



**Environmental Defense Fund Comments on
Modification of Significant New Use of a Certain Chemical Substance
EPA-HQ-OPPT-2011-0941
PMN P-03-325 & SNUN S-17-4
Submitted March 12, 2018**

Introduction

EPA is proposing to amend the significant new use rule (SNUR) promulgated in 2012 under § 5(a)(2) of the Toxic Substances Control Act (TSCA) for Oxazolidine, 3,3'-methylenebis[5- methyl- (CAS number: 66204-44-2; 40 C.F.R. § 721.10461), which was the subject of a 2003 premanufacture notice (PMN), a 2017 significant new use notice (SNUN) and a 2017 Consent Order signed by EPA and Schulke, Inc. 83 Fed. Reg. 5598, 5599-600 (Feb. 8, 2018). This action would amend the SNUR to allow certain new uses reported in the SNUN without requiring prior notification to EPA. *Id.* at 5600. On behalf of our members, supporters, and organization, Environmental Defense Fund (EDF) requests that EPA update its analysis to reflect all reasonably available information, place that information in the docket, and fully and publicly respond in writing to all of the issues identified herein before reaching any final decision on this amendment to the SNUR. Based on the available information and analysis, the amended SNUR may not comply with TSCA and EPA has not demonstrated that it will be sufficiently protective.

As discussed in more detail in these comments, EPA needs to more fully and transparently document and justify the exposure assumptions it used as the basis for conditions included in the proposed amended SNUR in order to demonstrate the adequacy of those conditions. Once it has done so, those assumptions need to be codified in the final amended SNUR as additional conditions that would trigger prior notification to EPA should a manufacturer or processor intend to deviate from them. EDF identifies those conditions in Part IV.b. EPA also should exercise its authority to require submission of records required to be kept under the amended SNUR (as well as under the Consent Order), both to validate its assumptions and to ensure compliance with conditions imposed based on those assumptions.

EPA needs to enhance the SNUR's worker protection requirements. The final amended SNUR must include all relevant requirements included in the Consent Order, which the current proposal has failed to do. EDF identifies the additional needed provisions in Part III. The precautionary statements on container labels that EPA has required under the Consent Order, and that would be incorporated in the amended SNUR, are inadequate and incomplete and should be rectified by the agency. EDF identifies the additional hazards that need to be identified on the labels in Part IV.f.

Finally, it does not appear that EPA has made any effort to account for other sources of formaldehyde exposures to workers using the SNUN substance. EPA needs to fully account for and address such exposures in finalizing the amended SNUR.

EDF acknowledges EPA's partial grant of our request for an extension and EPA's partial effort to complete the record.¹ Nonetheless, EPA did not provide EDF with the full time requested and warranted, did not provide anything approaching a complete record in the docket for this rulemaking, and also failed to rectify several of the procedural violations identified in that Request, leaving this SNUR legally vulnerable. EDF incorporates those prior comments identifying procedural issues by reference, and in Part V EDF briefly reiterates some of those points and advises EPA to resolve them in future rulemakings.

EDF notes that its comments are significantly constrained by the short timeframe and the lack of clarity in EPA's decision and record documents. In addition, the incomplete record greatly hampered our efforts. EPA did not disclose all of the relevant records identified in EDF's original request (see Part V) and EDF discovered that numerous additional relevant materials related to this chemical that are present in a separate EPA docket or that we identified through internet searches (see Part II), but are not included or referenced in any manner by EPA in this rulemaking docket. EDF only discovered many of those materials on March 8th and had limited time to review them.

Put colloquially, even where EPA may have done its homework, EPA did not document it clearly for the public and did not turn it in. *See, e.g., Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 48 (1983) (requiring an agency to "cogently explain why it has exercised its discretion in a given manner"); *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196-97 (1947) ("It will not do for a court to be compelled to guess at the theory underlying the agency's action ***.").

Nonetheless, EDF has done its best to provide accurate comments in these circumstances.

EDF notes that many of the concerns and specific comments we raise herein about the proposed amended SNUR also apply to the Consent Order. EPA should consider the need to revisit the terms of that Consent Order after evaluating these comments.

¹ *See* EDF Request for an Extension of the Comment Period on Modification of Significant New Use of a Certain Chemical Substance (Feb. 12, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0189>.

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I. Legal & factual background: When amending a SNUR, EPA must consider all reasonably available information, including hazard and exposure information, as well as the TSCA § 5(a)(2) factors.

TSCA § 26(k) requires that in carrying out § 5, EPA must consider “[r]easonably available information,” and specifically that EPA “shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to [EPA].” 15 U.S.C. § 2625(k). Thus, when amending a SNUR under TSCA § 5, EPA must consider all reasonably available “hazard and exposure information.” *Id.*

In addition, under TSCA § 5(a)(2), EPA must “consider[] all relevant factors,” including:

- (A) the projected volume of manufacturing and processing of a chemical substance,
- (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
- (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

15 U.S.C. § 2604(a)(2).

In the original SNUR, EPA “determined *** that use of the substance other than as a metalworking fluid, or any use of the substance resulting in surface water concentrations exceeding the freshwater and saltwater concentrations of concern may cause serious health effects and significant adverse environmental effects.” 77 Fed. Reg. 58,666, 58,675-76 (Sept. 21, 2012). Thus, EPA required the reporting of any use beyond use in metalworking fluid or exceeding those water concentrations as a significant new use. *See id.*

In the proposed amendment, EPA would allow use of the SNUN substance as “an anti-corrosive agent in oilfield operations and hydraulic fluids” without prior notification as long as the use meets certain workplace and other conditions. 83 Fed. Reg. 5598, 5600 (Feb. 8, 2018).

As explained below, the record does not establish that EPA has considered all reasonably available hazard and exposure information relevant to this new use.

II. EPA has failed to consider all reasonably available information and to consider relevant aspects of the problem.

Based on the record in the public docket, EPA’s proposed amendment to the SNUR ignores reasonably available information about this chemical, and it entirely fails to address numerous important issues raised by the amendment. As explained in more detail below, EDF has discovered that a product containing this chemical as an active ingredient is proposed to be registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), apparently for use “for fuel preservation in fuel storage tanks and pipelines.”² The most recent applicable FIFRA Master Label describes several types of uses and states that the product containing it is used “in oil and gas operating systems.”³ The information on this substance that EPA received and developed under FIFRA is relevant to EPA’s analysis under TSCA of the chemical’s proposed new uses in oilfield operations and hydraulic fluids. But EPA has neither included nor made any reference whatsoever to that FIFRA information in the docket, nor is there any evidence that has EPA included it in its analysis when proposing to amend the SNUR. Indeed, the proposal never mentions the word “FIFRA.” *See* 83 Fed. Reg. 5598. Nor, to the best of our knowledge, do any of the other documents in the docket. The proposal fails to identify and reconcile the differences between the restrictions imposed under FIFRA and the conditions

² EPA OPP, Memorandum In Lieu of FR Notice for Stabicide 71 Public Participation (June 20, 2013), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0997-0002>; *see also* EPA OPP, Oxazolidine, 3,3'-methylenebis[5-methyl-, https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:3:::NO::P3_XCHEMICAL_ID:3189 (Latest Registration Process: Pending Registration) (CAS number: 66204-44-2).

³ Master Label, grotamar® 71 & stabicide® 71 at p.1 (Jan. 29, 2018), https://www3.epa.gov/pesticides/chem_search/ppls/085808-00001-20180129.pdf.

requiring notification under the proposed amendment to the SNUR. The proposal also fails to address this chemical's biocidal properties, but these are relevant considerations with respect to potential environmental effects.

In addition, EDF has found evidence that the chemical has been marketed and sold for non-SNUR uses in the United States during the period *after* EPA had issued the initial SNUR for it and *prior* to EPA's receipt of the SNUN at issue here. These preexisting uses would have provided an opportunity to obtain real-world hazard and exposure information. In addition, these uses raise a concern that some uses may have violated TSCA because companies may have engaged in significant new uses without notifying EPA as required by TSCA § 5 and the SNUR. Failing to consider any of this reasonable available information violates EPA's statutory duties and is arbitrary and capricious.

