



MEMORANDUM

Via E-Mail

DATE: November 6, 2009

TO: Clients and Friends

FROM: The Acta Group, L.L.C.

RE: EPA Proposes SNURs for Carbon Nanotubes

Today the U.S. Environmental Protection Agency (EPA) proposed significant new use rules (SNUR) under Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances that were the subject of premanufacture notices (PMN). EPA identified the substances generically as multi-walled carbon nanotubes and single-walled carbon nanotubes. According to the notice, these substances are subject to TSCA Section 5(e) consent orders issued by EPA. The consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs are based on and consistent with the provisions in the underlying consent orders, and designate as a significant new use the absence of the protective measures required in the corresponding consent orders. Persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use would be required by the proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. Comments are due **December 7, 2009**.

EPA published direct final SNURs for these substances on June 24, 2009. EPA withdrew the direct final SNURs on August 21, 2009, in response to a notice of intent to submit adverse comments.



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Substances Subject to the Proposed SNURs

Today's proposed SNURs include the following information regarding the substances:

PMN Number P08177

Chemical name: Multi-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA Section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA Section 5(e) consent order: The PMN states that the generic (nonconfidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under Sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNT), EPA believes that the PMN substance may cause lung effects. To protect against this risk, the consent order requires use of a National Institute for Occupational Safety and Health (NIOSH)-approved full-face respirator with N100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the United States. The proposed SNUR would designate as a significant new use the absence of these protective measures.

Toxicity concern: There is a concern for lung health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.



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Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test Guideline 870.3465 or Organization for Economic Co-operation and Development (OECD) 413 test guideline) with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis; and certain material characterization data would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 C.F.R. § 721.10155.

PMN Number P08328

Chemical name: Single-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA Section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA Section 5(e) consent order: The PMN states that the generic (nonconfidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under Sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other CNTs, EPA believes that the PMN substance may cause health effects. To protect against this risk, the consent order requires use of a NIOSH-approved full-face respirator with N100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the



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United States. The proposed SNUR would designate as a significant new use the absence of these protective measures.

Toxicity concern: There is a concern for health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test Guideline 870.3465 or OECD 413 test guideline) with a post-exposure observation period of up to 3 months, including BALF analysis; and certain material characterization data would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 C.F.R. 721.10156.

Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to the proposed SNURs have undergone premanufacture review and are subject to TSCA Section 5(e) consent orders, which prohibit the PMN submitters from undertaking activities that EPA is proposing as significant new uses. EPA requests comments on whether any of the uses proposed as significant new uses are ongoing. EPA notes that it designates a use as a significant new use as of the date of publication of the proposed rule, rather than as of the effective date of the final rule. Thus, persons who begin commercial manufacture, import, or processing activities with the chemical substances that would be regulated as a significant new use through the proposed SNURs must cease any such activity before the effective date of final SNUR, if promulgated. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.



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Test Data and Other Information

EPA states that it recognizes that TSCA Section 5 does not require developing any particular test data before submission of a significant new use notice (SNUN), except where the chemical substance subject is also subject to a TSCA Section 4 test rule. Persons are required only to submit test data in their possession or control, and to describe any other data known to or reasonably ascertainable by them. EPA notes, however, that upon review of PMNs and SNUNs, it “has the authority to require appropriate testing.”

In the TSCA Section 5(e) consent orders for the two chemical substances regulated under the proposed SNURs, EPA has established production volume limits in view of the lack of data on the potential health risks that may be posed by the significant new uses or increased exposure to the chemical substances. EPA states that these limits “cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances.” EPA acknowledges that the recommended tests “may not be the only means of addressing the potential risks of the chemical substance,” but state that “SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter.”

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We hope this information is helpful. As always, please call if you have any questions.