**Environmental Defense Fund Comments on**
**Materials Supporting the Colour Index (C. I.) Pigment Violet 29 Risk Evaluation; Notice of Availability and Comment Opportunity**
**Docket ID: EPA-HQ-OPPT-2018-0604**
**Submitted Friday, May 17, 2019**

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on its release of "Materials Supporting the Colour Index (C. I.) Pigment Violet 29 Risk Evaluation; Notice of Availability and Comment Opportunity," noticed in the Federal Register on April 17, 2019 (84 Fed. Reg. 16011).

On January 14, 2019, EDF submitted extensive comments on EPA's draft risk evaluation for Colour Index (C. I.) Pigment Violet 29 (hereafter "PV29").[1] EDF reiterates and incorporates those comments herein by reference, as they remain just as relevant and accurate despite EPA's March 2019 release of certain additional information on PV29.[2]

Under TSCA § 6(b)(4)(A), EPA must determine whether PV29 "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk 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 its draft risk evaluation, EPA concluded that PV29 does not present an unreasonable risk. As detailed in our previous comments, EPA's draft risk evaluation cannot support that conclusion because EPA lacks sufficient information to characterize the hazards, exposures, and risks presented by PV29. In addition, the draft risk evaluation contains numerous logical flaws and unwarranted assumptions, rendering its final conclusion unsupported by substantial evidence, as required under TSCA. The resulting draft risk evaluation fails to consider reasonably available information or to use the best available science. These statements continue to apply – and, as

[1] EDF comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, January 14, 2019, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.
[2] EPA, "Draft Risk Evaluation for Pigment Violet 29," at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-risk-evaluation-pigment-violet-29.

detailed in these new comments, apply in some respects to an even greater degree – after our consideration of the supplementary materials EPA has recently released.

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1. **Despite EPA's release of some additional information on the 24 health and safety studies, EPA continues to illegally withhold from the public information to which it is entitled under TSCA.**

Following EPA's partial release of some additional information on or from the 24 health and safety studies, on April 19, 2019, EDF joined with numerous other organizations to send a letter to Alexandra Dunn, Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention, that raises serious concerns about EPA's continued withholding or redaction of these studies. That letter is attached as Appendix A.[3]

The letter notes two of the most serious concerns:

> [T]he Agency has withheld all but about 100 pages of the 430-page report for the BASF reproductive/developmental toxicity screening study on PV29.[4] The redacted portions of the report include the detailed animal-by-animal observations of reproductive performance and the results of pathology examinations. These data are essential to independently evaluating the study findings regarding the effects of PV29 exposure on the test animals. Importantly, this screening study plays a central role in the draft risk evaluation: its results form the basis for the Margin of Exposure (MOE) analysis that purports to show that PV29 is without harmful effects to workers, a finding that EPA then uses to determine the absence of risk to other exposed subpopulations.
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> In addition, 10 of the studies (# 1,2, 5-10, 12 and 13) are summarized in a single 10-page report prepared by BASF that lacks adequate supporting data.[5] The first page of and EPA's own filename assigned to this document use the word "summary" and "summaries," respectively, to describe its contents. These 10

[3] Letter to Assistant Administrator Alexandra Dunn, dated April 19, 2019, from multiple groups Re: Continued Withholding of Pigment Violet 29 Health and Safety Studies, available at http://blogs.edf.org/health/files/2019/05/PV29-FOLLOW-UP-LETTER-041919.pdf (attached as Appendix A).

[4] This study is #17 in the EPA table listing the 24 studies, available at https://www.epa.gov/sites/production/files/2019-03/documents/memo_transmitting_studies_for_pv29_and_attachment_a.pdf. The redacted version of the study is available at https://www.epa.gov/sites/production/files/2019-03/documents/study_17_repro-dev_toxicity_non-confidential.pdf.

[5] These studies are #s 1, 2, 5-10, 12 and 13 in the EPA table listing the 24 studies. https://www.epa.gov/sites/production/files/2019-03/documents/memo_transmitting_studies_for_pv29_and_attachment_a.pdf. The document containing the 10 study summaries is available at https://www.epa.gov/sites/production/files/2019-03/documents/study_s_1_2_5-10_12_13_toxicological_investigation_summaries_non-confidential.pdf.

summaries are even shorter than the robust summaries of these studies cited by EPA in its draft risk evaluation, and clearly do not constitute the "full study reports" that EPA claimed it possessed and had reviewed. This set of facts suggests either that EPA does not have the full study reports and is relying on these summaries prepared by the data owner in its risk evaluation, or that EPA does have the full study reports and is still not making them publicly available. Neither scenario is acceptable.

**A. EPA's withholding and redactions of health and safety data on PV29 call into question the reliability of EPA's analysis of and conclusions drawn from the studies.**

The heavy data redactions from the reproductive/developmental toxicity screening study are so extensive as to preclude the ability of the public to have any confidence at all in EPA's many decisions in the draft risk evaluation that are based on it, for the reasons noted in the letter cited above.

The newly provided summaries of 10 other studies, which were prepared by BASF, are even shorter (less than one page each) than the "robust summaries" available through the European Chemicals Agency (ECHA) that EPA referenced in its draft risk evaluation and posted copies of to the docket in November, 2018.[6] Yet in conjunction with its current release, EPA has misleadingly claimed that the 10-page document it provided – which clearly contains only summaries of the 10 studies – represents the release of the full study reports for these studies. The *Federal Register* notice EPA issued to announce the release of new materials states: "EPA has already made 24 *full study reports* on PV29 available to the public."[7] And the March 21, 2019 Transmittal Memo Accompanying New Release of Materials claims that the 10 studies are among those that "are completely released without redactions."[8] The entry in the leftmost column of the table attached to that memo claims that, for each of these 10 studies, the associated "CBI claim [was] fully withdrawn" and that what was released is the "full study report."

[6] Copies of those study summaries were posted by EPA on November 15, 2018, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002.
[7] 84 Fed. Reg. 16011 (April 17, 2019), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0038 (emphasis added).
[8] See 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), March 21, 2019 (hereafter "March 21, 2019 Transmittal Memo Accompanying New Release of Materials"), available at https://www.epa.gov/sites/production/files/2019-03/documents/memo_transmitting_studies_for_pv29_and_attachment_a.pdf.

In its draft risk evaluation for PV29, EPA also repeatedly claimed it had access to full study reports of all 24 studies on which it relied, including the 10 studies for which it has once again only provided summaries to the public:

> *The EPA obtained full study reports* associated with the European Chemicals Agency (ECHA) robust summaries (some of which are also presented in summary format in an FDA Food Additive Petition (FAP) 8B4626 (BASF, 2013) and used them to make a preliminary determination of hazard during problem formulation (U.S. EPA, 2018b). There are supporting materials (24 individual scientific studies) that contain information protected as Confidential Business Information (CBI). Twenty of these studies have been submitted to and summarized by the European Chemicals Agency (ECHA) as part of their information on registered substances and these ECHA robust summaries are publicly available. *The EPA has reviewed these full study reports and confirmed that the results are consistent* with the physical and chemical characteristics, environmental fate characteristics, and the determination of low environmental and human health hazards as presented in the ECHA robust summaries (presented in Appendices B-D). *The EPA reviewed these full study reports and assessed the quality of the methods and reporting of results of the individual studies* using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and concluded that they are of high or medium quality. In addition, *the EPA determined that the information presented in these full study reports is consistent with the robust summaries in the publicly available ECHA Database* (ECHA, 2017).

PV29 Draft Risk Evaluation, pp. 5-6; emphases added. (As EDF noted in our earlier comments on the PV29 draft risk evaluation (pp. 15-16), the robust summaries referred to in this excerpt were prepared by the registrants of the chemical under the EU's REACH Regulation, not by ECHA as EPA has claimed.)

This blatant discrepancy between EPA's characterization of what it has reviewed and what it has actually released would seem to be explained by only one of three possibilities, each of them unacceptable:

1. EPA has the full study reports, but still refuses to release them, while claiming it has done so. If true, this outcome is not only highly misleading but continues to preclude the ability of the public to independently assess the studies and their findings.
2. EPA does not have the full study reports despite its claims to have had and relied on them. If true, this outcome means EPA is relying on the data owner's summaries of its own studies with no ability for EPA to independently evaluate them, despite the statements above that it has done so.

3. Full study reports do not exist, despite EPA's claims to have them, rendering any reliance on these studies – which are more than 40 years old – highly suspect.[9]

**B. EPA's reliance on study summaries has adverse consequences on the Agency's ability to evaluate study quality.**

As discussed in subsection A, EPA has only made publicly available study summaries, rather than full study reports, for 10 of the 24 PV29 studies, raising questions as to whether EPA itself actually has access to the full study reports. This situation raises serious concerns over OPPT's ability to effectively evaluate study quality, including in applying the *Application of Systematic Review in TSCA Risk Evaluations* document (hereafter "TSCA systematic review method").[10] Study reports must include sufficient data and methodological information for OPPT to evaluate study quality, and in the case of the TSCA systematic review method, to assign scores to various data quality metrics. The PV29 study summaries we examined do not provide sufficient detail to reliably assign metric and overall scores per the guidance provided in the TSCA systematic review method.

We provide a non-exhaustive list of examples where the lack of study detail in these study summaries calls into question EPA's ability to reliably evaluate study quality (barring access to the full study reports). Any suggestion of a more appropriate score for a particular metric provided in the examples below are based solely on OPPT's criteria provided in its TSCA systematic review method, and do not in any way represent an endorsement of the criteria or the scoring approach OPPT has adopted:

*i. BASF 1975 eye irritation study:*[11]

- Reporting of doses/concentrations (Metric 9): OPPT assigned a scored of High, despite the fact that there is no information on substance concentration

[9] If EPA does not have access to the full study reports, then EPA cannot fully assess whether its decisions based on these studies are consistent with the "best available science." 15 U.S.C. § 2625(h). Absent access to the full study reports, details associated with the design and results of these studies would not be available, so those data could not be documented completely and clearly. *See id.* § 2625(h)(3). For example, as discussed in section 3 of these comments, EPA cannot rely on these summaries when contradicted by the full study reports that are available, and thus EPA cannot reasonably rely on the alleged water solubility value of 0.01 milligrams per liter (mg/L).

