



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


OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Memorandum

DATE: March 21, 2019

SUBJECT: Transmission of Background Materials Previously Claimed as Confidential Business Information (CBI) for the Toxic Substances Control Act's Scientific Advisory Committee on Chemicals (TSCA SACC) Reviewing the Draft Risk Evaluation for C.I. Pigment Violet 29 (PV29)

TO: Steven Knott
Executive Secretary
FIFRA Scientific Advisory Panel Staff
Office of Science Coordination and Policy

FROM: Mary C. Fehrenbacher, 
Acting Director
Risk Assessment Division
Office of Pollution Prevention and Toxics

Transmitted with this memorandum are copies of the 24 study reports which are being made available in the public docket¹ prior to the TSCA SACC expert panel peer review of the *Draft Risk Evaluation for C. I. Pigment Violet 29*. These study reports have been reviewed by the Agency to develop the *Draft Risk Evaluation for C.I. Pigment Violet 29* and were originally claimed in full as confidential business information (CBI) by the data owners. For this reason, these study reports were not originally included in the public docket.

The list of the 24 released study reports is attached and explained in Attachment A: C.I. Pigment Violet 29: List of publicly available study reports. Fifteen study reports are completely released without redactions (see study numbers 1 to 14, and 18, Attachment A), while nine study reports remain partially CBI with certain information redacted (e.g., personal information relating to laboratory personnel, certain company-related information and, in one instance, individual test animal data tables, see study numbers 15-17, 19-24, Attachment A).

Consistent with Agency regulations concerning the review of confidential business information claims located at 40 CFR Part 2, Subpart B, the Agency, in December 2018, requested substantiation of the CBI claims from the affected businesses.

¹ <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0604>

Subsequently these entities provided responses to the substantiation request. In fifteen instances, the CBI claims associated with the study reports were removed in full by the data owners. In nine instances, the CBI claims were reduced in scope. The Agency has made a final determination on the CBI claims and this can be accessed at FOIAonline at <https://foiaonline.gov/foiaonline/action/public/home> and then searching the FOIA request number, EPA-HQ-2019-001853. In all instances, non-CBI versions of the study reports were made available to the Agency and can now be accessed in the public docket.¹ In eight of the nine full study reports containing information determined to be CBI, robust summaries are available in the public docket. For the one study that is not being released in its entirety (study #21, HERO ID 4731542), for which a robust summary is not available, there is a redacted non-CBI version of the study in the public docket. Three additional studies which had no corresponding robust summaries are now publicly available as indicated in Attachment A.

As background information, twenty of these studies were summarized in the European Chemicals Agency (ECHA) registration dossier for C.I. Pigment Violet 29 and were made available in the public docket.² These summaries are referred to as “Robust Summaries” and were used to develop the *Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29* (June 2018).³ EPA compared the information contained in the robust summaries to the information contained in the study reports for accuracy.

Two additional matters should be noted: (1) while the information owners have asserted in some instances a reservation of rights for the use of the materials, no materials contain information claimed to be protected by copyright, and (2) all studies containing CBI (i.e., 9 partially-redacted study reports) have previously been provided without redaction to the SACC Peer Review Panel whose members are cleared for CBI access so that the verification of the ECHA robust summaries and EPA’s use of the data can be considered.

A link is being provided to EPA’s final risk evaluation rule which details the processes under which the PV29 draft risk evaluation was completed.⁴

² <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002>

³ https://www.epa.gov/sites/production/files/2018-06/documents/pv29_problem_formulation_5-31-18.pdf

⁴ [Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act - 82 FR 33726](#)

Attachment A

C.I. Pigment Violet 29: List of Non-Confidential Business Information (CBI) Study Reports¹

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
CBI claim fully withdrawn (Full study report)	1. Summary of toxicological investigations with CAS 81-33-4, 1.5 Eye Irritation Study. HERO ID: 4731519	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/3/?documentUUID=355c6cab-5b7e-417f-b083-4c3a890c339e					
CBI claim fully withdrawn (Full study report)	2. Summary of toxicological investigations with CAS 81-33-4, 2.5 Eye Irritation Study. HERO ID: 4731520	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/3/?documentUUID=123b8854-6e8f-4482-9e03-183d6380fcf8					

¹ The 24 study reports represent the following disciplines: #1-17 Human Health; #18-20 Environmental Hazard; #21-22 Environmental Fate, and #23-24 Physical Chemical properties. Study reports #1-13 and #18 were translated from German.

