

March 11, 2010

www.klgates.com

Author:

Thomas R. Carey

tom.carey@klgates.com

+1.312.807.4365

K&L Gates includes lawyers practicing out of 36 offices located in North America, Europe, Asia and the Middle East, and represents numerous GLOBAL 500, FORTUNE 100, and FTSE 100 corporations, in addition to growth and middle market companies, entrepreneurs, capital market participants and public sector entities. For more information, visit www.klgates.com.

EPA Switches Gears on Activated Phosphors Manufacturers / Importers Now Subject to TSCA Premanufacture Notification Submittal and Other Agency Notification and Review Requirements

On February 24, 2010, the United States Environmental Protection Agency (“EPA”) issued a “final clarification” that activated phosphors (a/k/a “doped phosphors”) will be classified as “new chemical substances” rather than “mixtures” as those terms are defined under the Toxic Substances Control Act or “TSCA.”¹ This clarification presents new regulatory burdens and other impacts on manufacturers and importers of activated phosphors.

Why? Because “mixtures” are generally not subject to TSCA’s Section 5 premanufacture notification (“PMN”) and other regulatory requirements.² New chemical substances, on the other hand, are regulated under TSCA. Manufacturers and importers of activated phosphors are now required to come into compliance with TSCA requirements (primarily filing PMNs and going through the EPA regulatory review process) by August 24, 2011. A failure to do so will result in an inability to continue to manufacture or import these substances after that date.

Activated phosphors are widely-used in the manufacture of florescent lighting, televisions, LEDs, and numerous other products. Their primary attribute is that they phosphoresce or “glow” when exposed to ultraviolet light or energized particles like electrons. An activated phosphor is typically produced through a chemical combination of a mixture of metal oxides, carbonates, phosphates or acid phosphates, chlorides, and/or fluorides – most frequently by sintering – along with a small amount of one or more dopants. When an activated phosphor is electrically excited, it emits light – the color and electrical efficiency of which is a function of the parent phosphor and of the dopant present.

Up to now, EPA has generally taken the position that activated phosphors constitute “mixtures” of phosphors and dopants and, therefore, were not subject to TSCA Section 5 PMN requirements. Under TSCA, a “mixture” is defined, in part, as follows: “any combination of two or more chemical substances *if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; . . .*”³ As stated above, mixtures are not subject to TSCA Section 5.

This initial classification of activated phosphors as mixtures by the agency is important. To begin with, it prevented some activated phosphor manufacturers from getting their substances on the Initial TSCA Inventory that was compiled from 1978 to 1979.⁴ The Initial TSCA Inventory essentially grandfathers the chemical

¹ See Federal Register, Volume 75, Number 36, pages 8266-8272 (February 24, 2010).

² So long as each constituent of the mixture is already listed on the TSCA Inventory.

³ See TSCA Section 3(8); 15 U.S.C. § 2602(8) (emphasis added).

⁴ According to the EPA’s final clarification, between 1978 and 1979 it did accept “many” doped phosphors for listing on the Initial TSCA Inventory.

substances listed therein from further TSCA regulatory requirements. In other words, some manufacturers who tried to get their activated phosphors listed in 1978-1979 were denied the benefits of grandfathering. Furthermore, classifying activated phosphors as “mixtures” allowed manufacturers and importers the freedom to set up their manufacturing and importing programs without the regulatory burden of complying with TSCA – so long as each phosphor and dopant used was already listed on the TSCA Inventory.

After further consideration, however, EPA now believes that the manufacturing process to create an activated phosphor is a *chemical reaction* that results in a new chemical substance being formed, rather than a simple mixture of phosphor and dopant – thus triggering the TSCA regulatory process. EPA’s rationale is detailed and set forth in the notification published in the Federal Register as noted above.

As a result of this reclassification from “mixture” to “new chemical substance,” manufacturers and importers of activated phosphors need to assess how to come into compliance with TSCA requirements by August 24, 2011.⁵ This may involve checking the TSCA inventory to see if the activated phosphor is one of the “many” that made it onto the Initial TSCA Inventory in 1978-1979.