[10] EPA Office of Chemical Safety and Pollution Prevention, Application of Systematic Review in TSCA Risk Evaluations (hereafter "TSCA systematic review method"), May 2018, EPA Document # 740-P1-8001, available at https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.

[11] BASF, Eye Irritation Study Summary (1975), identified as Study #1 in https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.

in the study summary. The study summary simply indicates that 50 microliters of the test substance was applied to the rabbits' eyes.

- Outcome assessment methodology (Metric 16): While OPPT assigned a score of Medium, this metric arguably should receive a score of Unacceptable, as the method used to score the endpoints is not described at all in the study summary. The reviewer comment notes: "The method used to score irritation was not discussed. However, it is understood the scoring scale as it is standard for the eye irritation tests. Other details were not discussed (e.g., criteria for study termination)."[12]
- Confounding variables in test setup and procedures (Metric 21) and Health outcomes unrelated to exposures (Metric 22): OPPT gave both metrics a score of Low, which appears appropriate given the criteria provided in the TSCA systematic review method. ,Nevertheless, the study summary does not provide enough detail to allow a robust evaluation of these metrics. Indeed, the reviewer comment for these metrics notes, "It is not possible to determine if there were confounding variables with the limited information given in the report."[13]

*ii. BASF 1978 acute oral toxicity study:*[14]

- Test animal characteristics (Metric 13): While OPPT assigned a score of Medium for this metric, it likely should have been scored Low, due to the lack of detail provided in the study summary. According to the TSCA systematic review method, a score assignment of Low is given when "[t]he source of the test animal was not reported."[15] The reviewer comment notes "Health status and age at initiation were not reported."[16]
- Adequacy and consistency of animal husbandry conditions (Metric 14): While OPPT assigned a score of Low for this metric, it likely should have been scored Unacceptable. The reviewer comment indicates that the "Study provided minimal information on the adequacy of animal husbandry conditions."[17]

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[12] PV29 Updated Systematic Review Supplemental File (hereafter "Updated SR Supplemental File"), April 2019, p. 39, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0040.
[13] Ibid.
[14] BASF, Acute Oral Toxicity Study Summary (1978), Study #10, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.
[15] TSCA systematic review method, p. 197.
[16] Updated SR Supplemental File, p. 17.
[17] Ibid.

*iii. BASF 1975 skin irritation study:*[18]

- Reporting of doses/concentrations (Metric 9): While OPPT assigned a score of Low for this metric, it likely should have been scored Unacceptable given the lack of information found in the study summary. The reviewer comment notes that the "Study report states that test substance was given as a 50% suspension, but no details are provided on the actual amount (e.g., grams) of test substance administered in the application."[19]
- Test animal characteristics (Metric 13): While OPPT assigned a score of Medium for this metric, it likely should have been scored Low given the lack of information found in the study summary. For example, the source of the test animal is not reported.
- Adequacy and consistency of animal husbandry conditions (Metric 14): While OPPT assigned a score of Low for this metric, it likely should have been scored Unacceptable. The reviewer comment indicates that the "Study provided minimal information on the adequacy of animal husbandry conditions."[20] The study summary does not include any information regarding animal husbandry.

EPA's failure to apply its own TSCA systematic review method appropriately and consistently to these summaries is arbitrary and capricious. *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is arbitrary and capricious if the agency "offered an explanation for its decision that runs counter to the evidence before the agency").

### C. OPPT's withholding from the public of health and safety information is illegal.

As EDF explained in our previous comments,[21] EPA must make public the full study reports EPA utilizes in the draft risk evaluation. While EPA has made some of the full study reports available, EPA has only provided short summaries of 10 of the studies and EPA has redacted nine of the remaining studies, with one of those studies quite heavily redacted. Failure to release the study reports in full violates section 14 of the Toxic Substances Control Act (TSCA), reflects a troubling lack of transparency, and violates the right of interested parties to review and submit comments on the science EPA cites to support its risk evaluation and to participate meaningfully in the peer review process.

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[18] BASF, Skin Irritation Study Summary (1975), Study #12, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.
[19] Ibid.
[20] Ibid.
[21] EDF comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, January 14, 2019, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.

Under section 14(b)(2), the law's restrictions on disclosure of confidential business information (CBI) do not apply to "any health and safety study which is submitted under this Act" for a chemical substance which "has been offered for commercial distribution." 15 U.S.C. § 2613(b)(2). TSCA defines "health and safety study" broadly, and such studies encompass "any study of any effect of a chemical substance or mixture on health or the environment or on both." *Id*. § 2602(8); 40 C.F.R. § 720.3(k). Here, EPA requested submission of the PV29 studies for the express purpose of conducting its risk evaluation under TSCA, the studies were shared with EPA with the explicit understanding that they would be used to carry out the Agency's TSCA responsibilities, and EPA relies on the studies throughout its draft risk evaluation. Accordingly, they are, under any definition of the term, "health and safety studies submitted under" TSCA.

TSCA section 14(b)(2)(B) independently requires the disclosure of "any information reported to, or otherwise obtained by, the Administrator from a health and safety study" on a chemical offered for distribution in commerce. EPA does not, and cannot, deny that the data withheld from the PV29 studies constitutes information, obtained by EPA, from a health and safety study of a commercially available chemical.

Moreover, EPA's obligation to disclose these studies cannot be satisfied merely by releasing "robust summaries" or other summaries, but requires public access to the full study reports. EDF's prior comments explained why study summaries are inadequate to allow meaningful public comment. EDF reiterates and incorporates those points by reference here.

With respect to chemical substances, the only portion of a health and safety study or underlying information that can be treated as CBI under section 14(b)(2) is information "that discloses processes used in the manufacture or processing of a chemical substance." Many of the redactions in the documents EPA has released do not appear to cover information meeting this description, and in the event any of the studies contain legitimate and substantiated CBI of this type, it can be redacted while all health and safety information is disclosed as provided for in section 14(b)(1).

In particular, the reproductive/developmental toxicity screening study undoubtedly qualifies as a health and safety study under TSCA § 14(b)(2), and the hundreds of pages of data withheld from that study do not appear to contain process information. Rather, EPA has withheld data reported in a health and safety study, in direct violation of TSCA § 14(b)(2).

EPA's withholding of the full study reports also violates the requirements of public notice and comment codified in TSCA § 6(b)(4)(H). 15 U.S.C. § 2605(b)(4)(H). "Under APA notice and comment requirements, '[a]mong the information that must be revealed for public evaluation are the "technical studies and data" upon which the agency relies [in its rulemaking].'" *Am. Radio*

*Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (quoting *Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006)). In *American Radio Relay League*, the D.C. Circuit found that an agency could not fulfill its notice-and-comment obligations by providing redacted versions of underlying studies, and the Court ruled that the agency had to provide the full studies for public comment. *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 238 (D.C. Cir. 2008). As the Court explained, no authority suggests that an agency may "rely on the studies in a rulemaking but hide from the public parts of the studies that may contain contrary evidence, inconvenient qualifications, or relevant explanations of the methodology employed." *Id.* at 239. EPA's hiding of the data in the reproductive/developmental toxicity screening study violates the rule laid out in *American Radio Relay League*.

Without the data tables from the reproductive/developmental toxicity screening study and the full study reports from the 10 summarized studies, it remains impossible to evaluate whether these study summaries' reported findings accurately reflect the study results. Thus, the public will be unable to comment fully on whether the studies support EPA's claim that PV29 does not present unreasonable risk, including a developmental or reproductive risk. Nor is it currently possible for the public to provide informed feedback to the Scientific Advisory Committee on Chemicals (SACC) when it considers these studies during its peer review of the PV29 draft risk evaluation.

As EDF previously explained in the letter we and other organizations sent to Assistant Administrator Dunn:

> The Agency's approach to the PV29 studies has troubling implications for the transparency of future TSCA risk evaluations. Many chemicals that are and will be candidates for risk evaluations under TSCA have been the subject of health and safety studies conducted by foreign chemical manufacturers. If EPA could rely on those studies in its risk evaluations without disclosing them for public review, or release only such data from these studies as industry approves, then public participation in chemical safety decisions under TSCA would be held hostage to the willingness of chemical manufacturers to share their data with the public. That plainly is not what Congress intended when it enacted section 14(b)(2), and it would deny the public a meaningful opportunity to comment on key EPA scientific findings that rely on industry-supplied data. The credibility of future EPA priority listings and risk evaluations will be seriously impaired if they are based on scientific studies that, in whole or in part, are withheld from the public.
>
> Industry has warned that it will not provide EPA with health and safety studies conducted outside the US on chemicals subject to future risk evaluations if EPA does not commit to shielding such studies from public review. This threat cannot justify compromising the transparency that Congress required under TSCA section 14(b). If industry chooses not

to share test data relevant to TSCA risk evaluations, EPA has ample authority to require US manufacturers and importers to develop and submit such information under section 4(a)(2), which authorizes EPA to issue test orders or rules "necessary . . . to perform a risk evaluation" or for "prioritizing a chemical substance." Studies conducted pursuant to EPA's use of these authorities would need to be disclosed to the public under the plain language of section 14(b)(2).