² ECHA Robust summaries were published to the docket at the following link: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002>

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
CBI claim fully withdrawn (Full study report)	3. Perylimid ³ Testing the acute dermal irritant effects/caustic effects on rabbits. HERO ID: 4731534	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Hoechst Pharma Research Toxicology, Germany. Report No. 84.0228 (OECD- 404 skin irritation;	No ⁴
CBI claim fully withdrawn (Full study report)	4. Perylimid Testing the acute irritant effects/caustic effects on the rabbit eye. HERO ID: 4731524	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Hoechst Pharma Research Toxicology, Germany. Report No. 84.0229 OECD-405; eye irritation)	No
CBI claim fully withdrawn (Full study report)	5. Summary of toxicological investigations with CAS 81-33-4, 1.2 Acute inhalation toxicity with rats. HERO ID 4731525	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=2baa5685-0c63-41a2-88e0-6539146fda83					

³ Perylimid-German name for pigment violet

⁴ Summarized below are the four additional full study reports that were not described in the ECHA database.

- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion
- OECD Guideline 209: Determination of the inhibition of oxygen consumption by activated sludge

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
CBI claim fully withdrawn (Full study report)	6. Summary of toxicological investigations with CAS 81-33-4, 2.2 Acute inhalation toxicity with rats. HERO ID: 4731526	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=2064a5d4-7557-4aed-b389-59bae4eb97d7					
CBI claim fully withdrawn (Full study report)	7. Summary of toxicological investigations with CAS 81-33-4, 1.3 Acute intraperitoneal toxicity with mice. HERO ID: 4731527	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/5/?documentUUID=38e65d5f-6d87-4037-9153-a2a123481983					
CBI claim fully withdrawn (Full study report)	8. Summary of toxicological investigations with CAS 81-33-4, 2.3 Acute intraperitoneal toxicity with mice. HERO ID: 4731528	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/5/?documentUUID=7eed1bdb-9d2c-44ab-9d49-ccb48bfe7ec2					
CBI claim fully withdrawn	9. Summary of toxicological investigations with CAS 81-33-4, 1.1 Acute oral toxicity with rats. HERO ID: 4731529	BASF	1975	Sun Chemical	BASF Report XXV/454. Product Safety Basel, BASF Schweiz AG, Switzerland.	Yes

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
(Full study report)				(The Netherlands)		
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/2/?documentUUID=e73c9b1a-2e30-4c7b-856f-be9c27b62e3a					
CBI claim fully withdrawn (Full study report)	10. Summary of toxicological investigations with CAS 81-33-4, 2.1 Study report for CAS 81-33-4, Acute oral toxicity with rats. HERO ID: 4731530	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/2/?documentUUID=2627a9d8-85f8-408a-8a92-7db3e9edbc32					
CBI claim fully withdrawn (Full study report)	11. Testing the acute oral toxicity in the male and female Wistar rat. HERO ID: 4731531	Rupprich, N, Weigand, W	1984	Clariant (Germany)	Report No. 84.0225 (OECD-401)	No
CBI claim fully withdrawn (Full study report)	12. Summary of toxicological investigations with CAS 81-33-4, 1.4 Skin irritation study. HERO ID: 4731532	BASF	1975	Sun Chemical (The Netherlands)	BASF Report XXV/454	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/2/?documentUUID=991935ed-8813-45d4-a578-e985e45529c7					

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
CBI claim fully withdrawn (Full study report)	13. Summary of toxicological investigations with CAS 81-33-4, 2.4 Skin irritation study. HERO ID: 4731533	BASF	1978	Sun Chemical (The Netherlands)	BASF Report 77/360	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/4/2/?documentUUID=787aa890-cd18-4595-832b-7cc30e58641b					
CBI claim fully withdrawn (Full study report)	14. Perylimid Study of the Mutagenic Potential in Strains of <i>Salmonella Typhimurium</i> (Ames Test) and <i>Escherichia coli</i> . HERO ID: 4731535	Jung, R., Weigand, W	1983	FDA (Food Additive Petition) (Clariant, Germany filing)	Hoechst Aktiengesellschaft, Germany. Report No. 83.0695	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/7/2/?documentUUID=029bc6b6-17f3-49df-8a18-d363003217df					
CBI claim partially withdrawn (Redacted copy)	15. Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT) With Paliogen Violet 5011. HERO ID: 4731536	Wollny, H	2012	Sun Chemical (The Netherlands)	Harlan Cytotest Cell Research GmbH, Germany. Report No. 1443105.	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/7/2/?documentUUID=ce0e96f3-e018-4a7e-bbfc-07cfdbbc2b9e					
CBI claim partially withdrawn (Redacted copy)	16. Perylimid F: Local Lymph Node Assay. HERO ID: 4731537	Johnson, I.R.	1999	Sun Chemical (The Netherlands)	Central Toxicology Laboratory, UK. Project No. CTL/P/6194 (OECD-406)	Yes