As noted above, TSCA § 26(k) requires that in carrying out § 5, EPA must consider "[r]easonably available information." 15 U.S.C. § 2625(k). In a recent regulation, EPA interpreted "[r]easonably available information" in § 26(k) to include "information that EPA possesses." 40 C.F.R. § 702.33 (promulgated at 82 Fed. Reg. 33,726, 33,748 (July 20, 2017)) (emphasis added).⁴ EPA "possesses" the information submitted to or developed by EPA as part of the FIFRA program, even if it is a separate program from the TSCA program.

First, in the proposal to amend the SNUR, EPA fails to reference the information or analyses EPA obtained or developed through the FIFRA program. The TSCA docket also appears not to contain these materials. The FIFRA docket appears at: <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0997>. The FIFRA docket includes reasonably available hazard and exposure information that EPA needed to consider when deciding whether to amend the SNUR. For example, the FIFRA docket includes an occupational and residential exposure and risk assessment for the chemical.⁵ This document states that: "The toxicology database for Stabicide 71 includes an acute dermal toxicity study, three mutagenicity studies, an oral prenatal developmental study in rabbits and a 90 [*sic*] oral toxicity study in rats."⁶ Yet we did not find any reference to this assessment in the TSCA docket, nor to the oral prenatal developmental study in rabbits, nor to the other studies it cites, with the possible exception of acute dermal toxicity (such a study was included as an attachment to the original 2003 PMN for the SNUN substance). Similarly, this FIFRA assessment states that: "Handlers will be exposed to formaldehyde during the addition of Stabicide 71 to drilling muds and diesel fuels."⁷ This information and any information on which this statement is based is relevant to analyzing the risks of the proposed new use under TSCA, but EPA did not include the assessment or

⁴ While that regulation applies to risk evaluations, 40 C.F.R. § 702.31, EPA adopted this interpretation of § 26(k) with the knowledge that it would apply more broadly. *See* 82 Fed. Reg. 33,748, 33,731 (July 20, 2017). In addition, information that EPA possesses is reasonably available under any interpretation of that language.

⁵ EPA OPP, Occupational and Residential Exposure and Risk Assessment for the New Active Ingredient N, N'-methylenebis (5-methyloxazolidin) (Stabicide 71) (June 28, 2010), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0997-0011>.

⁶ *Id.* at 2.

⁷ *Id.*

related information in its TSCA docket. Based on an initial review, it appears that the FIFRA record contains extensive hazard and exposure information and analyses—including toxicity and worker exposure studies—that are directly relevant to the proposal to amend the SNUR, but EPA failed to consider or even make reference to the existence of that information. In doing so, EPA violated its duty to consider “[r]easonably available information” under TSCA § 26(k). If EPA did consider this information, EPA should have included it and the associated analysis of it in the docket and record for this decision.

Second, EPA has not reconciled why some of the restrictions imposed under FIFRA appear to be more stringent than the conditions for notification in the SNUR. As a result, there is a risk that companies will try to elude their obligations under FIFRA by pointing to the SNUR’s conditions. Based on our initial review, companies could comply with their obligations under both statutes by following the more restrictive conditions in each instance, but EPA should make that obligation clear.

For example, under the current FIFRA label, companies appear to be foreclosed from applying this chemical to water, or areas where surface water is present, and companies are forbidden to contaminate water when disposing of the chemical.⁸ The proposed amended SNUR would allow limited discharges to water without notification. *See* 83 Fed. Reg. at 5602. Similarly, the current FIFRA labels state that the containers holding these chemicals may not be reused or refilled.⁹ This restriction does not appear in the SNUR. Given that EPA found these restrictions necessary in the context of the FIFRA use and labelling, EPA should similarly make them conditions of a SNUR. Alternatively, at a minimum, EPA should explain why they are unnecessary in this context. EPA should also clarify that these requirements cannot be evaded because of the SNUR.

Third, the FIFRA registration label identifies this chemical as a “microbiocide.”¹⁰ But, based on our review of the record, the TSCA docket makes no mention of this functional property of the SNUN substance; nor does it contain *any* analysis of the associated environmental effects. Instead, the TSCA record indicates that this chemical provides anticorrosive benefits “by forming a film within the equipment that prevents corrosion on metal surfaces.”¹¹ In addition, “a reaction product of [this chemical] and H₂S [hydrogen sulfide] is dithiazine which is a well known corrosion inhibitor.”¹² Hence, it appears that the SNUN substance imparts its anti-corrosive effect through two distinct means, one biological (the result of its microbiocidal properties) and one strictly chemical (that just described). This circumstance makes it all the more important and appropriate that EPA should assemble a complete record

⁸ *See* Master Label, grotamar® 71 & stabcide® 71 at 1-2 (Jan. 29, 2018), https://www3.epa.gov/pesticides/chem_search/ppls/085808-00001-20180129.pdf.

⁹ *See id.* at 3.

¹⁰ *Id.* at 1.

¹¹ EPA-HQ-OPPT-2011-0941-0191, Attachment # 3, Environmental Benefits of using MBO in both hydraulic fluids and petroleum operations, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0190>.

¹² *Id.*

drawing information received and analysis gleaned about both its FIFRA and TSCA uses in evaluating its potential risks.

In addition, while EPA may have concluded that risks posed by the SNUN substance's microbiocidal properties are reasonable (and they arguably pale in comparison to the numerous other toxic effects of this chemical), nothing in the TSCA record indicates it has done so. EPA needs to at least analyze the environmental effects associated with the substance's microbiocidal properties when deciding whether to amend the SNUR.

Fourth, EDF has found evidence that this chemical was marketed and used in the United States for non-SNUR uses *after* EPA published the SNUR and *before* EPA received the SNUN. Information about these uses is relevant to the decision to amend the SNUR for several reasons.

Many of these uses refer to the chemical's use as a microbiocide, and they may or may not have been covered by FIFRA; EDF cannot express any position on that issue in the available timeframe. But these uses appear very similar to the uses at issue here. For example, the most recent FIFRA Master Label for this chemical states that the product containing it "is recommended for the decontamination and control of microorganisms in oil and gas operating systems," and the label directs people to add the chemical "to drilling fluids, workover fluids, well completion fluids, packer fluids, hydraulic fracturing fluids, hydrotest fluids in closed system tanks and pipelines via closed system dosing."¹³ These uses are similar to the new uses that will be allowed under the proposed amendment to the SNUR, which would allow use as "an anti-corrosive agent in oilfield operations and hydraulic fluids" under certain conditions without prior notification. 83 Fed. Reg. 5598, 5602 (Feb. 23, 2018) (to be codified at 40 C.F.R. § 721.10461(a)(2)(iii)).

Given the existence of ongoing uses of the SNUN substance that are similar to (or the same as) those considered in the SNUR, EPA should have collected and analyzed reasonably available information based on those ongoing uses. EPA's decision not to do so is unreasonable. Given the similarity of the uses, the information from the FIFRA uses is indisputably relevant to EPA's decision to amend the SNUR.

In addition, some evidence suggests that companies may be using this chemical in violation of the SNUR. For example, we have attached a Safety Data Sheet for Phillips 66 Quintolubric® 818-02 dated June 22, 2016, *after* EPA published the SNUR and *before* EPA received the SNUN.¹⁴ This Safety Data Sheet identifies the relevant use as "Hydraulic Fluid," and the Manufacturer/Supplier's address is in Houston, TX.¹⁵ It identifies 3,3'-Methylenebis(5-methyloxazolidine) CASRN: 66204-44-2 as an ingredient.¹⁶ "Phillips 66® Quintolubric 818-02 is a synthetic, high water content anti-wear hydraulic fluid concentrate developed for use in hydraulic systems operating in areas subject to fire hazards, such as in steel mills, foundries, and

¹³ Master Label, grotamar® 71 & stabicide® 71 at 1 (Jan. 29, 2018), https://www3.epa.gov/pesticides/chem_search/ppls/085808-00001-20180129.pdf.