Appendix A.[22]

**2. Despite the new release, EPA still lacks sufficient information to support its sweeping conclusions that PV29 does not present any unreasonable risks.**

The following statements from the summary of our earlier comments,[23] discussed in detail therein, still apply:

- EPA relies heavily on a single, poorly documented value for water solubility while failing to account for other available data on water solubility. EPA has still not made the study itself available, only a summary prepared by the manufacturer. It is not at all clear whether EPA has the actual study and if it does, why it has failed to make it available.
- EPA fails to address the implications of the very high persistence of PV29 in the environment.
- EPA also lacks any measured data that directly assess the potential for PV29 to bioaccumulate in humans or other organisms; instead EPA relies upon modeled values derived using an estimation program lacking sufficient data on similar chemicals.
- EPA lacks any actual data characterizing environmental, consumer, and general population exposures.
- EPA also has no actual data on the levels of PV29 released to, or present in: air, soil, sediment, surface water, people, other organisms, or products containing or made from the chemical.
- For occupational inhalation exposures, EPA relies on a single value for a workplace air concentration reported in a private personal communication from a manufacturer of PV29; EPA has not provided any detail about this value and appears to lack any supporting information necessary to assess the accuracy or certainty of the value.

[22] Letter to Assistant Administrator Alexandra Dunn, dated April 19, 2019, from multiple groups Re: Continued Withholding of Pigment Violet 29 Health and Safety Studies, available at http://blogs.edf.org/health/files/2019/05/PV29-FOLLOW-UP-LETTER-041919.pdf (attached as Appendix A).

[23] EDF comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, January 14, 2019, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.

- For inhalation, dermal, and oral routes of exposure, EPA lacks any data on absorption of PV29.
- EPA has no information on chronic aquatic toxicity, terrestrial toxicity, or toxicity to sediment-dwelling organisms.
- For human health hazard, EPA relies on studies, most of which examined only acute lethal effects and none of which assessed chronic toxicity. EPA relies on a study of reproductive and developmental toxicity where EPA's own guidance asserts that it "will not provide evidence for definite claims of no effects."
- EPA also concludes that PV29 is not carcinogenic on the basis of insufficient information and unsupported assumptions. EPA dismisses the potential for increased adverse effects on susceptible subpopulations based on studies that failed to look for such effects.
- EPA has also completely failed to analyze a residual of PV29: naphthalimide. EPA provides no explanation for this failure.

### 3. PV29 data owners' selective modifications to their "robust summaries" of health studies amplifies concerns over EPA's failure to make full study reports publicly available.

When EPA first released a draft of its PV29 risk evaluation for comment, it refused to make public the underlying health and safety studies. Instead, it only provided copies of and links to brief summaries – misleadingly called "robust summaries" – of the studies, which were prepared by companies that make PV29. The companies had submitted the summaries to the European Chemicals Agency (ECHA) when they registered PV29 under the European Union's REACH Regulation.

After first claiming the studies had to be withheld because they were protected as confidential business information (CBI) under TSCA, EPA recently made public more of the content of these health and safety studies. Unfortunately, EPA is still withholding key parts of that body of information under a different, equally flawed theory it has advanced to allow companies to hide health and safety information that TSCA requires be made public; for more detail on this, see section 1.C of these comments, as well as a recent letter[24] sent to EPA by groups, including EDF,

[24] Letter to Assistant Administrator Alexandra Dunn, dated April 19, 2019, from multiple groups Re: Continued Withholding of Pigment Violet 29 Health and Safety Studies, available at http://blogs.edf.org/health/files/2019/05/PV29-FOLLOW-UP-LETTER-041919.pdf (attached as Appendix A).

who sought to obtain the studies through a Freedom of Information Act (FOIA) request[25] that EPA now has denied with respect to the full release of these studies.[26]

As EDF began to prepare these comments on EPA's additional, partial release of PV29 information, we discovered that some of the "robust summaries" have changed: The current versions of at least two of those summaries now posted on ECHA's REACH registration website show deletions of certain information that was in the versions EPA first made available. We noticed the changes because *the deleted information is the same information EDF had cited in our earlier comments as undermining a key conclusion EPA had drawn about PV29's water solubility*.

In EDF's earlier comments on PV29, we questioned EPA's reliance on a single value – 0.01 milligrams per liter (mg/L) – to assert that PV29's water solubility is very low, and then its repeated reliance on that property to dismiss a host of other concerns. Among our arguments was that the summaries of two other studies EPA cited[27] indicated much higher values for PV29's water solubility:

- Study 15: The summary of a 1988 study that reported testing of PV29's short-term toxicity to fish, which used OECD Test Guideline #203 and indicated it complied with Good Laboratory Practices (GLP), listed the chemical's water solubility as 670 mg/L – 67,000 times higher than the value EPA relies on.
- Study 18: The summary of a 1999 study measuring PV29's biodegradability, which used OECD Test Guideline #301F and was GLP-compliant, reported the chemical's water solubility as "<500 mg/L," or up to 50,000 times higher than the value EPA relies on.[28]

These two summaries have now been selectively altered: The *only change made to each* is simply to delete the water solubility values of 670 mg/L and <500 mg/L that EDF had cited.

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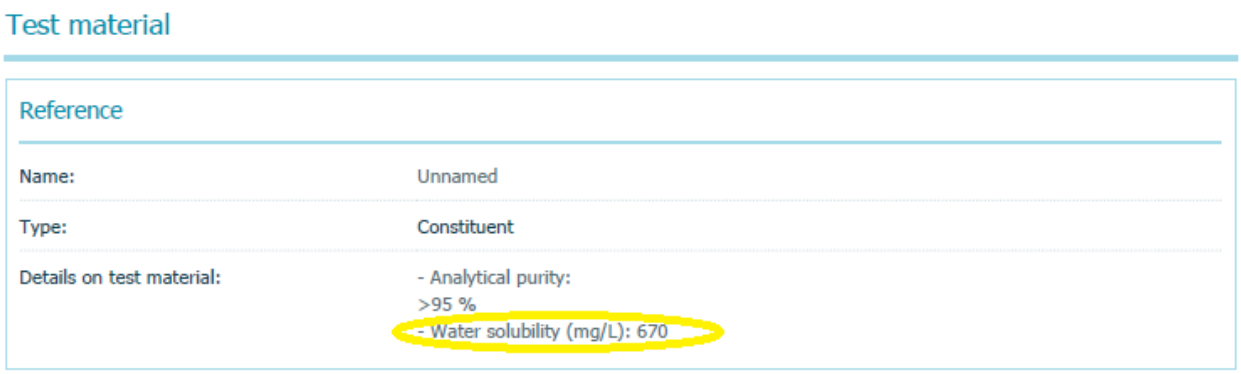
[25] The FOIA request is available at https://www.foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2019-001853&type=request.

[26] EPA's denial letter dated April 18, 2019, is available at http://blogs.edf.org/health/files/2019/05/epa.hq_.2019.001853.response.4.18.192019-04-18-150225.pdf.

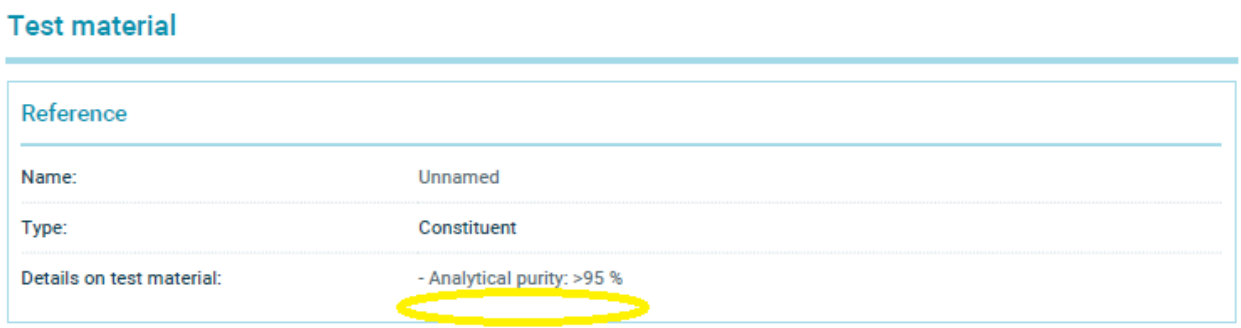
[27] The copies of the study summaries, posted by EPA to the docket on November 15, 2018, are available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002.

[28] In describing the relevant values from these two study summaries in EDF's earlier comments, we had erroneously referred to them as representing the "chemical's solubility in the *test solution*." In fact, as the screen shots from the summaries included below make clear, both studies identify these values as the substance's "water solubility," and hence they are directly to be compared to and contrasted with EPA's assumed value of 0.01 mg/L for PV29's water solubility.

Study 15:
The summary of Study 15 that EPA printed from the ECHA website on November 13, 2018, is still posted in EPA's PV29 docket.[29] Below is a screen shot of the relevant section of that summary where we have circled the water solubility value:



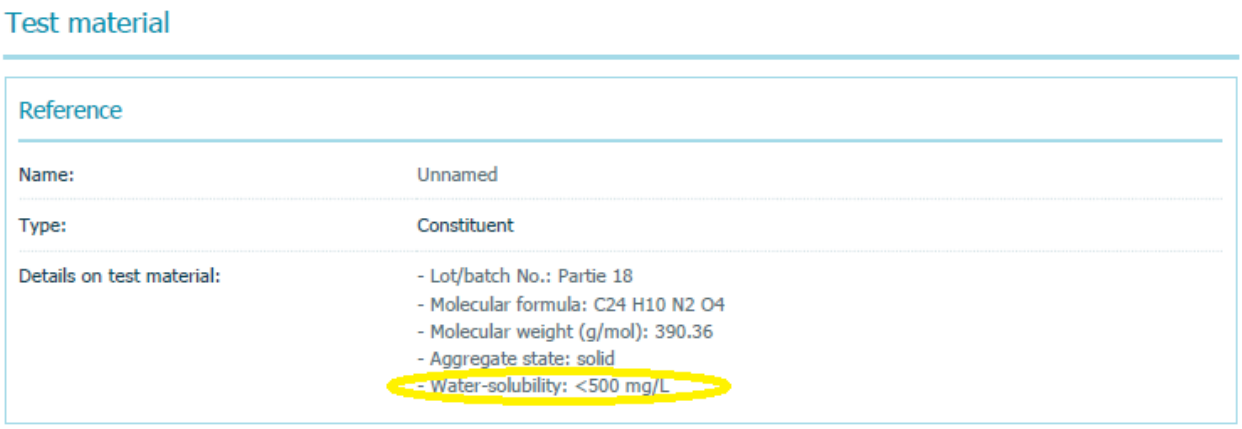

Below is a screen shot of the same section of the summary of that same study that EDF retrieved and printed from the ECHA website on May 17, 2019,[30] where we have circled where the water solubility value has been deleted:




[29] Study 15. Short-term toxicity to fish study summary, key experimental result, printed by EPA (based on document footer) on November 13, 2018, available at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0604-0002&attachmentNumber=15&contentType=pdf.

