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Request to Finalize the EPA Reporting and Recordkeeping Rule for Nanoscale Materials
(RIN:2070-AJ54)

We write this letter to encourage OMB to finalize EPA's Proposed Rule on Nanomaterials Reporting and Recordkeeping.¹ Under its TSCA Section 8(a) authority, EPA is proposing to require persons that manufacture (defined by statute to include import) or process, or intend to manufacture or process these chemical substances to electronically report to EPA certain information, which includes the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects. This proposal involves one-time reporting for existing nanoscale materials and one-time reporting for new discrete nanoscale materials before they are manufactured or processed.²

Nanoscale chemicals (nanomaterials) are in products from all commercial sectors ranging from sports equipment to agrochemicals to clothing. Increased concern for potential health and environmental impacts of chemicals, including nanomaterials, in consumer products is driving demand for greater transparency regarding potential risks. To that end, we recently published the results of our research using the GreenScreen hazard assessment method to show both hazards and data gaps for conventional silver and nanosilver approved by EPA for commercial uses.³ The ability to conduct hazard assessments, like the GreenScreens we published, depends on reliable and publicly available information. EPA's Rule is an important tool to gather relevant data on nanomaterials to inform hazard assessment, regulatory decisions, and industrial product design and development.

Unfortunately, we disagree with EPA's proposal to exclude from the requirements of this rule nanoclays, zinc oxide, and chemical substances manufactured at the nanoscale as part of a film on a surface. We

¹ J Sass submitted comments to EPA on this proposed rule in August, 2016 (EPA-HQ-OPPT-2010-0572-0126)

² OIRA update on the nano rule : <http://www.reginfo.gov/public/do/eoDetails?rrid=126831>

³ Sass J, Heine L, Hwang N. Use of a modified GreenScreen tool to conduct a screening-level comparative hazard assessment of conventional silver and two forms of nanosilver. *Environ Health*. 2016 Nov 8;15(1):105. Free Full Text Available here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5101654/>

disagree with EPA's position that these materials are either well-characterized or that they present little exposure potential. We believe that exclusions should not be given without the data to support the claims. EPA, the public, processors, formulators, risk assessors, and others need robust, reliable, and publicly available information to evaluate and validate product and material safety claims. We would urge EPA to drop the proposed exclusions in the final rule.

Thank you for your consideration of our request to finalize EPA's Proposed Rule.

Respectfully,



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