¹⁴ See Attachment A.

¹⁵ *Id.* at 1.

¹⁶ *Id.*

underground mining equipment.”¹⁷ This description, particularly the reference to underground mining equipment, seems to advertise the use of this chemical beyond uses as “metalworking fluid,” so it seems that the company should have notified EPA before engaging in that use. *See* 77 Fed. Reg. 58,666, 58,696 (Sept. 21, 2012) (codified at 40 C.F.R. § 721.10461). EDF is unaware of any evidence that the company submitted a SNUN. It is also not clear that the use is authorized under FIFRA; the SDS makes no mention of an EPA registration or the applicability of any requirements under FIFRA.

Given that EDF managed to find information on ongoing uses, including potential violations of the prior SNUR, in the limited time available during this comment period, EPA should have identified these uses and potential violations as well. EPA needed to consider this use and compliance information because it is relevant to whether EPA should expand the authorized uses for this chemical. Existing uses of the SNUN substance that could already be resulting in worker exposures should have been taken into account in analyzing the additional exposures that could arise under the amended SNUR. Allowing more uses without notification only increases the risk that the use of the chemical will expand to additional, unauthorized uses. In addition, these uses would provide an opportunity for EPA to obtain available information on exposure and hazard.

In sum, EPA has failed to consider all reasonably available information. EPA’s failure to identify or analyze any of these issues reflects a failure to consider important aspects of the problem presented by the decision to amend the SNUR.

III. EPA needs to enhance the SNUR’s worker protection requirements.

a. EPA should enhance the SNUR’s incorporation of the industrial hygiene hierarchy of controls.

The industrial hygiene hierarchy of controls (HOC) – under which engineering, work practice, and administrative controls are to be the primary means used to reduce employee exposure to occupational hazards – is well-established as the preferred approach to managing chemical and other risks in workplaces. The HOC is a basic tenet of industrial hygiene,¹⁸ as well as a longstanding foundational element of the Occupational Safety and Health Administration’s (OSHA) workplace safety policy¹⁹ and of the National Institute for Occupational Safety and Health’s (NIOSH) workplace safety guidance.²⁰

¹⁷ QUINTOLUBRIC® 818-02, <https://www.phillips66lubricants.com/product/quintolubric-818-02> (last visited Mar. 12, 2018).

¹⁸ *See* OSHA, Informational Booklet on Industrial Hygiene (1998), [https://www.osha.gov/Publications/OSHA3143/OSHA3143.htm#How do](https://www.osha.gov/Publications/OSHA3143/OSHA3143.htm#How%20do).

¹⁹ *See* CHEMICAL HAZARDS AND TOXIC SUBSTANCES, CONTROLLING EXPOSURES, <https://www.osha.gov/SLTC/hazardoustoxicsubstances/control.html> (last visited Mar. 12, 2018).

²⁰ *See* WORKPLACE SAFETY AND HEALTH TOPICS, HIERARCHY OF CONTROLS, <https://www.cdc.gov/niosh/topics/hierarchy/> (last visited Mar. 12, 2018).

EDF largely supported EPA's October 2016 proposed changes²¹ to its general regulations governing Significant New Use Rules (SNURs), which would have designated as a significant new use of a chemical a company's failure to implement, where feasible, the HOC to protect workers.²² While this proposed rule has yet to be finalized, we recognize and support EPA's decision to apply these tenets in the current proposed modifications to this specific SNUR by incorporating the preference for use of engineering and administrative control measures and designating the unloading, processing, or use of the substance other than in fully enclosed equipment to be a significant new use.

However, consistent with our earlier comments, EDF is concerned about the use of the language "where feasible." The current proposed SNUR specifies that:

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (3), (4) (use of the respirator only applies to inhalation exposures to the substance when manufactured in the United States), when determining which persons are reasonably likely to be exposed as required for §721.63 (a)(1) and (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, *where feasible*, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6)(v), (vi), (b) (concentration set at 0.1 percent), and (c). It is a significant new use for the substance to be unloaded, processed and used other than with fully enclosed equipment. (emphasis added)

In our earlier comments, EDF urged EPA either to clarify that its references to "feasible" have the same meaning as does that term in the Occupational Safety and Health Act,²³ or to conform its language to directly mirror that of the OSH Act or OSHA's regulation ("to the extent feasible" or "as far as feasible"). We noted that the term "feasible" has been held by the Supreme Court to mean "capable of being done." *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 508-09 (1981). The Court specifically rejected an argument that determining feasibility requires OSHA to weigh costs versus benefits. *Id.* at 509-12. We urged EPA to confirm in its final rule, consistent with the Supreme Court's decision, that the requirement to consider and implement the hierarchy of controls where "feasible" applies wherever it is "capable of being done," regardless of cost.

EDF incorporates our earlier comments herein by reference. Given that EPA has not yet finalized that proposed rule – and thus has not to date clarified the intent of the "feasibility"

²¹ See 81 Fed. Reg. 49598 (July 28, 2016), <https://www.federalregister.gov/documents/2016/07/28/2016-15005/significant-new-uses-of-chemical-substances-updates-to-the-hazard-communication-program-and>.

²² See EDF Comment on EPA's Proposed SNUR Regulations (Nov. 21, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052>.

²³ 29 U.S.C. § 655(b)(5).

language – EDF recommends strengthening the language in the current amended SNUR through one of the means just described. Otherwise, the current language (“engineering control measures *** or administrative control measures *** shall be considered and implemented to prevent exposure, where feasible”) would allow a manufacturer or processor of the chemical to simply assert that they considered such measures but decided they were not feasible. This could in turn lead them to decide on their own that use of the chemical without engineering or administrative controls would not constitute a significant new use requiring filing of a SNUN, in which case EPA would not have the opportunity to review such use and that associated claim of infeasibility. In other words, EPA would be forgoing its authority to review uses of the chemical where engineering or administrative controls are not employed.

b. Personal protective clothing testing and use requirements in the SNUR are not as protective as those in the Consent Order.

EPA must ensure that the final amended SNUR directly mirrors the requirements set forth in the Consent Order so that new manufacturers or processors must notify EPA if they intend to deviate from any of the requirements that apply to the current SNUN submitter (Schulke, Inc.). In at least one respect, it appears that the proposed amended SNUR is less protective than the associated Consent Order (i.e., some of the conditions that new manufacturers or processors must comply with to avoid notifying EPA appear to be less stringent than those established in the Consent Order).

The Consent Order has more stringent requirements for personal protective clothing and gloves than the proposed amended SNUR. While the proposed SNUR does require (by cross-reference) permeation testing for chemical protective clothing (or alternatively, evaluation of the specifications from the manufacturer/supplier of the chemical protective clothing),²⁴ it appears to stop short of the requirements applicable to testing and use in the Consent Order. Specifically, the following requirements are included in the Consent Order but are not listed as conditions in the proposed amended SNUR:

Permeation testing must be conducted according to the American Society for Testing and Materials (“ASTM”) F739 “Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact.” Results must be reported as the cumulative permeation rate as a function of time, and must be documented in accordance with ASTM F739 using the format specified in ASTM F 1194-99(2010) “Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials.” Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the SNUN substance.²⁵

²⁴ See 40 C.F.R. § 721.3 (“Chemical protective clothing” is defined to include, but not limited to, full body protective clothing, boots, coveralls, gloves, jackets, and pants).

²⁵ EPA-HQ-OPPT-2011-0941-0184, Sanitized Consent Order 7-8 (Oct. 31, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0184> (“Consent Order”).