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/5/2/?documentUUID=a548f01b-ceec-4805-8bac-9d5b1126db46					
CBI claim partially withdrawn (Redacted copy)	17. Reproduction/developmental Toxicity Screening Test in Wistar Rats Oral Administration (Gavage). HERO ID: 4731538	Stark, D., Treumann, S., Van Ravenzwaay, B	2013	Sun Chemical (The Netherlands)	BASF SE, Germany. Project No. 80R0223/11C162 (OECD-421)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/9/2/?documentUUID=9a37a3a9-d311-48a2-a34b-6359b6bef6e0					
CBI claim fully withdrawn Full study report	18. Perylimid Testing the acute toxicity in the fish model Zebra danio (<i>Brachydanio rerio</i>) over the course of 96 hours. HERO ID: 4731539	Market, D.I. Jung, R.	1988	Clariant (Germany)	Study conducted by Pharma Research Toxicology and Pathology, Hoechst Corporation (Study Completion Date: July 1st, 1988), Frankfurt, Germany. (OECD-203)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/2/?documentUUID=975f8535-c960-4857-b6c3-596d913e5461					
CBI claim partially withdrawn (Redacted copy)	19. Paliogen Violet 5011, <i>Lemna gibba</i> L., CPCC 310 Growth Inhibition Test. HERO ID: 4731540	BASF	2012	Sun Chemical (The Netherlands)	Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. Pszczyna, Poland (OECD-221)	Yes

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/7/?documentUUID=396286a2-97c2-4f76-97e0-6dfd58eb90bc					
CBI claim partially withdrawn (Redacted copy)	20. Paliogen Violet 5011, <i>Daphnia magna</i> , Acute immobilization test. HERO ID: 4731541	BASF	2012	Sun Chemical (The Netherlands)	Study conducted by Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicology. (Study Completion Date: May, 2012), Pszczyna, Poland. (OECD- 202)	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/4/?documentUUID=983ec9ec-9efc-4350-9a86-b6c1f572f5ba					
CBI claim partially withdrawn (Redacted copy)	21. Determination of the Inhibition of Oxygen Consumption by Activated Sludge by Perylimid F in the Activated Sludge Respiration Inhibition Test according to GLP, EN 45001 and ICO 9002. HERO ID: 4731542	BASF	1999	Sun Chemical (The Netherlands)	Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (OECD-209)	No
CBI claim partially withdrawn (Redacted copy)	22. Determination of the Biodegradability of Perylimid F in the Manometric Respirometry Test according to GLP, EN 45001 and ISO 9002. HERO ID: 4731543	BASF	1999	Sun Chemical (The Netherlands)	Study conducted by BASF Aktiengesellschaft Ecology and Environmental Analytics Laboratory of Ecology D-67056 Ludwigshafen (OECD 301-F)	Yes

Availability of public version	Study Number/Title (and Link to ECHA summary if applicable)	Author(s)	Year	Original Submitter to EPA (e.g., Sun Chemical or Clariant)	Study ID (OECD Guideline if applicable)	Availability of ECHA Robust Summaries ²
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/5/3/2/?documentUUID=c6149dae-22a5-4dda-85f4-34da02afc03f					
CBI claim partially withdrawn (Redacted copy)	23. Physical-Chemical properties of “Paliogen Violet 5011” (LogKOW) ⁵ . HERO ID: 4731544	BASF	2013	Sun Chemical (The Netherlands)	BASF Study No. 11L00105	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/4/8/?documentUUID=53829854-0728-48dd-9184-2045facf18f2					
CBI claim partially withdrawn (Redacted copy)	24. Physical-Chemical properties of “Paliogen Violet 5011” (Melting point) ⁵ . HERO ID: 4731544	BASF	2013	Sun Chemical (The Netherlands)	BASF Study No. 11L00105	Yes
ECHA Link	https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/4/3/?documentUUID=0ed13da2-4ef1-4d4e-b923-4d6b88bc38a2					

⁵ Study reports 23 and 24 (see two separate ECHA links) were submitted under one report (BASF Study No. 11L00105) describing the physical chemical properties of C.I. Pigment Violet 29.