[30] Short-term toxicity to fish study summary, key experimental result, last viewed on May 17, 2019, at https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/2/?documentUUID=7dfc75e4-5e7a-4c8a-9e94-ab41aa928ccf.

Study 18:
The summary of Study 18 that EPA printed from the ECHA website on November 13, 2018, is still posted in EPA's PV29 docket.[31] Below is a screen shot of the relevant section of that summary where we have circled the water solubility value:

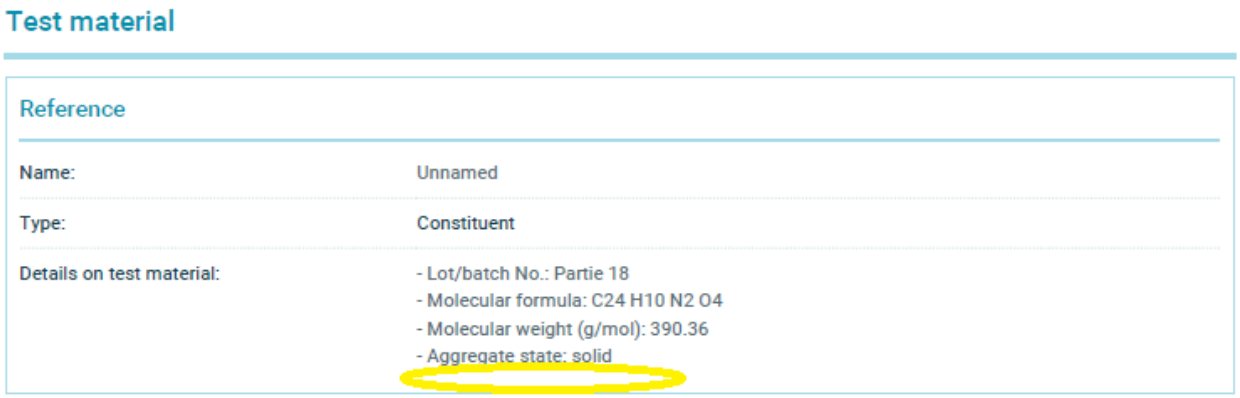


Test material

Reference

| | |
|---|---|
| Name: | Unnamed |
| Type: | Constituent |
| Details on test material: | - Lot/batch No.: Partie 18<br>- Molecular formula: C24 H10 N2 O4<br>- Molecular weight (g/mol): 390.36<br>- Aggregate state: solid<br>- Water-solubility: <500 mg/L |

Below is a screen shot of the same section of the summary of that same study that EDF retrieved and printed from the ECHA website on May 17, 2019,[32] where we have circled where the water solubility value has been deleted:



Test material

Reference

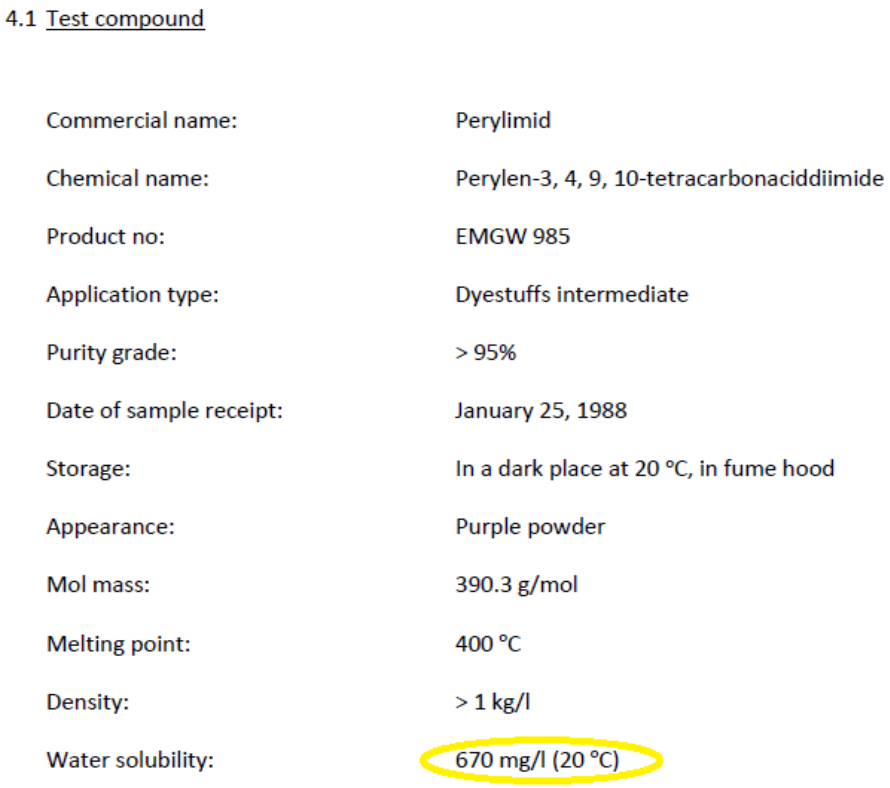
| | |
|---|---|
| Name: | Unnamed |
| Type: | Constituent |
| Details on test material: | - Lot/batch No.: Partie 18<br>- Molecular formula: C24 H10 N2 O4<br>- Molecular weight (g/mol): 390.36<br>- Aggregate state: solid |

[31] Biodegradation in water: screening tests study summary, key experimental result, printed by EPA (based on document footer) on November 13, 2018, available at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0604-0002&attachmentNumber=18&contentType=pdf.

[32] Biodegradation in water: screening tests study summary, key experimental result, last viewed on May 17, 2019, at https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/5/3/2/?documentUUID=2ffd2e7d-92a6-4211-8478-4ba814b2ff50.

EPA has now made full study reports (one with some redactions) publicly available; upon examining these, we found that the values now missing from the current study summaries are in the full study reports.

Here is a screen shot from page 8 of the full study report corresponding to Study 15 (which EPA has now renumbered to be Study #18)[33] showing the value that was in the original summary but has now been deleted from the currently posted summary:



4.1 Test compound

| | |
|---|---|
| Commercial name: | Perylimid |
| Chemical name: | Perylen-3, 4, 9, 10-tetracarbonaciddiimide |
| Product no: | EMGW 985 |
| Application type: | Dyestuffs intermediate |
| Purity grade: | > 95% |
| Date of sample receipt: | January 25, 1988 |
| Storage: | In a dark place at 20 °C, in fume hood |
| Appearance: | Purple powder |
| Mol mass: | 390.3 g/mol |
| Melting point: | 400 °C |
| Density: | > 1 kg/l |
| Water solubility: | 670 mg/l (20 °C) |

Here is a screen shot from page 7 of the full study report for Study 18 (which EPA has now renumbered to be Study #22)[34] showing the value that was in the original summary but has now been deleted from the currently posted summary:[35]

[33] "Study #18_Acute toxicity_Zebra danio_non-confidential," last viewed on May 17, 2019, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0030.
[34] "Study #22_Biodegradability_non-confidential," last viewed on May 17, 2019, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0034.
[35] On page 3 of the full study report, the "test concentration" of the substance is listed as "100 mg/l." This value, which is consistent with the study's reported water solubility value of <500 mg/l, also greatly exceeds the 0.01 mg/l water solubility level EPA's draft risk evaluation utilized.

**9 SPECIFICATION OF THE TEST SUBSTANCE BY THE SPONSOR**

| | | |
|---|---|---|
| Name of test substance | : | Perylimid F |
| Chemical name | : | Perylene-3,4,9,10-Tetracarboxydiimide |
| Batch number | : | Partie 18 |
| Date of production | : | 2.Quartal 96 |
| Product number | : | 073209 |
| CAS number | : | 81-33-4 |
| Molecular formular | : | C24 H10 N2 O4 |
| Molecular weight [g/mol] | : | 390.36 |
| Aggregate state | : | solid |
| Density [kg/l] | : | 0,3 (20°C) |
| Water-solubility | : | < 500 mg/l [1] |
| Colour | : | violet/red |
| Purity of the test substance [%]: | | 98,9% [3] |
| Impurities | : | no data |
| Homogeneity | : | yes |
| Instability against | : | Heat: No Light: No Oxygene: No<br>Water: No Acid: No Alcali: No |
| Limited storage | : | No |
| Special storage conditions | : | ca. 4°C: No under N2: No<br><= -15°C: No Light exclusion: No |
| Further remarks | : | none |

While EPA has now made public the full study reports (one with some redactions) in this case, as noted earlier, EPA has only provided industry-prepared summaries for 10 other studies. This perpetuates the myriad problems associated with EPA expecting the public simply to trust its analysis of the full study reports. The public cannot independently assess EPA's claims about the representativeness of the summaries vis-à-vis the full study reports, or judge the conclusions EPA has drawn, without access to the full study reports.