In finalizing the amended SNUR, EPA needs to incorporate such language to ensure that new manufacturers and processors will comply with ASTM methods for permeation testing and that gloves are used only for the duration analyzed through such permeation testing.

c. Respirators need to be required for processing and other downstream uses as well as in manufacturing settings.

It appears that the proposed amended SNUR would, to avoid triggering notification, only require manufacturers – but not processors – to provide workers with respiratory protection during manufacture of the SNUN substance. The proposed amended SNUR states: “use of the respirator only applies to inhalation exposures to the substance when manufactured in the United States.” 83 Fed. Reg. at 5602. Why are respirators only required for manufacturing in the U.S. and not processing or other downstream uses? How will EPA ensure that oil field workers processing or utilizing this substance are adequately protected from airborne exposure to the substance? Were oilfield workers considered in any risk assessment EPA conducted to develop the Consent Order and associated SNUR?²⁶ If so, was respiratory protection assumed? Given the clear health hazards from inhalation exposure to formaldehyde and the fact that TSCA allows EPA to impose conditions on manufacturers and processors through SNURs, it is unclear why EPA has not required respirator use in such settings.

We note that this same concern applies to the Consent Order. EPA should consider amending the Consent Order to rectify this problem.

IV. EPA has not explained and justified its exposure assumptions and has not fully and adequately incorporated them into the proposed amended SNUR.

EPA is proposing to amend the SNUR to expand the uses of the SNUN substance that do not require prior notification to and review by EPA. The uses allowed in the amended SNUR would be expanded beyond that in the original 2012 SNUR – use in metalworking fluid – to include use as an anti-corrosive agent in oilfield operations and hydraulic fluid as long as certain conditions that parallel most of those imposed by the Consent Order are complied with. Specifically, the amended SNUR “requires the SNUN submitter to provide personal protective equipment and respirators to workers to prevent dermal and inhalation exposure, refrain from unloading, processing, or using the substance without using enclosed equipment or systems, label containers and provide worker training, and use the substance only as anti-corrosive agent in oilfield operations and hydraulic fluids and as a metal working fluid.” 83 Fed. Reg. at 5600. The amended SNUR would retain the same water release limits that would trigger prior EPA notification that are in the existing SNUR.

As discussed in the Introduction and in Part V of these comments, EDF has been severely hampered in its review of the proposed amended SNUR by the exceptionally short amount of time provided by EPA for public comments and by significant omissions of key information in the docket for this rulemaking. We have discussed in more detail in Part V of these comments

²⁶ No such risk assessment has been provided or referenced in the docket for this proposed amended SNUR, so it is not clear whether such an assessment was conducted.

why these constraints imposed by EPA are unacceptable. Nevertheless, these constraints should be borne in mind in reading these comments.

a. EPA has not sufficiently described and documented several key aspects of its risk review leading to the proposed modifications to the existing SNUR.

The proposed modifications to the SNUR are based on concerns arising “based on test data on the substance and on new data regarding the expected release of formaldehyde from the substance.” 83 Fed. Reg. at 5600. The Consent Order states, “[i]nformation available to EPA indicates that there is a potential for human or environmental exposure to the SNUN substance and that the SNUN substance may present a risk to workers for irritation, sensitization, and other toxicological endpoints, and may present a risk to aquatic organisms if released to water in sufficient quantity.”²⁷ EPA indicates that risks to workers are posed through exposure via both the dermal and inhalation routes.

EPA appears to have based the conditions imposed by the Consent Order and that it is proposing to include in the amended SNUR in part on exposure and environmental release parameters summarized in a table included in the Consent Order.²⁸ Based on our time- and information-constrained review, it appears to EDF that EPA has failed to adequately explain and justify the exposure assumptions described in this table.

Below we discuss each of these assumptions.

i. The number of sites where the SNUN substance is used: 16 sites (Use 1, Oilfield operations) and 34 sites (Use 2, Hydraulic fluids).

EPA has estimated the number of sites associated with the SNUN substance as 16 and 34 for oilfield operations and hydraulic fluid operations, respectively, using what appears to be a combination of models and assumptions.

The Initial Review Engineering Report for S-17-0004 indicates that the SNUN “[s]ubmission does not provide the number of sites for this use [Use 1: Oilfield: Anti-Corrosive].”²⁹ The Report goes on to say, “The GS for Chemicals Used in Oil Well Production estimates the number of sites as ~16 (based on Eqn 3-lb). Calculation:***=16 sites.”³⁰ Similarly, EPA later indicates in the report that the SNUN “[s]ubmission does not provide any information on the number of sites or d/y of operation [for Use 2: Hydraulic Fluid Anti-Corrosive]. ***Same submitter, same chemical past case P03-0325 provided 50-100 sites for a

²⁷ *Consent Order*, at vii.

²⁸ *Id.* at vi.

²⁹ EPA-HQ-OPPT-2011-0941-0185, S-17-0004 Sanitized Engineering Report 5, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0185> (“Engineering Report”).

³⁰ *Id.*

PV of 80,000 kg/yr for this use. EPA assumes for a PV of 27,500 kg/yr, and 250 d/yr, the number of sites will be approximately 34.”³¹

For Use 1, because no site data were provided by the SNUN submitter, EPA is relying on a source (described only as “the GS for Chemicals Used in Oil Well Production”) for which no reference is provided and which is not in the rulemaking docket. For Use 2, EPA appears to be relying on data submitted by the company in or attached to its original 2003 PMN – which was for a different use – while asserting it pertains to “this use” (i.e., the use for which the SNUN was submitted). Given how different the uses are, EPA has provided no justification for using site data from the original PMN for this new use.

EPA needs to fully document and justify the basis for its site number values, and provide citations and place copies of the relevant documents in the rulemaking docket.

ii. The number of workers per site where the SNUN substance is used: 8 workers/site (Use 1, Oilfield operations) and 3 workers/site (Use 2, Hydraulic fluids).

EPA has assumed the number of workers per site associated with the SNUN substance to be eight and three, for oilfield operations and hydraulic fluid operations, respectively. As with the number of sites discussed above, EPA appears to be making assumptions on the number of workers exposed per site without providing sufficient detail and explanation of the basis of these assumptions.

With regard to the number of workers exposed, the Initial Review Engineering Report for S-17-0004 states, “[t]ot. # of workers exposed via assessed routes: 128. Basis: Submission does not provide any information on the number of workers exposed. The GS for Chemicals Used in Oil Well Production estimates 8 workers/site potentially exposed.”³² Similarly, EPA later indicates in the report that, “[t]ot. # of workers exposed via assessed routes: 102. Basis: Submission does not provide any information on the number of workers exposed. EPA assumes 3 workers per site.”³³

Here again, it is not clear what sources EPA used or how EPA has arrived at these estimates for the number of workers potentially exposed to the SNUN substance.

After hours of searching on our part, it appears that EPA may have relied on the Organization for Economic Co-operation and Development (OECD) Emission Scenario Document on Chemicals Used In Oil Well Production,³⁴ to arrive at the first of the two numbers of workers exposed per site it used. As far as we can tell, the only reference to this document in

³¹ *Id.* at 12.

³² *Id.* at 9.

³³ *Id.* at 14.

³⁴ OECD, Emission Scenario Document on Chemicals Used In Oil Well Production (Mar. 19, 2012), [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2012\)7&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)7&doclanguage=en) (“OECD Emission Scenario Document”).

the rulemaking docket is in the Internal Review Engineering Report for S-17-0004 where it indicates, “[f]or the oil well additives use: the 2013 ESD was referenced for release estimates and numbers of workers potentially exposed.”³⁵ Based on that obscure hint of a source, we surmised that the source might be the OECD document. Nowhere did EPA use the full name of this document or provide a citation to it, nor was it provided in the docket, forcing members of the public like ourselves seeking to comment on this SNUR to rely on scant information to understand how such critical exposure parameters were established by EPA.

This is unacceptable. EPA must fully document and justify the basis for its number of workers per site values, and provide citations and place copies of the relevant supporting documents in the rulemaking docket.

