



## TSCA Advisory

June 17, 2008

### EPA Reverses Its Position on TSCA Statutory Mixtures

Reversing thirty years of seemingly consistent guidance, the Environmental Protection Agency has declared that six categorical TSCA Inventory listings commonly known as “statutory mixtures” listings on which industry has relied for decades do not in fact cover any chemical substance produced during manufacture of these statutory mixtures. EPA now says that producers of alloys, inorganic glasses, ceramics, frits or cements who manufacture chemical substances during their production processes must separately report each such substance for the Inventory, using the premanufacture notification (PMN) process, despite the presence on the Inventory of these broad categorical listings, which by their terms cover all chemicals manufactured during the production of alloys, ceramics, etc. EPA’s apparent about-face places whole industries at risk of TSCA non-compliance.

In 1977-78, while EPA was developing guidance on how manufacturers should report chemicals for inclusion on the Initial TSCA Inventory, both EPA and industry recognized the huge difficulty in identifying the particular chemical substances created during the production of six types of products. Consequently, EPA created the following six categorical Inventory listings to cover any and all chemicals created during their production:

Cement, Portland, Chemicals	(65997-15-1)
Cement, Alumina, Chemicals	(65997-16-2)
Glass, Oxide, Chemicals	(65997-17-3)
Frits, Chemicals	(65997-18-4)
Steel Manufacture, Chemicals	(65997-19-5)
Ceramic Materials and Wares, Chemicals	(66402-68-4)

EPA stated that manufacturers of products falling within one of these six categories could use the appropriate categorical CASRN to simultaneously report all of the individual chemical substances manufactured during the production of their product. Therefore, it was unnecessary to report separately each individual substance.

EPA declared that these six types of products would be considered “statutory mixtures,” i.e., treated as though they were physical mixtures, even though it was obvious that chemical reactions would take place among the starting materials during production of these products. EPA’s position, later repeated in informal guidance, indicated that after publication of the Initial Inventory, manufacturers had no PMN obligation for any new chemical substances formed during production of new products falling within these six categories, so long as the final product satisfied one of the six Inventory-listed definitions (alloy, inorganic glass, ceramic, etc.). As EPA stated in its 1995 Guidance on Statutory Mixtures: “. . . instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include the various substances formed when cement, glass, frits or ceramics are produced.”

In September 2007, having been alerted to EPA’s new position, the American Chemical Council (ACC) sent a letter that we drafted, which questioned whether the Agency was changing its longstanding guidance. Responding to ACC in a May 28, 2008 letter, however, the Agency stated that its position “is consistent with long-standing policy” and reaffirmed that “the existing statutory mixture description should not be used to cover the chemically manufactured products in question for Inventory and TSCA reporting purposes.”

TSCA § 5(a)(1) prohibits manufacture of any “new chemical substance” (one not listed on the TSCA Inventory) unless the manufacturer submits a PMN to EPA at least 90 days before beginning commercial manufacture. Under EPA’s recent guidance, the six categorical listings on the Inventory have no apparent legal effect, and (in EPA’s view) manufacturers of products falling within any of these six categories may find themselves out of compliance if they have relied on those

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listings instead of filing PMNs on individual substances. Indeed, we believe that over the last three decades industry has heavily relied upon these Inventory categories to obviate the need for filing PMNs on any new chemical substances contained in their new products which qualified as a statutory mixture. Hence, EPA's decision to disallow such reliance is both troubling and troublesome, since it could cause potentially enormous TSCA penalties (\$32,500 per day of violation) and widespread business disruption. While individual companies should assess their compliance with EPA's new policy, the affected industries as a whole need to consider immediately whether they will challenge the Agency's abrupt policy reversal.

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