In its draft risk evaluation, EPA emphasized that study summaries could be trusted because EPA had verified that they accurately reflected the underlying studies. Now with this new development, we have learned three new things: *First*, these summaries can be altered at will, without any apparent notice or explanation; in this case, we suspect the changes were made in direct reaction to EDF's comments citing the now-deleted information. *Second*, persons preparing robust summaries may exclude relevant information, and it is not clear that EPA reviews the summaries to ensure they are "complete," as well as "accurate." *Third*, because of these changes, the full study reports are NOT, as EPA claimed in its draft risk evaluation (page 8), "consistent with the physical and chemical characteristics … as presented in the ECHA robust summaries" currently provided in the online ECHA dossier for PV29. As explained above, values for a key physical-chemical characteristic of PV29 have vanished from the study summaries now posted on ECHA's website.

We know of this inconsistency *only because* EPA had posted the earlier versions of the study summaries to its docket and because it has finally made public the full study reports (one of them with some redactions) that correspond to the two altered summaries; hence, we could confirm that the values for that key PV29 characteristic deleted from the current summaries are still in the full study reports. (Presumably, those full reports, which date back to 1988 and 1999, would be much more difficult to alter without drawing attention.) In sum, it was largely happenstance in this case (coupled with considerable time spent in investigation) that we were able to discern the deletions.

Despite the clear expression of Congressional intent in TSCA – dating back to the original law enacted in 1976 – that health and safety studies and associated information on chemicals should be public, EPA and the chemical industry continue to seek ways to circumvent that intent. The intentional alteration of robust summaries to remove inconvenient data that we report here adds yet another reason why it is wholly unacceptable to expect the public to rely on summaries prepared by the companies making a chemical under review, or to trust EPA's assertion that the summaries accurately reflect the underlying studies. Public access to full study reports on chemicals to which we are or may be exposed remains a paramount need.

## 4. Updated data evaluation scoring sheets deepen concerns over data inadequacy.

### A. OPPT's reevaluation of two inhalation toxicity studies and determination that these studies warrant an overall study quality score of Unacceptable highlight serious flaws with OPPT's TSCA systematic review method and further undermines EPA's conclusion of no hazard or risk for PV29.

#### *i. OPPT has failed to provide a clear explanation for why two fundamentally flawed acute inhalation toxicity studies were not excluded from the draft risk evaluation of PV29 per application of its TSCA systematic review method.*

In its draft risk evaluation of PV29, OPPT identified two acute inhalation toxicity studies: a BASF 1975 acute inhalation toxicity study[36] and a BASF 1978 acute inhalation toxicity study.[37] These are the only inhalation toxicity studies available for PV29 according to EPA's review of the available evidence. It should be noted that OPPT has still not made available full study reports for these two studies; in its recent release of additional information on PV29, OPPT still provided only brief (ca. one-page) summaries prepared by BASF – and different from the study summaries the company submitted under the European Union's REACH Regulation that EPA

[36] BASF, Acute Inhalation Toxicity Study Summary (1975), identified as Study #5, p. 2, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.
[37] BASF, Acute Inhalation Toxicity Study Summary (1978), identified as Study #6, p. 6, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.

first made available. See section 1 of these comments for more discussion of this failure to provide full study reports.

In our previous comments, EDF raised serious concerns about OPPT's reliance on these studies in its draft risk evaluation given that in the summaries of the studies in the PV29 dossier submitted under REACH, the registrant itself clearly indicated that these studies are "not reliable."[38] Specifically, the registrant described each study as follows: "unsuitable test system as the inhalation hazard test is insufficient for non-volatile substances."[39] Illustrating a monumental deficiency in its application of the TSCA systematic review method, OPPT originally scored the overall quality level of both studies Medium.[40]

In the face of this criticism, OPPT reevaluated the data quality of the two inhalation toxicity studies and dramatically changed their overall study quality scores from Medium to Unacceptable. OPPT's Memo Transmitting Updated Systematic Review Documents (hereafter "April 4, 2019 Transmittal Memo for Updated SR Documents") states:[41]

> EPA's initial data quality evaluation determined that the studies were of medium confidence, but deficiencies in methods were also noted in the reviewer's comments following the method described in the Application of Systematic Review in TSCA Risk Evaluations document. However, these technical concerns in the data evaluation scoring sheets, not previously made available to the public, were erroneously omitted from EPA's determination on the confidence score of the studies.

Unfortunately, OPPT has never provided reviewer comments from the initial study quality evaluations that it now claims included technical concerns raised by the reviewers in evaluating

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[38] EDF comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, January 14, 2019, p. 79, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.

[39] See "4. Acute Toxicity Inhalation Study 1978" and "5. Acute Toxicity Inhalation Study" at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0002. Note: The current versions of the registrants' summaries for these two studies posted in the ECHA dossier as of May 17, 2019, have slightly altered this language, and now state that each "inhalation hazard test is insufficient for non-volatile substances." These study summaries are available at https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=1b8b25af-5c53-45f0-9661-148c12e6af39 and https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/3/?documentUUID=ba039660-3390-47da-9a8e-6d71f92ce426

[40] Draft PV29 Systematic Review Supplemental File November 8, 2018, pp. 15-18, at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0604-0002&attachmentNumber=22&contentType=pdf.

[41] EPA, PV29 Transmittal Memo on Systematic Review April 4, 2019 Signed by Cathy Fehrenbacher (hereafter "April 4, 2019 Transmittal Memo for Updated SR Documents"), p. 3, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0039.

the inhalation studies. As a result, it is impossible to know whether and which reviewer comments in the updated data evaluation scoring sheets[42] have been carried over from the initial study data quality evaluations and which are entirely new.

Per the TSCA systematic review method, if reviewers had identified and noted significant deficiencies ("serious flaws") then they should have assigned the corresponding data quality metrics and overall study quality Unacceptable. If reviewers identified and noted significant study deficiencies, but did not give any metric a score of Unacceptable, this raises even more serious concerns about the agency's TSCA systematic review method and its application.

EPA should always make reviewer comments public in order for the public to understand the rationale behind its scoring decisions and to have a transparent record of when and why changes to scores are made. One of the fundamental purposes of systematic review is to increase transparency.

*ii. OPPT's updated scoring sheets for the two acute inhalation toxicity studies raise further concerns about the TSCA systematic review method.*

In the updated data evaluation scoring sheets for both acute inhalation toxicity studies, OPPT changed several metric scores to Unacceptable following a reevaluation of study quality. For these studies and metrics, we list below the original scores and the reviewer comment provided in the updated data evaluation scoring sheets:

| **Acute Inhalation Toxicity Study** | **Metric** | **Original Score** | **Reviewer Comment in Updated Scoring Sheet** |
|---|---|---|---|
| BASF 1975 | Consistency of exposure administration | Low | Reviewer cannot determine whether consistency of exposure was achieved due to lack of analytical method to measure exposure in the chamber (e.g., only nominal concentrations were reported). |
| BASF 1975 | Reporting of doses/concentrations | Low | Nominal but not actual concentrations were reported. Nominal concentrations are usually quite close to actual concentrations for gases, but they can be much greater for vapor and aerosols. This creates a major uncertainty in the study. |

[42] Updated SR Supplemental File, p. 8.

| Acute Inhalation Toxicity Study | Metric | Original Score | Reviewer Comment in Updated Scoring Sheet |
|---|---|---|---|
| BASF 1975 | Exposure route and method | High | The study aimed at investigating animal toxicity to an atmosphere saturated with vapors of the volatile component of PV29. Since the study said that dust is expected by inhalation, this is an inappropriate exposure method. Further, specific details were missing such as the equipment and method used to generate the chamber atmosphere, description of the inhalation chamber, failure to use an analytical method to analyze the test atmosphere concentrations. Also, the authors admitted the limitations of the study by indicating that "the inhalation hazard test is insufficient for non-volatile substances." |
| BASF 1978 | Negative and vehicle controls | Not rated | The study did not use a vehicle control. The study used a concurrent control. |
| BASF 1978 | Consistency of exposure administration | Low | Reviewer cannot determine whether consistency of exposure was achieved due to lack of analytical method to measure exposure in the chamber (e.g., only nominal concentrations were reported). |
| BASF 1978 | Reporting of doses/concentrations | Low | Nominal but not actual concentrations were reported. Nominal concentrations are usually quite close to actual concentrations for gases, but they can be much greater for vapor and aerosols. This creates a major uncertainty in the study. |
| BASF 1978 | Exposure route and method | High | The study aimed at investigating animal toxicity to an atmosphere saturated with vapors of the volatile component of PV29. Since the study said that dust is expected by inhalation, this is an inappropriate exposure method. Further, specific details were missing such as the equipment and method used to generate the chamber |

| Acute Inhalation Toxicity Study | Metric | Original Score | Reviewer Comment in Updated Scoring Sheet |
|---|---|---|---|
| | | | atmosphere, description of the inhalation chamber, failure to use an analytical method to analyze the test atmosphere concentrations. Also, the authors admitted the limitations of the study by indicating that "the inhalation hazard test is insufficient for non-volatile substances." |
| BASF 1978 | Negative control response | Not rated | The biological responses of the negative control group(s) were not addressed in the study. |
| BASF 1978 | Reporting of data | High | Data presentation was inadequate (e.g., the report does not differentiate among findings between air control and treatment groups). |

The score changes for the "exposure route and method" metric, initially scored High and then downgraded to Unacceptable in both studies, is especially notable. For a study to score High for this metric, the method of exposure must be "suited to the test substance,"[43] yet the company's own summaries of these inhalation toxicity studies clearly indicate that the test method is "insufficient for non-volatile substances."[44] Setting aside the fact that TSCA systematic review method is unaligned with best practices of systematic review,[45] that a study metric was initially scored High when it should have been scored Unacceptable raises *additional* alarm bells around whether OPPT has the appropriate expertise and objectivity to appropriately evaluate study quality. EPA must ensure that its scientists and contractors are appropriately trained and equipped and given the scientific independence to conduct robust evaluations of study quality—a need that will become even more imperative in the next set of draft risk evaluations where the evidence base is substantially more voluminous. (See subsection B for additional discussion of this issue).