Assuming the “ESD” document is in fact the OECD document, it references the 2002 U.S. Census for arriving at 8 workers per site: “According to the 2002 U.S. Census, an average of 13 workers employed at each site for crude petroleum and natural gas extraction (NAICS code 211111)” and further that, “*** approximately 62% of these workers are production workers *** [and] *** therefore it is assumed that 62% of the 13 workers per site, or up to 8 workers per site, are potentially exposed to the oil well chemicals.”³⁶ This means that this estimate value is 16 years old; given the explosion in domestic oil production and hydraulic fracturing activities since 2002, there is no reason to believe that value reflects current occupational exposures in this sector. EPA needs to account for this factor and adjust its estimates accordingly.

iii. The number of days per year that a worker may be exposed to the SNUN substance: 8 days/year (Use 1, Oilfield operations) and 4 days/year (Use 2, Hydraulic fluids).

EPA has assumed the number of days per year that a worker may be exposed to the SNUN substance to be eight and four, for oilfield operations and hydraulic fluid operations, respectively. Acknowledging our review is based on the very incomplete docket EPA has provided for this rulemaking, and had to be done in the extremely limited amount of time EPA has afforded for public comment, it does not appear that EPA has explained how it arrived at these numbers. It is also unclear whether EPA examined the likelihood that workers may in fact work at multiple sites over the course of a year, which would obviously increase their exposure to the SNUN substance.

Because of these failures on EPA’s part, the public has no ability to know whether these numbers reflect real-world worker exposures, and cannot judge whether the proposed amendments to the SNUR are sufficient.

³⁵ *Engineering Report*, at 4 (emphasis added).

³⁶ *OECD Emission Scenario Document*, at 41.

iv. The level of dermal and inhalation exposure of the SNUN substance to a worker.

Based on our time and information-constrained review of the docket, EPA does not appear to have provided the basis for its derivation of either: a) a worker dermal exposure level of 2,200 mg/day for the SNUN substance in both oilfield operations and hydraulic fluid operations, or b) a worker inhalation exposure level of 0.053 mg/day and 0.035 mg/day for use of the SNUN substance in oilfield operations and hydraulic fluids, respectively. While these exposure values are identified in the Internal Review Engineering Report for S-17-0004,³⁷ EPA has not adequately shown how and from what information they were derived. As such, the public has no ability to know whether these exposure levels reflect real-world conditions, and cannot judge whether the proposed exposure controls in the amendments to the SNUR are sufficient.

In sum, in its review of the SNUN substance, EPA appears to have been working with entirely insufficient information from the SNUN submitter bearing on worker exposure to the SNUN substance. Instead, the agency appears to have relied on models, uncited or insufficiently cited sources, or in some cases what seem to be complete guesses. We have found no information in the docket to suggest this is not the case.

The consequence of course is that the public has no ability to assess the adequacy of the additional requirements EPA is proposing in its amendments to the existing SNUR.

b. EPA must codify its exposure assumptions as notification triggers in the amended SNUR.

Given that EPA has chosen to rely on a number of exposure assumptions in its review of the SNUN that serve as the basis for its proposed amendments to the SNUR, and presuming these assumptions can be adequately justified and documented (per our comments above), the agency must incorporate these assumptions as notification triggers in the amended SNUR itself. The only way EPA and the public can be assured that the amended SNUR will adequately protect human (including worker) and environmental health is by making enforceable the exposure parameters it has used to justify the conditions in the SNUN substance's Consent Order and the amendments to the SNUR. Failure to do so leaves open the possibility for the SNUN substance to be used in a manner that leads to greater-than-intended risks to the environment and workers without EPA's knowledge and ability to review.

Specifically, EPA should amend the SNUR to designate as a significant new use any handling or use of the SNUN substance that results in exposures exceeding those derived using the agency's assumptions (e.g., number of workers per site where the SNUN substance is used, number of days per year a worker may be exposed to the SNUN substance, and the level of dermal or inhalation exposure that a worker may experience).

³⁷ *Engineering Report*, at 10, 11, & 15.

c. EPA should exercise its authority to require submission of records required to be kept under the amended SNUR.

Given the critical role that the exposure assumptions EPA has made play in determining the level of risk that will be allowed under the amended SNUR without triggering notification, it is essential that EPA determine what the actual conditions are. It should use its existing authorities to require submission of records from companies using the SNUN substance for the uses to be allowed under the amended SNUR, *and* from the company under the Consent Order.³⁸ These companies must maintain records of their compliance with the use restrictions under the amended SNUR and the Consent Order, information that would assist EPA in two ways. First, EPA can use them to determine the extent of compliance with provisions in an amended SNUR that codify those assumed exposure values, as we call for in Subpart b. above. Second, the records can help to validate whether those assumptions in fact represent real-world conditions for chemicals used in these ways, to inform evaluations of the risks both of the SNUN substance and of other chemicals used in the same or similar ways.

Specifically, EPA should use its authority under § 11 to request the records that companies must maintain under both the amended SNUR and the Consent Order. Section 11(c) broadly states “the [EPA] may by subpoena require *** the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary.” 15 U.S.C. § 2610(c). Because the records maintained by companies using the SNUN substance are critical to validating the assumptions the agency made about exposure, EPA should subpoena these records from any company EPA determines manufactures, processes or uses the SNUN substance. EPA’s generally applicable SNUR regulation anticipates these types of requests, and states, “[f]ailure or refusal to permit access to or copying of records, as required by section 11 of the Act, is a violation of [TSCA].” 40 C.F.R. § 721.35(c).

The Consent Order separately provides that “[p]ursuant to § 11 of TSCA *** EPA may request *** [r]ecords required by the Recordkeeping section of this Consent Order; and/or, [a]ny other information reasonably related to determining compliance with this Consent Order or conducting an inspection for that purpose.”³⁹ At a minimum, EPA should use this provision from the Consent Order to collect the records of compliance from the SNUN submitter and confirm the agency’s assumptions.

EDF notes that EPA also has authority under TSCA section 8 to require submission of such records.

d. EPA needs to explain and justify why a NIOSH-certified respirator with an assigned protection factor (APF) of at least a 1,000 is sufficient to ensure protection against exposure via inhalation.

The SNUN substance’s Consent Order and the amended SNUR proposal stipulate that workers must be provided National Institute of Occupational Safety and Health (NIOSH)-

³⁸ See *Consent Order*, at 24-26.

³⁹ *Consent Order*, at 26-27.

certified respirators with an Assigned Protection Factor (APF) of at least a 1,000. While EDF strongly supports such requirements to protect workers from exposure to the SNUN substance via the inhalation route, EPA has not provided an explanation for, nor has it justified, why a respirator with an APF of 1,000 will be sufficiently protective. EPA should provide this explanation and post it in the docket.

e. Key health and safety studies are missing from the docket, preventing the public from understanding and independently assessing the consequences of the agency's proposed amendments to the SNUR.

As noted in Part V, the Consent Order for the SNUN substance refers to two sources of health and safety information that are absent from the docket: 1) an acute inhalation study conducted according to OECD guideline 436, and 2) monitoring studies of formaldehyde release in specific industrial settings. The Consent Order indicates that these studies were submitted as part of the SNUN submitted by the Company. In addition, as noted in the Introduction of these comments, we have only recently discovered that this same chemical is proposed to be registered under FIFRA as a biocide for the same or similar uses, and that numerous additional health and safety studies submitted in the context of that registration exist. Yet, despite their clear relevance to this amended SNUR, none of these are in the SNUR docket.

In the absence of access to this information, which bears on both the hazard and exposure characteristics of the SNUN substance, neither EDF nor other members of the public can effectively assess the sufficiency of the proposed modifications of the SNUR.

Before finalizing this amended SNUR, EDF urges EPA to enter this information into the docket, evaluate all of the information together and document how it has done so and the outcomes, and include such documentation both in the docket and in its response to comments received on this proposed amended SNUR.

f. The precautionary statements EPA has required under the Consent Order, and that would be incorporated in the amended SNUR, are inadequate and should be rectified by the agency.

