] Internal Standard Method, NMRI-Wiga mice, result: LD50 ca. 9,000 mg/kg bw, 1978.
[5] Internal Standard Method, NMRI-Ivanovas mice, result: LD50 ca. 7,000 mg/kg bw, 1976.
[6] Inhalation-risk test (IRT), rat, result: none of the animals died during the exposure period, 1976.
[7] Inhalation-risk test (IRT), rat, result: none of the animals died during the exposure period, 1978.
[8] OECD Guideline 404: Acute Dermal Irritation/Corrosion, Weißer Wiener Rabbits, result: not irritating, 1978.
[9] OECD Guideline 404: Acute Dermal Irritation/Corrosion, Weißer Wiener Rabbits, result: not irritating, 1976.
[10] OECD Guideline 429: Skin Sensitisation: Local Lymph Node Assay, mice, result: not sensitizing, 1999.
[11] OECD Guideline 405: Acute Eye Irritation/Corrosion, Weißer Wiener Rabbits, result: not irritating, 1978.
[12] OECD Guideline 405: Acute Eye Irritation/Corrosion, Rabbits, results: not irritating, 1976.
[13] OECD Guideline 476: *In vitro* Mammalian Cell Gene Mutation Test and EU Method B.17: Mutagenicity - In Vitro Mammalian Cell Gene Mutation Test and EPA OPPTS 870.5300: In vitro Mammalian Cell Gene Mutation Test, Chinese hamster lung fibroblasts (V79), result: negative, 2012.
[14] OECD Guideline 421: Reproduction / Developmental Toxicity Screening Test and OPPTS 870.3550: Reproduction/Developmental Toxicity Screening Test, gavage, Wistar rats, result: NOAEL 1,000 mg/kg bw/day, 2013.
[15] OECD Guideline 203: Fish, Acute Toxicity Test, *Danio rerio*, result: LC50 >5000mg/L, 1988.
[16] OECD Guideline 202: Daphnia sp. Acute Immobilisation Test, *Daphnia magna*, result: EC0 => 100 mg/L, EC100 > 100 mg/L, NOEC => 100 mg/L, 2012.
[17] OECD Guideline 221: Lemna sp. Growth Inhibition test, *Lemna gibba*, result: ErC50 > 100 mg/L, EbC50 > 100 mg/L, 2012.
[18] OECD Guideline 209: Activated Sludge, Respiration Inhibition Test, result: EC20 ca. 1.8 mg/L, EC50 ca. 6.5 mg/L, 1999.
[19] OECD Guideline 301 F: Ready Biodegradability: Manometric Respirometry Test, result: 0-10% degradation, 1999.
[20] BASF Product Safety Datasheet for PALIOGEN® Red K 3580, pg. 10, eight-week bioaccumulation study; http://www2.basf.us/additives/pdfs/Paliogen_Redviolet_K5011.pdf
[21] Solubility in organic solvents/fat solubility, result: < 0.07 mg/L, 2001.
[22] OECD Guideline 102: Melting point/Melting Range, result > 400°C, 2013.