[43] TSCA systematic review method, p. 196.
[44] Studies identified as Study #5 (p. 2) and Study #6 (p. 6) at https://www.epa.gov/sites/production/files/2019-03/documents/study_s_1_2_5-10_12_13_toxicological_investigation_summaries_non-confidential.pdf
[45] See EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.

As to the TSCA systematic review method itself, we reiterate our earlier comments that the method is fundamentally flawed and that a prompt peer review of it by the National Academies is of paramount importance.[46]

*iii. OPPT's revised overall study quality score of the two inhalation toxicity studies as Unacceptable further highlights the lack of sufficient information available to evaluate PV29's risks.*

As described in subsection A.i.., based on the agency's review of the available evidence, the BASF 1975 and 1978 acute inhalation toxicity studies are the only inhalation toxicity studies available for PV29. Despite their clear unreliability, OPPT repeatedly relied on these two studies in the draft risk evaluation to conclude that PV29 presents no hazard via inhalation. For example, OPPT stated that "…full study reports concluded that *no adverse effects were observed for all routes of exposure (oral, dermal, inhalation)*, nor were dermal or eye irritation effects reported. As a result, the EPA concludes that [PV29] presents a low hazard to human health."[47]

Given that the two BASF acute inhalation toxicity studies have been downgraded to Unacceptable, and therefore cannot be relied on in OPPT's risk evaluation of PV29, EPA has insufficient information to draw any conclusion of no hazard or risk via inhalation.

OPPT relied on overall study quality scores, including for the inhalation toxicity studies, to bolster its sweeping assertions that PV29 does not present hazards by any route of exposure:

> Furthermore, the EPA has reviewed these [PV29 studies] according to the data quality evaluation criteria found in The Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018a) and concludes that these studies are of high or medium confidence based on the evaluation metrics for human health hazard studies.[48]

In the case of the acute inhalation studies, this line of argument now collapses.

As discussed in detail in our previous comments, OPPT has insufficient information to conduct a robust risk evaluation or reach a sound risk determination for PV29. The elimination of two studies from PV29's already spotty evidence base only further supports this conclusion, and underscores the critical need for EPA to use its information authorities to fill data gaps.

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[46] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.
[47] EPA Draft Risk Evaluation for Pigment Violet 29, p. 25 (emphasis added), at https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf.
[48] EPA Draft Risk Evaluation for Pigment Violet 29, p. 26.

EPA's failure to consider any acceptable inhalation studies is also a failure to consider "reasonably available" information under TSCA because it is information that EPA could "reasonably generate *** for use in [the] risk evaluation[], considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33. EPA must develop this information, as EDF previously explained in our comments, incorporated here by reference.[49]

### B. An apparent lack of sufficient toxicological expertise among OPPT staff and contractors applying the TSCA systematic review method jeopardizes the risk evaluation process.

OPPT acknowledges that some errors in its initial evaluation of study quality for PV29 were due to a lack of toxicological expertise. In the April 4, 2019 Transmittal Memo for Updated SR Documents, OPPT notes, "EPA has also corrected technical errors in systematic review data evaluation scoring sheets of some specific studies where toxicological expertise was needed to evaluate specific criteria."[50] Evidence of these "technical errors" and apparent lack of toxicological expertise is abundantly clear in the reevaluation of the two inhalation toxicity studies just discussed (see subsections A.i.. and A.ii.).

In the April 4, 2019 Transmittal Memo for Updated SR Documents, OPPT states that "…public comments identified major methodological deficiencies in the [inhalation] studies based on information published in the European Chemicals Agency (ECHA) database."[51] EPA should not have to rely on the public to identify such obvious, critical deficiencies in study quality.

The apparent lack of toxicological expertise for evaluation of study quality raises serious concerns for future draft risk evaluations where the evidence base will be significantly larger. EPA must ensure that its staff and contractors are appropriately trained and equipped to conduct robust evaluations of study quality.

[49] See EDF's January 14, 2019, comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.
[50] April 4, 2019 Transmittal Memo for Updated SR Documents, p. 2.
[51] April 4, 2019 Transmittal Memo for Updated SR Documents, p. 3.

### C. The significant changes in OPPT's updated data evaluation scoring sheets reveal numerous inconsistencies and inaccuracies, and further call into question the TSCA systematic review method itself.

#### *i. The extent of changes made raises significant concerns about the TSCA systematic review method.*

Upon reevaluating the quality of PV29 studies, OPPT made numerous changes to scores assigned to individual study quality metrics and consequently to overall study quality scores. For example:

- OPPT downgraded the overall study quality scores for eight (one-third) of the 24 studies; no studies were upgraded in study quality. As already discussed, two of these eight studies were downgraded to Unacceptable.
- In addition to the eight studies whose overall study quality were downgraded, eleven of the 24 studies had at least 20% of their metric scores revised.
- Across all of the studies, 117 of 525 metric scores (22%) were changed.
- Only four studies had no changes made to their metric scores, meaning OPPT only fully agreed with its initial study quality evaluations for one-sixth of the studies.

As discussed further in subsection F and detailed extensively in our previous comments,[52] the TSCA systematic review method is not in alignment with best practices for systematic review. The extent of revisions made to the individual metric and overall study scores for PV29 from one application to the next of the TSCA systematic review method underscores our concerns. Future risk evaluations under TSCA are jeopardized until EPA significantly improves its TSCA systematic review method and bolsters quality assurance steps.

#### *ii. OPPT scored certain data quality metrics inconsistently across studies, raising further concerns about its approach to systematic review.*

In the case of the TSCA systematic review method, in which OPPT has elected – against best practices – to employ a numerical scoring methodology, inconsistent evaluation of data quality metrics can produce a situation where two studies are given different overall study quality scores when the score would otherwise be the same. As a result, EPA may artificially give greater weight to one study versus another when evaluating and making determinations of risk. It is worth noting that OPPT has yet to develop or describe its approach to data integration.

Examples where reviewers appear to have inconsistently applied data quality metric criteria are provided below. This is not a comprehensive list, but is representative of a larger problem OPPT

[52] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.

must address. EPA's inconsistent application of its TSCA systematic review method to similar studies results in arbitrary and capricious decisions.

*a. "Statistical methods" metric*

OPPT's "statistical methods" scoring criteria for animal studies are as follows:[53]

| Confidence Level (Score) | Description |
|---|---|
| High (score = 1) | Statistical methods were clearly described and appropriate for dataset(s) **OR** no statistical analyses, calculation methods, and/or data manipulation were conducted but sufficient data were provided to conduct an independent statistical analysis |
| Medium (score = 2) | Statistical analysis was described with some omissions that would unlikely have a substantial impact on results. |
| Low (score = 3) | Statistical analysis was not described clearly, and this deficiency is likely to have a substantial impact on results. |
| Unacceptable (score = 4) | Statistical methods were not appropriate (e.g., parametric test for non-normally distributed data) **OR** statistical analysis was not conducted **AND** data were not provided preventing an independent statistical analysis. These are serious flaws that make the study unusable. |
| Not Rated/Applicable | |

EPA inconsistently scored similar studies as "High" or "Not Rated" for this metric, and the reasons for the different scores are difficult to comprehend if not contradictory. Indeed, at times, EPA originally scored a study as "High" for this metric and then switched the score to "Not Rated," but we cannot discern the reasons for these various scores or the changes.

Taking the BASF 1975 acute oral toxicity study[54] as an example, OPPT's "statistical methods" metric score was changed from High originally to Not Rated upon reevaluation. The reviewer comment for this metric score states: "Reviewer implied that the investigators did not conduct a statistical analysis."[55]

[53] TSCA systematic review method, p. 203.
[54] BASF, Acute Oral Toxicity Study (1975), Study #9, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035
[55] Updated SR Supplemental File, p. 15.

First, it is entirely unclear what is meant by "reviewer implied." If the comments included in the scoring sheets are provided directly by reviewers, then there would be no need for a reviewer to imply anything – the reviewer simply provides and describes the basis for his or her expert judgment on the matter. This comment suggests that the reviewer comments provided in the study scoring sheets are not in fact the actual comments made by reviewers themselves, which is alarming. Across the data evaluation scoring sheets, the phrase "reviewer implied" occurs eight times for the "statistical methods" metric (as well as twice for the "sampling adequacy" metric[56]), demonstrating that this is not an isolated instance.