The Consent Order for the SNUN substance details the human health, environmental hazard, exposure, and precautionary statements that must appear on container labels containing the SNUN substance as well as on SDS and MSDS sheets. A number of required human health hazard statements pertain to formaldehyde that is released by the SNUN substance. Notably missing from the list of hazard statements is "cancer." Formaldehyde is classified as a known human carcinogen by the U.S Department of Health and Human Services in its latest Report on Carcinogens,⁴⁰ a probable human carcinogen by the U.S. EPA Integrated Risk Information

⁴⁰ See Dep't of Health & Human Servs., Report on Carcinogens: Formaldehyde (4th ed. 1985), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf>.

System (IRIS) program,⁴¹ and a known human carcinogen by the World Health Organization (WHO) International Agency for Research on Cancer (IARC).⁴²

According to the Structure Activity Team report submitted with the original PMN for the SNUN substance, the substance is also a “severe skin and eye irritant.”⁴³ These toxicological endpoints are also absent from the required list of human health hazard statements to be included on labels and SDS and MSDS sheets.

EPA should rectify these glaring and health consequential omissions. Specifically, EPA should update its proposed modifications to the SNUR to require that cancer and skin and eye irritation be included in specific human health hazard statements required to comply with all relevant hazard communication requirements.

g. EPA has not taken into account other sources of formaldehyde exposures to workers using the SNUN substance.

Based on our time- and information-constrained review of the docket, it does not appear that the agency took into account other sources of formaldehyde exposure to workers exposed to the SNUN substance. If true, this is a serious deficiency in EPA’s evaluation of the SNUN substance, as formaldehyde is known to be released under several operational circumstances associated with oil and gas development that may well involve the same workers as those using the SNUN substance.⁴⁴ EPA’s exclusion from consideration of these other sources of formaldehyde, means that the agency has likely significantly underestimated the risks associated with SNUN substance.

EPA needs to explain whether and if so, how, it took these additional potential exposures into account in establishing conditions to limit exposure included in the proposed amended SNUR. If it has not considered such exposures, before finalizing this amended SNUR, EPA needs to evaluate all of the exposures together. In either case, EPA needs to describe and document its analysis and the outcomes, and include such description and documentation both in the docket and in its response to comments received on this proposed amended SNUR.

⁴¹ See U.S. EPA, IRIS Assessment for Formaldehyde 7 (1989), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0419_summary.pdf.

⁴² See IARC, Monograph on Formaldehyde (2006), <http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf>.

⁴³ EPA-HQ-OPPT-2011-0941-0191, SAT report on PMN P-03-0325 at 2, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0043>.

⁴⁴ See, e.g., G.P. Macey et al. (2014) “Air concentrations of volatile compounds near oil and gas production: a community-based exploratory study,” *Environmental Health* 13:82, available at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-82>; see also W.T. Stringfellow et al. (2017) “Comparison of chemical-use between hydraulic fracturing, acidizing, and routine oil and gas development,” *PLOS One*, available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0175344#pone.0175344.ref021>.

V. EPA failed to rectify the procedural violations identified by EDF in our request for an extension.

a. EPA has failed to complete the docket with critical health and safety information.

In response to EDF's request, EPA disclosed sanitized versions of the SNUN and its attachments, and a less redacted 2007 version of the 2003 SAT Report on the original PMN for the SNUN substance. While this was a step in the right direction, EPA still failed to disclose critical health and safety studies that EPA considered during its analysis. Specifically, as we noted in our extension request, the Consent Order refers to an acute inhalation study (OECD 436) and monitoring studies of formaldehyde release in specific industrial settings that are still not in the docket. Consent Order at p. v. Similarly, the engineering report repeatedly refers to various supplemental documents provided by the submitter that EPA considered, yet they too are not in the docket.

Based on their titles *and* EPA's references to them, these documents are critical because they contain highly relevant information on hazard and exposure. In order for EDF or other members of the public to meaningfully comment on whether the conditions identified by EPA in the SNUR are sufficient, access to the hazard and exposure information EPA considered is necessary. Moreover, the modifications proposed to be made to the SNUR in this case are in part meant to address EPA's concern about release of formaldehyde, and the very documents that describe the release of formaldehyde have not been provided. EDF is hard pressed to develop comments on a SNUR when information and analysis on the risks the SNUR is meant to deal with have not been made public.

Even if these documents were not critical to EDF's ability to meaningfully comment, EPA is nevertheless required to release them under TSCA. As EDF previously [explained](#) in its request for an extension, which EDF incorporates here by reference, these documents constitute health and safety studies, which EPA must disclose under TSCA. In short summary, TSCA requires disclosure of "any health and safety study which is submitted under [TSCA] with respect to *** any chemical substance or mixture *** for which notification is required under section 5." 15 U.S.C. § 2613(b)(2)(A). In addition, TSCA requires disclosure of "any information reported to, *or otherwise obtained by*, [EPA] *from* a health and safety study which relates to [such] a chemical substance." *Id.* § 2613(b)(2)(B) (emphases added). Thus, any health and safety study or other data on health or environmental effects or assessment of risk must be disclosed.

Despite these mandates, EPA has [once again](#) failed to disclose health and safety information. The acute inhalation study, formaldehyde monitoring studies, and supplemental documents all constitute or contain health and safety information,⁴⁵ yet EPA did not even

⁴⁵ Also missing from the docket are large portions of the original PMN submission. However, because hundreds of pages are missing, it is difficult to tell how much of this is health and safety information, but at a minimum, it is clear that some health and safety information is missing, i.e. Safety Data Sheets and complete copies of listed toxicity studies.

provide a *redacted* copy of these documents. *See* 15 U.S.C. § 2613(b)(1) (if CBI and non-CBI information are included in the same submission, only the CBI information is eligible for protection while the non-CBI information is to be disclosed). In addition, much of the information in the FIFRA record discussed in Part II also qualifies as health and safety information that must be disclosed.

In the future, EPA must ensure that its dockets are complete at the time the public comment period begins, and in particular ensure that all health and safety studies and other health and safety information are included in the public dockets.

b. EPA has provided an inadequate amount of time for the public to comment based on a full record.

EPA partially granted EDF’s extension request so that the total comment period ran 32 days. As a result, assuming EPA has a basis for using an expedited procedure to promulgate this amended SNUR, EPA may have a non-frivolous argument that it narrowly complied with its regulations. *See* 40 C.F.R. § 721.160(c)(4)(i) (“Persons will be given 30 days to comment.”). Undoubtedly, this comment period after extension is preferable to the flatly illegal 15-day comment period that EPA originally proposed, and EPA wisely chose to avoid such a flagrant legal violation. EPA should avoid such flagrant violations in the future as well.

Nonetheless, as a practical matter, EPA partially denied EDF’s request and violated EPA’s procedures in doing so, because EPA did not provide the public with at least a 30-day comment period based on a *complete* record. As explained above, the failure to provide a complete record violates the law, standing alone. In addition, even if the new record were complete (which it is not), EPA needed to provide the public with 30 days to comment on the complete record. Instead, EPA added foundational documents—including the SNUN—to the record on February 20, 2018, ignored our request for additional documents to be added, and then only provided the public with 20 days to comment on the proposal. Thus, EPA violated its duty to provide persons with 30 days to comment under any reasonable interpretation of its regulation.

