

Comment Info: =====

General Comment: The following comments from The Soap and Detergent Association are also found in the attached PDF file:

July 25, 2007

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Docket ID No. EPA-HQ-OPPT-2007-0490

The Soap and Detergent Association (SDA) appreciates the opportunity to comment on the petition (Docket ID No. EPA-HQ-OPPT-2007-0490) on nonylphenol (NP) and nonylphenol ethoxylates (NPEs) received by the U.S. Environmental Protection Agency (EPA) under section 21 of the Toxic Substances Control Act (TSCA) and described in the notice published in the June 10, 2007 Federal Register (72 FR 37530).

SDA is a 100 plus-member national trade association representing the formulators of soaps, detergents and general cleaning products used in household, industrial, institutional and commercial settings, and the companies that supply ingredients and packaging for these products. Some SDA members produce and supply NP and NPEs, and formulate cleaning products containing them.

This petition was received from the Sierra Club, the Environmental Law & Policy Center, the Pacific Coast Federation of Fishermen's Association, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE on June 6, 2007. They are petitioning EPA to exercise its authority under TSCA section 4 to require manufacturers and importers of NP and NPEs to conduct specific health and safety studies, and under TSCA section 6(a) to require labeling on all products containing NP and NPEs and to limit their use in certain circumstances.

SDA urges EPA to deny this petition. The petitioners have not provided sufficient data or information for EPA to exercise its authority under TSCA section 4 or 6(a).

Petitioners' Request under TSCA Section 4

Under TSCA section 4 there are four criteria with respect to exposure that must be met in order for EPA to require testing (15 U.S.C. 2603(a)(1)(B)).

Specifically,

? the substance must be produced in substantial quantities,

? the substance must be released to the environment in substantial quantities,

or there must be substantial human exposure to the substance,

? there must be insufficient data and experience with the substance such that

the human health and environmental effects cannot be determined or predicted, and
? testing must be necessary to develop data on human health and environmental effects.

In 1993 in response to a decision by the 5th Circuit Court regarding a TSCA Section 4 Final Test Rule, EPA published the following criteria to clarify language in TSCA related to the first two bullets above (58 FR 28736; May 14, 1993) (1):

- ? Substantial production/importation is 1 million pounds.
- ? Substantial release is 1 million pounds or 10% of production/importation.
- ? Substantial exposure is 1,000 workers, 10,000 consumers or 100,000 general population.

1. Production. The petition states on page 5 that production of NP was 230 million pounds in the U.S. in 1998, and production of NPEs was 391 million pounds in the U.S. in 2003. SDA agrees that NP and NPEs are produced in substantial quantities in the U.S. and therefore meet the criterion under 15 U.S.C. 2603(a)(1)(B)(i).

2. Release to the environment. On page 8, the petitioners made a ?back of the envelope? calculation of the release of NP and NPEs to the environment. The calculation is deficient and does not support a conclusion that NP or NPEs ?enter or may reasonably be anticipated to enter the environment in substantial quantities? (15 U.S.C. 2603(a)(1)(B)(i)(I)), or ?there is or may be significant or substantial human exposure to such substances or mixtures? (15 U.S.C. 2603(a)(1)(B)(i)(II)). Therefore, the petitioners? request does not meet this criterion.

3. Adequacy of data and experience to determine or predict environmental and human health effects. The human health and environmental effects of NP and NPEs have been studied extensively and there are ample data available in the public domain. For example:

? Nonylphenol and nonylphenol ethoxylates are included in a High Production Volume Chemical submission to EPA for alkylphenols.(2)

? According to an EPA report regarding testing of chemicals under TSCA, there

were results from 19 environmental fate and ecotoxicological tests of branched 4 nonylphenol (CAS No 84852-15-3) published in the Federal Register in 1990 (55 FR 53348).(3)

? In December 2005, EPA published its Final Aquatic Life Ambient Water Quality

Criteria for Nonylphenol. As part of the document, EPA evaluated dozens of acute and chronic ecotoxicological studies for freshwater and saltwater plants and animals.

SDA believes there is sufficient data and experience with nonylphenol and nonylphenol ethoxylates such that the human health and environmental effects can reasonably be determined or predicted. In addition, as part of its TSCA Chemical Testing Policy, EPA indicates that in order for this criterion to be met, that is, a ?Data Adequacy? finding, ?EPA must show that existing data are inadequate for risk assessment.?(4) SDA believes that sufficient data exist for

risk assessment. Therefore, the petitioners? request does not meet the criterion under 15 U.S.C. 2603(a)(1)(B)(ii).

4. Necessity of testing. As noted in the item above, SDA believes sufficient data exist in the public domain such that further testing is not necessary to develop data regarding the human health and environmental effects of nonylphenol and nonylphenol ethoxylates. In addition, as part of its TSCA Chemical Testing Policy, EPA indicates that in order for this criterion to be met, that is, a "Testing is Necessary" finding, "EPA must show that testing is needed to develop the necessary data to conduct the needed risk assessment."⁴ SDA believes that sufficient data exist for risk assessment and no further testing is necessary. Therefore, the petitioners' request does not meet the criterion under 15 U.S.C. 2603(a)(1)(B)(iii).

The petitioners' request does not meet the four criteria under TSCA section 4 with respect to exposure therefore EPA should not require the testing proposed.

Furthermore, in a notice in the Federal Register of June 18, 2007 (72 FR 33486), EPA announced a draft list of chemicals to be tested under section 408(p) of the Federal Food Drug and Cosmetic Act for potential hormonal effects.

This program, the Endocrine Disruptor Screening Program (EDSP), will initially focus on High Production Volume pesticide active and inert ingredients where EPA believes there is a high exposure potential. NP and NPEs are High Production Volume chemicals that are used as inert ingredients in pesticide formulations; however, EPA did not include them among the chemicals that will be tested initially under the EDSP. While EPA's analysis of exposure to NP and NPEs as pesticide inert ingredients was not discussed in the notice, it appears that EPA believes exposure to NP and NPEs is not of the highest concern which would support SDA's assertion that EPA should not require further testing under TSCA section 4.

Petitioners' Request under TSCA Section 6(a)

The petitioners requested that EPA take action with regard to nonylphenol and nonylphenol ethoxylates including banning them for certain uses, restricting use only to facilities where certain minimum wastewater treatment technologies are employed, mandating pollution prevention planning at facilities where more than 2000 kg of NP or NPEs are used, and certain labeling of products containing NP and NPEs. EPA may have the authority to take such action. However, it may only do so when "there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment?" (15 U.S.C. 2605(a)). SDA does not believe that the petitioners have provided sufficient data for EPA to conclude that there is an unreasonable risk of injury to health or the environment as a result of the use of NP or NPEs. In addition, SDA believes the EPA's December 2005 Final Aquatic Life Ambient Water Quality Criteria for Nonylphenol "accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare that might be expected from the presence of [nonylphenol] in any body of water, including ground water." As such, SDA does not believe the petitioners' request provides a basis for EPA to take further action under TSCA section 6(a).

We appreciate your consideration of our comments and look forward to your response to this petition.

Sincerely,

Paul C. DeLeo, PhD.

Director, Environmental Safety

- (1) See <http://www.epa.gov/oppt/chemtest/pubs/sct4rule.htm>
- (2) See <http://www.epa.gov/oppt/chemrtk/pubs/summaries/alkylphn/c13007tc.htm>.
- (3) See <http://www.epa.gov/oppt/chemtest/pubs/casnochart.pdf>
- (4) See <http://www.epa.gov/oppt/chemtest/pubs/sct4main.htm>