More broadly, OPPT scores the "statistical methods" metric inconsistently across studies. For the BASF 1975 acute oral toxicity study, the reviewer comment indicates that statistical analysis was not conducted. Based on similar reviewer comments for this metric in other studies similarly scored, it appears that OPPT assigned a Not Rated score where it believed that statistical analysis was not necessary given the nature of the data provided. For example, for the BASF 2012 *Daphnia Magna*, Acute immobilization test, the reviewer comment accompanying a score of Not Rated for the "statistical methods" metric is "No statistics necessary because the test was conducted as a limit test."[57] For the BASF 1988 Zebra danio acute toxicity study, the reviewer comment accompanying a score of Not Rated for the "statistical methods" metric is "Given that no effects were observed for the one test concentration used in the experiment, no statistics were necessary."[58]

In total, OPPT revised this metric score from High to Not Rated for eight studies. However, OPPT was not consistent in making this change across all studies, as there are instances where the "statistical methods" metric was originally scored High and remained High following EPA's reevaluation, despite those reviewers also having stated that such statistical analyses were not required. For example, Rupprich & Weigand 1984 was given a score of High for the "statistical methods" metric, yet the reviewer comment states, "The data was provided, but statistical analysis is not required." This same outcome occurred for five of the studies OPPT reviewed.[59] If statistical analysis is not required, it would seem EPA should have assigned the same score of

[56] For the BASF 1975 and 1978 acute inhalation toxicity studies, the reviewer comment for the "sampling adequacy" metric is: "Details regarding sampling of outcomes were not reported. Mortality incidence was recorded in the data table at five exposure times (3 min, 10 min, 1 hr, 3 hrs and 7 hrs). The *reviewer implied* that the investigators assessed mortality and clinical signs frequently during the 8-hr exposure, but this was not explicitly explained in the report. Rats were observed for 7 days after cessation of exposure." (emphasis added)
[57] Updated SR Supplemental File p. 11.
[58] Updated SR Supplemental File p. 13.
[59] Rupprich & Weigand, 1984, acute oral toxicity (Study #11); Rupprich & Weigand 1984, acute dermal irritant effects (Study #3); Rupprich & Weigand, acute irritant effects (Study #4); Johnson 1999, local lymph node assay (Study #16); Jung & Weigand 1983, mutagenic potential (Study #14).

Not Rated to this metric for these studies as it did for the BASF 1975 oral toxicity studies and seven others. Instead OPPT rating this data quality metric High in those six cases.

This inconsistency has broader implications for the TSCA systematic review method: it demonstrates that OPPT's current TSCA systematic review method allows for two studies of equivalent experimental design to receive different metric scores for the "statistical methods" metric, and potentially others, if one study contains non-essential, if potentially useful, additional analyses. Significantly, this situation could lead to different overall study quality scores being assigned based on other factors that are not germane to study quality.

*b. "Number per group" metric*

For the two acute inhalation toxicity studies (BASF 1975 and BASF 1978), the "number per group" metric was scored differently despite similar reviewer comments. Originally this metric was scored High for both studies, but upon reevaluation, the 1975 study was given a metric score of Medium while the 1978 study was given a score of Low. The reviewer comments for both studies state: "Number of animals per treatment group/sex was considered adequate for an acute inhalation study."[60] This discrepancy is difficult to understand, and OPPT has not explained it; although it does not affect the overall study quality scores for these studies (since they were both deemed Unacceptable based on other metrics), such inconsistencies are troubling and in future risk evaluations could affect the conclusions that EPA draws from its evaluations of study quality.

*c. "Negative and vehicle controls" metric*

For each of the two acute inhalation toxicity studies (BASF 1975 and BASF 1978), the score for the "negative and vehicle controls" metric was changed from an original score of Not Rated– but to different new scores: In the 1975 study the updated score is Medium, while in the 1978 study the updated score is Unacceptable. Yet the reviewer comment is exactly the same for this score in each of these studies: "The study did not use a vehicle control. The study used a concurrent air control."[61] Here again, OPPT appears to be scoring a metric inconsistently across studies, and provides no explanation for the apparent discrepancy.

*iii. In some cases, OPPT appears to incorrectly assign metric scores, given the TSCA systematic review method's scoring guidelines.*

There are several instances in the updated data evaluation scoring sheets where the score given to a study metric appears to be incorrect based on the scoring guidelines provided in the TSCA systematic review method. The examples below are by no means exhaustive, but are representative of this broader problem. Additionally, any suggestion of a more appropriate score

[60] Updated SR Supplemental file, p. 21 and p. 24.
[61] Updated SR Supplemental file, p. 20 and p. 26.

for a particular metric provided in the examples below is based solely on OPPT's criteria provided in its TSCA systematic review method, and does not in any way represent an endorsement of the criteria or the scoring approach OPPT has adopted.

EPA's failure to apply its own TSCA systematic review method appropriately and consistently to these studies is arbitrary and capricious. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is arbitrary and capricious if the agency "offered an explanation for its decision that runs counter to the evidence before the agency").

*a. "Negative and vehicle controls" metric*

For the BASF 1975 eye irritation study,[62] OPPT assigned a score of High for the "negative and vehicle controls" metric, with the reviewer comment indicating that "[t]he eye treated with talcum powder served as the negative control."[63] No additional comment is provided. However, the OECD 405 test guideline,[64] which according to the ECHA dossier the BASF 1975 eye irritation study is "equivalent or similar to," indicates that the *untreated* eye should be the negative control. According to the TSCA systematic review method, it would seem that this metric should have received a score of Unacceptable.

*b. "Number per group" metric*

The criterion for an Unacceptable score for the "number per group" metric for animal studies is: "The number of animals per study group was not reported OR the number of animals per study group was insufficient to characterize toxicological effects (e.g. 1-2 animals in each group)."[65] For the BASF 1975 skin irritation study, the "number per group" metric was scored Low, even though the reviewer comment notes that "Only two animals were treated".[66] Similarly, this metric was given a score of Medium for the BASF 1975 eye irritation study, despite the reviewer comment stating, "Generally at least three animals are used for eye irritation tests. But in this case, study authors used only 2 animals."[67] It is unclear why these studies were not scored Unacceptable for this metric given that they appear to meet the criterion for Unacceptable per the

[62] BASF, Eye Irritation Study Summary (1975), identified as Study #1 in https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0035.
[63] Updated SR Supplemental File, p. 38.
[64] OECD, Test No. 405: Acute Eye Irritation/Corrosion, at https://www.oecd-ilibrary.org/docserver/9789264185333-en.pdf?expires=1557763716&id=id&accname=guest&checksum=DA9447CBA417623675AE0BF30A282788.
[65] TSCA systematic review method, p. 199.
[66] Updated SR Supplemental File, p. 32.
[67] Updated SR Supplemental File, p. 38.

TSCA systematic review document. It is also unclear why these two studies were scored differently for this metric.

*iv. EPA should provide more explicit criteria and descriptions for the Not Rated/Applicable score determination.*

Currently, it is difficult to gauge whether a score of Not Rated/Applicable is appropriate for a given study quality metric, as non-specific criteria in the TSCA systematic review method are provided for this rating.[68] Just as OPPT has specified criteria for scoring metrics High, Medium, Low, or Unacceptable, it should have clear criteria for scoring a metric as Not Rated/Applicable (e.g., when the particular conditions of a study make the metric unnecessary). At a minimum, reviewers should provide more detail in comments when a score of Not Rated/Applicable is assigned for a metric especially given the current lack of criteria for this score in the TSCA systematic review method.

### D. EPA has failed to provide the original reviewer comments, and the Agency's original concerns about CBI in reviewer comments appear unwarranted.

As noted in subsection C.i., numerous scoring changes were made following OPPT's reevaluation of study quality for PV29. Given the extent of these changes and the questions we have raised about the lack of accuracy and consistency in EPA's current study evaluation process, it is critical for the public to be able to understand why the score changes were made. To that end, EPA must make publicly available a complete record of reviewer comments.

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[68] Appendix A, Strategy for Assessing the Quality of Data/Information Supporting Risk Evaluations, of the TSCA systematic review method (https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf) provides a very generic discussion of when a score of Not rated/applicable is given: "Rating of this metric is not applicable to the data/information source being evaluated [no score]. Not rated/applicable will also be used in cases in which studies cite a literature source for their test methodology instead of providing detailed descriptions. In these circumstances, EPA will score the metric as Not rated/not applicable and capture it in the reviewer's notes. If the data/information source is not classified as "unacceptable" in the initial review, the cited literature source will be reviewed during a subsequent evaluation step and the metric will be rated at that time." (TSCA systematic review method. p. 33).

However, the specific guidance for scoring individual metrics for animal toxicity studies, provided for in Table G-14, Data Quality Criteria for Animal Toxicity Studies, provides no direction on when a metric should be scored Not rated/applicable (TSCA systematic review method document, pp. 190-204). Taken together, OPPT has provided insufficient detail for when Not rated/applicable should be assigned for any particular data quality metric.

OPPT asserted CBI concerns to justify withholding reviewer comments from its original data evaluation scoring sheets for PV29. Specifically, the introduction to the updated data evaluation scoring sheets states that "the EPA initially released the SR Supplemental File without the EPA's reviewer comments on the metric score determinations due to concerns that the comments might have CBI information."[69] However, upon reviewing the reviewer comments from the reevaluation EPA has now made public, it is difficult to glean any basis for the initial concerns about CBI information. None of the reviewer comments even approach constituting CBI, suggesting that EPA's original justification for not making reviewer comments publicly available lacks basis. Even were there such a basis, EPA could have redacted any CBI content from the comments, rather than withholding them in toto.

### E. It is unclear whether EPA is using at least two reviewers to evaluate each study, as is consistent with best practices in systematic review.

In its TSCA systematic review method, OPPT stated that it aimed to have two reviewers evaluate each study, yet indicated that this might not always be the case, stating: "Ideally, each data/information source will be screened by two reviewers, but one reviewer may be used."[70] As EDF wrote in our comments on the TSCA systematic review method,[71] the use of at least two reviewers is a standard practice in systematic review that has been shown empirically to reduce bias, and EPA should be applying this practice for all studies that it reviews.

Despite the agency's own goal of having two reviewers per study, it appears that EPA may have relied on only one reviewer to evaluate each study in the reevaluation of the PV29 studies. All references to reviewer input in the April 4, 2019 Transmittal Memo for Updated SR Documents say "reviewer's comments," which implies there was just one reviewer. Additionally, for the statistical methods metric multiple comments state, "Reviewer implied that the investigators did not conduct a statistical analysis," and the use of the singular again suggests that only one reviewer evaluated these studies.