If not already listed on the TSCA Inventory, and the activated phosphor is not subject to a TSCA exemption (e.g. R&D, Low Volume Exemption, Test Marketing – all having their own regulatory requirements that will need to be followed), the manufacturer or importer will need to timely submit a TSCA Section 5 PMN application to the agency so that PMN review will be completed on or before the effective date of August 24, 2011.⁶

⁵ Examples of potentially-impacted industries flagged by EPA include, but are not limited to, the following: (i) Chemical Manufacturers and Importers (NAICS Codes 325, 3251); and (ii) Electric Lighting Equipment Manufacturing, Electric Lamp Bulb and Part Manufacturing and Importing (NAICS Codes 3351, 33511).

⁶ The agency held the door open for some activated phosphor manufacturers / importers to demonstrate that their products / imports are still mixtures despite its final clarification, stating: “EPA will work closely with manufacturers to resolve chemical identity issues for any specific material that the manufacturer

The PMN review process as it relates to the effective date presents some important logistics and timing considerations. In this regard, the PMN review process for new chemical substances is a statutory ninety (90) days; with allowances for review extensions up to an additional ninety (90) days.⁷ According to the EPA’s final clarification, the ninety (90) day PMN review period will require manufacturers to file PMNs at least ninety (90) days prior to the effective date of August 24, 2011.⁸ Since EPA has up to an additional ninety (90) days to review the PMN, manufacturers and importers may want to submit required PMNs 180 days prior to the August 24, 2011 effective date; or by February 24, 2011 – a year from now – to be on the safe side. As one of the commenters to the proposed clarification noted, “... EPA rarely meets the 90-day review period for inorganic substances.”⁹

Finally, EPA’s final clarification states that the PMN process will not be relaxed to address activated phosphors. PMN submittals will require all information typically required, including a detailed description of the chemical identity of the activated phosphor, anticipated impurities, synonyms or trade names, description of byproducts, estimated maximum production volumes, intended categories of use, and toxicity data on the chemical substance that are in the possession or control of the notice submitter (or known to or reasonably ascertainable by the notice submitter).¹⁰ Manufacturers and importers of activated phosphors who are not in compliance with, or exempted by, TSCA by August 24, 2011 must cease manufacture and import activities after that date or face significant penalties for non-compliance.

believes should be viewed as a mixture.” See Federal Register, Volume 75, Number 36, page 8269.

⁷ See TSCA Section 5(c); 15 U.S.C. § 2605(c).

⁸ *Id.* at 8269.

⁹ See Federal Register, Volume 75, Number 36, page 8271.

¹⁰ See 40 CFR § 720.45.

Anchorage Austin Beijing Berlin Boston Charlotte Chicago Dallas Dubai Fort Worth Frankfurt Harrisburg Hong Kong London
Los Angeles Miami Moscow Newark New York Orange County Palo Alto Paris Pittsburgh Portland Raleigh Research Triangle Park
San Diego San Francisco Seattle Shanghai Singapore Spokane/Coeur d'Alene Taipei Tokyo Washington, D.C.

K&L Gates includes lawyers practicing out of 35 offices located in North America, Europe, Asia and the Middle East, and represents numerous GLOBAL 500, FORTUNE 100, and FTSE 100 corporations, in addition to growth and middle market companies, entrepreneurs, capital market participants and public sector entities. For more information, visit www.klgates.com.

K&L Gates is comprised of multiple affiliated entities: a limited liability partnership with the full name K&L Gates LLP qualified in Delaware and maintaining offices throughout the United States, in Berlin and Frankfurt, Germany, in Beijing (K&L Gates LLP Beijing Representative Office), in Dubai, U.A.E., in Shanghai (K&L Gates LLP Shanghai Representative Office), in Tokyo, and in Singapore; a limited liability partnership (also named K&L Gates LLP) incorporated in England and maintaining offices in London and Paris; a Taiwan general partnership (K&L Gates) maintaining an office in Taipei; a Hong Kong general partnership (K&L Gates, Solicitors) maintaining an office in Hong Kong; and a Delaware limited liability company (K&L Gates Holdings, LLC) maintaining an office in Moscow. K&L Gates maintains appropriate registrations in the jurisdictions in which its offices are located. A list of the partners or members in each entity is available for inspection at any K&L Gates office.

This publication is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer.

©2010 K&L Gates LLP. All Rights Reserved.