This limited time harms the ability of “interested persons *** to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553(c). Notably, EDF’s request for 30 days to comment on a full record was *more* conservative than the Administrative Conference’s recommendation, which is that even a thirty-day comment period is “an inadequate time to allow people to respond to proposals that are *complex or based on scientific or technical data.*” The Administrative Conference *** suggests a sixty-day period as ‘a more reasonable minimum time for comment.’” *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (emphasis added). As our prior comments highlight, there can be no question that the proposed amended SNUR is complex and based on scientific and technical data. EPA’s decision to provide only 20 days to comment on the only partially supplemented record was unreasonable. EPA has also provided *no* rationale for such a short comment period, and such short comment periods usually require truly “exigent circumstances.” *See N.C. Growers’ Ass’n v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012) (finding 10-day comment period violated the APA). EPA’s extension notice failed to mention any reason why the extension was only half of the minimum period EDF requested, let alone any exigent circumstances that necessitated a shortened

comment period. *See* 83 Fed. Reg. 8235 (Feb. 26, 2018). Considering that EPA created the initial SNUR because this chemical substance poses hazards to human health and the environment, and the current information continues to confirm that the chemical substance presents hazards, EPA has no justification for rushing the public comment period or its own decision-making.

Conclusion

EPA should more fully and transparently document and justify the exposure assumptions it used as the basis for conditions included in the proposed amended SNUR in order to demonstrate the adequacy of those conditions. Once it has done so, those assumptions need to be codified in the final amended SNUR as additional conditions that would trigger prior notification to EPA should a manufacturer or processor intend to deviate from them. EPA also should exercise its authority to require submission of records required to be kept under the amended SNUR, both to validate its assumptions and to ensure compliance with conditions imposed based on those assumptions.

The final amended SNUR must include all relevant requirements included in the Consent Order, which the current proposal has failed to do. The precautionary statements EPA has required under the Consent Order, and that would be incorporated in the amended SNUR, are inadequate and incomplete and should be rectified by the agency.

EPA needs to fully account for and address other sources of formaldehyde exposures to workers using the SNUN substance before finalizing the amended SNUR.

Moreover, in the future, EPA should ensure that the docket is complete when a proposed SNUR is placed in the Federal Register, in particular ensuring that all health and safety studies are available to the public. EPA must also comply with the APA, and its own regulations, and provide the public at least 30 days to comment on a proposed rule (or 60 days if it is highly technical or complex).

Attachment A

Safety Data Sheet

According to OSHA HCS 2012 (29 CFR 1910.1200)



SECTION 1: Identification

Product Identifier Quintolubric® 818-02
Other means of identification Phillips 66 Quintolubric® 818-02
SDS Number LBPH827740
Relevant identified uses Hydraulic Fluid
Uses advised against All others
24 Hour Emergency Phone Number CHEMTREC 1-800-424-9300
CHEMTREC Mexico 01-800-681-9531

Manufacturer/Supplier Phillips 66 Lubricants P.O. Box 4428 Houston, TX 77210	SDS Information Phone: 800-762-0942 Email: SDS@P66.com URL: www.Phillips66.com	Customer Service U.S.: 800-368-7128 or International: 1-832-765-2500 Technical Information 1-877-445-9198
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SECTION 2: Hazard identification

Classified Hazards **Hazards Not Otherwise Classified (HNOC)**

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200. PHNOC: None known

HHNOC: None known

Label Elements

No classified hazards

SECTION 3: Composition/information on ingredients

Chemical Name	CASRN	Concentration ¹
Ethanolamine	141-43-5	<5
3,3'-Methylenebis(5-methyloxazolidine)	66204-44-2	<5
Isopropanolamine	78-96-6	<5

¹ All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

Eye Contact: If irritation or redness develops from exposure, flush eyes with clean water. If symptoms persist, seek medical attention.

Skin Contact: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water or a waterless hand cleaner. If irritation or redness develops and persists, seek medical attention.

Inhalation: First aid is not normally required. If breathing difficulties develop, move victim away from source of exposure and into

fresh air in a position comfortable for breathing. Seek immediate medical attention.

Ingestion: First aid is not normally required; however, if swallowed and symptoms develop, seek medical attention.

Most important symptoms and effects, both acute and delayed: Prolonged or repeated contact may dry skin and cause irritation. Inhalation of oil mists or vapors generated at elevated temperatures may cause respiratory irritation. Accidental ingestion can result in minor irritation of the digestive tract, nausea and diarrhea.

SECTION 5: Firefighting measures

NFPA 704 Hazard Class

Health: 0 Flammability: 0 Instability: 0



0 (Minimal)
1 (Slight)
2 (Moderate)
3 (Serious)
4 (Severe)

Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Specific hazards arising from the chemical

Unusual Fire & Explosion Hazards: No unusual fire or explosion hazards are expected. If container is not properly cooled, it can rupture in the heat of a fire.

Hazardous Combustion Products: Combustion may yield smoke, carbon monoxide, and other products of incomplete combustion. Oxides of sulfur, nitrogen or phosphorus may also be formed.

Special protective actions for firefighters: For fires beyond the initial stage, emergency responders in the immediate hazard area should wear protective clothing. When the potential chemical hazard is unknown, in enclosed or confined spaces, a self contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8).

Isolate the hazard area and deny entry to unnecessary and unprotected personnel Stop spill/release if it can be done safely. Move undamaged containers from immediate hazard area if it can be done safely Water spray may be useful in minimizing or dispersing vapors and to protect personnel. Cool equipment exposed to fire with water, if it can be done safely.

See Section 9 for Flammable Properties including Flash Point and Flammable (Explosive) Limits

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures: Stay upwind and away from spill/release. Avoid direct contact with material. For large spillages, notify persons down wind of the spill/release, isolate immediate hazard area and keep unauthorized personnel out. Wear appropriate protective equipment, including respiratory protection, as conditions warrant (see Section 8). See Sections 2 and 7 for additional information on hazards and precautionary measures.

Environmental Precautions: Stop and contain spill/release if it can be done safely. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways. Use water sparingly to minimize environmental contamination and reduce disposal requirements. If spill occurs on water notify appropriate authorities and advise shipping of any hazard.

Methods and material for containment and cleaning up: Notify relevant authorities in accordance with all applicable regulations. Immediate cleanup of any spill is recommended. Dike far ahead of spill for later recovery or disposal. Absorb spill with inert material such as sand or vermiculite, and place in suitable container for disposal. If spilled on water remove with appropriate methods (e.g. skimming, booms or absorbents). In case of soil contamination, remove contaminated soil for remediation or disposal, in accordance with local regulations.

Recommended measures are based on the most likely spillage scenarios for this material; however local conditions and regulations may influence or limit the choice of appropriate actions to be taken. See Section 13 for information on appropriate disposal.

SECTION 7: Handling and storage

Precautions for safe handling: Wash thoroughly after handling. Use good personal hygiene practices and wear appropriate personal protective equipment (see section 8). Spills will produce very slippery surfaces. Do not enter confined spaces such as tanks or pits without following proper entry procedures such as ASTM D-4276 and 29CFR 1910.146. Do not wear contaminated clothing or shoes.

Conditions for safe storage: Keep container(s) tightly closed and properly labeled. Use and store this material in cool, dry, well-ventilated areas. Store only in approved containers. Keep away from any incompatible material (see Section 10). Protect container(s) against physical damage.

SECTION 8: Exposure controls/personal protection

Chemical Name	ACGIH	OSHA	Phillips 66
Ethanolamine	STEL: 6 ppm TWA: 3 ppm	TWA: 3 ppm TWA: 6 mg/m ³	---

Note: State, local or other agencies or advisory groups may have established more stringent limits. Consult an industrial hygienist or similar professional, or your local agencies, for further information.

Engineering controls: If current ventilation practices are not adequate to maintain airborne concentrations below the established exposure limits, additional engineering controls may be required.

Eye/Face Protection: The use of eye protection that meets or exceeds ANSI Z.87.1 is recommended to protect against potential eye contact, irritation, or injury. Depending on conditions of use, a face shield may be necessary.

Skin/Hand Protection: The use of gloves impervious to the specific material handled is advised to prevent skin contact. Users should check with manufacturers to confirm the breakthrough performance of their products. Suggested protective materials: Nitrile

Respiratory Protection: Where there is potential for airborne exposure above the exposure limit a NIOSH certified air purifying respirator equipped with R or P95 filters may be used.