As described in subsection C, EPA's reevaluation of the body of evidence for PV29 led to many changes to both metric and overall study scores. In addition to reducing reviewer bias, using two reviewers could have improved the accuracy and consistency of the initial score determinations. As noted by the Institute of Medicine in its standards for systematic review in healthcare: "Without two screeners, SRs may miss relevant data that might affect conclusions about the effectiveness of an intervention. Edwards and colleagues (2002), for example, found that using

[69] Updated SR Supplemental File, p. 1.
[70] TSCA systematic review method, p. 26.
[71] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, p. 26, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.

two reviewers may reduce the likelihood that relevant studies are discarded."[72] Going forward, EPA should work to ensure that studies are evaluated by at least two reviewers. This would not only be in alignment with best practices in systematic review, but would likely reduce the frequency of scoring errors.

### F. EPA's reevaluation of studies for PV29 does not address fundamental problems with OPPT's TSCA systematic review method, and its application to PV29, that have been enumerated in prior public comments submitted to EPA.

As EDF detailed in our earlier comments to the Agency,[73] OPPT's TSCA systematic review method is not consistent with best practices in systematic review, including those empirically-derived and recommended by systematic review experts at the National Academy of Sciences (NAS),[74] in academia,[75] and across government chemical assessment programs.[76] In particular, EPA's decision to adopt a numerical scoring approach with weighted metrics is explicitly advised against by leading experts and frameworks across the systematic review field. According to best practices and authoritative sources on systematic review, the use of numerical scoring and weighting to arrive at an overall study score is not supported by empirical evidence, cannot be validated, and is "nearly impossible to justify."[77] As we also noted in our prior comments, the TSCA systematic review method includes numerous metrics that reflect reporting quality rather than study quality, which places undue emphasis on whether or not study details are reported rather than on how well a study is designed.

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[72] Inst. of Med. of the Nat'l Acads., *Finding What Works in Health Care: Standards for Systematic Reviews* at chp. 3, p. 112 (Mar. 2011), https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0079446/.

[73] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.

[74] Nat'l Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process (2014), https://www.ncbi.nlm.nih.gov/books/NBK230072/.

[75] Navigation Guide, https://prhe.ucsf.edu/navigation-guide (last visited Aug. 15, 2018); Tracey J. Woodruff, et al., An Evidence-Based Medicine Methodology to Bridge the Gap Between Clinical and Environmental Health Sciences, 30:5 HEALTH AFFAIRS 931 (May 2011), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2010.1219?siteid=healthaff&keytype=ref&ijkey=z58MCEPW2X49.&.

[76] U.S. Dep't of Health & Human Servs., Nat'l Toxicology Program, Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration (Jan. 2015), https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf.

[77] Nat'l Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process (2014), https://www.ncbi.nlm.nih.gov/books/NBK230072/.

For PV29, OPPT also relied heavily on personal communications with industry representatives to draw its conclusions of low release and exposure, despite the fact that the agency readily admitted that its TSCA systematic review method is ill-suited for this type of information.[78] Instead, OPPT simply chose not to evaluate the quality of such information at all. EDF maintains that EPA cannot rely on such unsubstantiated and undisclosed information in its risk evaluations and should instead use its information authorities to fill such information gaps with actual data.

For further discussion of these and other concerns associated with the TSCA systematic review method, we refer EPA to EDF's comments on the draft risk evaluation for PV29[79] and on the TSCA systematic review method.[80]

In its April 4, 2019 Transmittal Memo for Updated SR Documents, OPPT indicates that, following its reevaluation of the evidence base for PV29, the Agency made changes to its systematic review process, stating that "public input was valuable in that it led to review of our systematic review process and revealed both process and technical inconsistencies which led EPA to implement procedures for further optimization."[81] However, OPPT does not describe these "procedures for further optimization" beyond vaguely stating that the Agency "has made improvements in our quality assurance procedures and training of reviewers."[82] OPPT should provide more detail regarding the specific improvements made if public confidence in its ability to evaluate study quality is to improve.

Finally, the fundamental flaws that continue to plague OPPT's study evaluation approach and the numerous score changes, inconsistencies, and apparent errors in its the reapplication of its approach for PV29 (see section III above) lend even greater urgency to the need for EPA to immediately initiate an independent peer review of its TSCA systematic review method by the National Academy of Sciences and use the feedback to revise its review process to align with best practices in systematic review. In a January 4, 2019, letter to Senator Tom Carper, EPA Administrator Andrew Wheeler committed to promptly subjecting the TSCA systematic review

[78] On page 18 of the PV29 draft risk evaluation, EPA states that its systematic review approach "is not well suited for the review" of such "correspondences with industry … used to inform the likelihood of exposure," and "[a]s a result, formal data quality evaluation of these references according to the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018a) was not conducted."
[79] EDF comments on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29, January 14, 2019, p. 77, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0013.
[80] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations, August 16, 2018, at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.
[81] April 4, 2019 Transmittal Memo for Updated SR Documents, p. 2.
[82] April 4, 2019 Transmittal Memo for Updated SR Documents, p. 2.

method to NAS peer review.[83] The agency has yet to initiate the NAS review and should do so immediately.

## 5. In contrast to EPA's asserted clean bill of health for PV29, authorities under REACH have formally declared it a suspected PBT and suspected vPvB, and hence a suspected substance of very high concern.

In our earlier comments, EDF noted that PV29 had been proposed to be listed under the European Union's REACH Regulation as a suspected "substance of very high concern" (SVHC). More specifically, its proposed listing was as a "suspected PBT/vPvB" that would undergo a full substance evaluation in 2021.[84]

At the time, we noted that EDF had not yet been able to obtain more detail on the basis for this proposed listing of PV29. But on March 19, 2019, ECHA published an update to its Community Rolling Action Plan (CoRAP) that formally lists PV29 as a chemical to be subject to a full substance evaluation and confirms its designation as a "suspected PBT/vPvB."[85] The listing is accompanied by a "justification document" for PV29's designation.[86]

The justification document, prepared by the Belgian Competent Authority (BE CA) under REACH and endorsed by REACH authorities, echoes many of the concerns about PV29 and EPA's draft risk evaluation that EDF had raised in our earlier comments.

First, BE CA notes that "the registrants [of the chemical under REACH] state in their dossier that the substance[] [is] neither soluble in water nor soluble in organic solvents, therefore a very low

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[83] The letter is available at http://src.bna.com/Ese.

[84] European Chemicals Agency, *Draft Community Rolling Action Plan (CoRAP) update for years 2019-2021*, p. 22 (Oct. 2018), at https://echa.europa.eu/documents/10162/13628/corap_list_2019-2021_en.pdf/3be44b84-5d72-01fe-f8d7-3a5a9c27951e. "PBT" stands for persistent, bioaccumulative and toxic; and "vPvB" stands for very persistent and very bioaccumulative. Substances meeting either of these designations are deemed to be "substances of very high concern" (SVHCs) under the REACH Regulation. Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, title VII, 2006 O.J. (L 396), at http://data.europa.eu/eli/reg/2006/1907/2018-03-01.

[85] European Chemicals Agency, Community rolling action plan (CoRAP) update covering the years 2019, 2020 and 2021, March 19, 2019, at https://echa.europa.eu/documents/10162/13628/corap_update_2019-2021_en.pdf/12451cec-ce6e-d156-5fef-7d09cb77b324.

[86] Belgian Competent Authority (BE CA) under REACH, Justification Document for the Selection of a CoRAP Substance, March 19, 2019, at https://echa.europa.eu/documents/10162/387374b8-62fa-c857-e60f-65e1cd9fd821.

bioavailability is expected." But with respect to water solubility, BE CA goes on to state that it considers "the reliability of the water solubility and partition coefficient data for [PV29] as questionable" due to the divergence of values derived from both direct measurements and estimations using predictive models.

The Belgian authority specifically questions the registrants' reliance on the single value of 0.01 milligrams per liter – the very same value EPA relies on extensively in its draft risk evaluation to dismiss a host of potential concerns. (We note with particular concern, the registrants' selective deletion of much higher water solubility values for PV29 from two study summaries in its dossier, discussed in section 3 of these comments.)

BE CA concludes: "Because the estimated values substantially diverge from the value given in the registration dossier and because water solubility is a crucial element, it seems appropriate not to use the value presented by [the registrants] as an argument to deny the B-[bioaccumulation] concern."

Regarding solubility in organic solvents (an indirect measure of fat solubility and hence bioaccumulation potential), BE CA raises similar concerns about the lack of measured data and the variability of model estimates and concludes that "a reliable conclusion on the bioavailability of this substance is not possible based on the currently available data."

BE CA flags as a concern the lack of experimental data on bioaccumulation in aquatic or terrestrial organisms. It also points to other data, including estimates of PV29's octanol-air partition coefficient, that suggests potential for bioaccumulation in air-breathing terrestrial organisms, including mammals.

Regarding persistence, BE CA states: "Screening information does not indicate (bio)degradation. In view of the structure of the substance[], it is reasonable to expect that the P and the vP criterion are met for [this] substance[] and [structure-activity relationship] estimations support this concern." The Belgian authority also notes that the registrants' assessment "does not consider the possibility that in field conditions (slow) degradation of the parent compounds takes place."

BE CA then notes the dearth of ecotoxicity data for PV29 other than for acute aquatic toxicity. Pointing to the substance's "wide dispersive use, high tonnage and the environmental exposure," BE CA concludes that a "potential risk [to] the environment cannot be excluded."

Finally, BE CA identifies numerous additional needed data on toxicity, fate and behavior, and physical-chemical properties, consistent with our flagging of major data gaps that have not been acknowledged or addressed by EPA.

In finalizing its risk evaluation, EPA needs to take seriously and forthrightly address the data gaps, uncertainties and potential risks of PV29 including those flagged by EU authorities, rather than continue to rely on poor analysis and wholly insufficient information to support its unfounded assertion that the substance does not present any unreasonable risks.

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EDF appreciates the opportunity to provide comments and EPA's consideration of them.