A respiratory protection program that meets or is equivalent to OSHA 29 CFR 1910.134 and ANSI Z88.2 should be followed whenever workplace conditions warrant a respirator's use. Air purifying respirators provide limited protection and cannot be used in atmospheres that exceed the maximum use concentration (as directed by regulation or the manufacturer's instructions), in oxygen deficient (less than 19.5 percent oxygen) situations, or under conditions that are immediately dangerous to life and health (IDLH).

Suggestions provided in this section for exposure control and specific types of protective equipment are based on readily available information. Users should consult with the specific manufacturer to confirm the performance of their protective equipment. Specific situations may require consultation with industrial hygiene, safety, or engineering professionals.

SECTION 9: Physical and chemical properties

Note: Unless otherwise stated, values are determined at 20°C (68°F) and 760 mm Hg (1 atm). Data represent typical values and are not intended to be specifications.

Appearance: Yellow-green

Physical Form: Liquid

Odor: Petroleum

Odor Threshold: No data

pH: 9.8

Vapor Density (air=1): No data

Upper Explosive Limits (vol % in air): No data

Lower Explosive Limits (vol % in air): No data

Evaporation Rate (nBuAc=1): No data

Particle Size: Not applicable

Percent Volatile: No data

Flammability (solid, gas): Not applicable

Solubility in Water: Soluble

Flash Point: Not applicable

Test Method: Not applicable

Initial Boiling Point/Range: No data

Vapor Pressure: No data

Partition Coefficient (n-octanol/water) (Kow): No data

Melting/Freezing Point:

Auto-ignition Temperature: No data

Decomposition Temperature: No data

Specific Gravity (water=1): 1.015 @ 60°F (15.6°C)

Bulk Density: 8.47 lbs/gal

Viscosity: 7.7 cSt @ 40°C

Pour Point: 26 °F / -3 °C

SECTION 10: Stability and reactivity

Reactivity: Not chemically reactive.

Chemical stability: Stable under normal ambient and anticipated conditions of use.

Possibility of hazardous reactions: Hazardous reactions not anticipated.

Conditions to avoid: Extended exposure to high temperatures can cause decomposition.

Incompatible materials: Avoid contact with strong oxidizing agents and strong reducing agents.

Hazardous decomposition products: Not anticipated under normal conditions of use.

SECTION 11: Toxicological information

Information on Toxicological Effects

Substance / Mixture

Acute Toxicity	Hazard	Additional Information	LC50/LD50 Data
Inhalation	Unlikely to be harmful		>5 mg/L (mist, estimated); 5 percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalation)
Dermal	Unlikely to be harmful		> 2 g/kg (estimated); 5 percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal)
Oral	Unlikely to be harmful		> 5 g/kg (estimated); 5 percent of the mixture consists of ingredient(s) of unknown acute toxicity (oral)

Aspiration Hazard: Not expected to be an aspiration hazard.

Skin Corrosion/Irritation: Causes mild skin irritation. Repeated exposure may cause skin dryness or cracking.

Serious Eye Damage/Irritation: Causes mild eye irritation.

Skin Sensitization: No information available on the mixture, however none of the components have been classified for skin sensitization (or are below the concentration threshold for classification).

Respiratory Sensitization: No information available.

Specific Target Organ Toxicity (Single Exposure): No information available on the mixture, however none of the components have been classified for target organ toxicity (or are below the concentration threshold for classification).

Specific Target Organ Toxicity (Repeated Exposure): No information available on the mixture, however none of the components have been classified for target organ toxicity (or are below the concentration threshold for classification).

Carcinogenicity: No information available on the mixture, however none of the components have been classified for carcinogenicity (or are below the concentration threshold for classification).

Germ Cell Mutagenicity: No information available on the mixture, however none of the components have been classified for germ cell mutagenicity (or are below the concentration threshold for classification).

Reproductive Toxicity: No information available on the mixture, however none of the components have been classified for reproductive toxicity (or are below the concentration threshold for classification).

SECTION 12: Ecological information

GHS Classification:
No classified hazards

Toxicity: Not expected to be harmful to aquatic life

Persistence and Degradability: Not expected to persist in the environment if spilled or released.

Bioaccumulative Potential: Not expected to bioaccumulate in the environment based on its physical properties.

Mobility in Soil: Expected to have low mobility in soil and sediments with adsorption being the predominant physical process.

Other adverse effects: None anticipated.

SECTION 13: Disposal considerations

The generator of a waste is always responsible for making proper hazardous waste determinations and needs to consider state and local requirements in addition to federal regulations. This material, if discarded as produced, would not be a federally regulated RCRA "listed" hazardous waste and is not believed to exhibit characteristics of hazardous waste. See Sections 7 and 8 for information on handling, storage and personal protection and Section 9 for physical/chemical properties. It is possible that the material as produced contains constituents which are not required to be listed in the SDS but could affect the hazardous waste determination. Additionally, use which results in chemical or physical change of this material could subject it to regulation as a hazardous waste. This material under most intended uses would become "Used Oil" due to contamination by physical or chemical impurities. Whenever possible, Recycle used oil in accordance with applicable federal and state or local regulations. Container contents should be completely used and containers should be emptied prior to discard.

SECTION 14: Transport information

U.S. Department of Transportation (DOT)

UN Number: Not regulated

UN proper shipping name: None

Transport hazard class(es): None

Packing Group: None

Environmental Hazards: This product does not meet the DOT/UN/IMDG/IMO criteria of a marine pollutant

Special precautions for user: None

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

SECTION 15: Regulatory information

CERCLA/SARA - Section 302 Extremely Hazardous Substances and TPQs (in pounds):

This material does not contain any chemicals subject to the reporting requirements of SARA 302 and 40 CFR 372.

CERCLA/SARA - Section 311/312 (Title III Hazard Categories)

Acute Health Hazard:	No
Chronic Health Hazard:	No
Fire Hazard:	No
Pressure Hazard:	No
Reactive Hazard:	No

CERCLA/SARA - Section 313 and 40 CFR 372:

This material does not contain any chemicals subject to the reporting requirements of SARA 313 and 40 CFR 372.

EPA (CERCLA) Reportable Quantity (in pounds):

This material does not contain any chemicals with CERCLA Reportable Quantities.

California Proposition 65:

This material does not contain any chemicals which are known to the State of California to cause cancer, birth defects or other reproductive harm at concentrations that trigger the warning requirements of California Proposition 65.

International Hazard Classification

Canada:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the Regulations.

International Inventories

All components are either listed on the US TSCA Inventory, or are not regulated under TSCA.
All components are either on the DSL, or are exempt from DSL listing requirements.

U.S. Export Control Classification Number: EAR99

SECTION 16: Other information

Issue Date:	Previous Issue Date:	SDS Number	Status:
22-Jun-2016	22-Jun-2016	LBPH827740	FINAL

Revised Sections or Basis for Revision:
New SDS

Guide to Abbreviations:

ACGIH = American Conference of Governmental Industrial Hygienists; CASRN = Chemical Abstracts Service Registry Number; CEILING = Ceiling Limit (15 minutes); CERCLA = The Comprehensive Environmental Response, Compensation, and Liability Act; EPA = Environmental Protection Agency; GHS = Globally Harmonized System; IARC = International Agency for Research on Cancer; INSHT = National Institute for Health and Safety at Work; IOPC = International Oil Pollution Compensation; LEL = Lower Explosive Limit; NE = Not Established; NFPA = National Fire Protection Association; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = Permissible Exposure Limit (OSHA); SARA = Superfund Amendments and Reauthorization Act; STEL = Short Term Exposure Limit (15 minutes); TLV = Threshold Limit Value (ACGIH); TWA = Time Weighted Average (8 hours); UEL = Upper Explosive Limit; WHMIS = Worker Hazardous Materials Information System (Canada)

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