

**§ 180.568 Flumioxazin; tolerances for residues.**

(a) \* \* \* Tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flumioxazin.

Commodity	Parts per million
* * *	* *
Hop, dried cones .....	0.05
Leaf petioles subgroup 4B ...	0.02
* * *	* *
Vegetable, cucurbit, group 9	0.03
* * *	* *

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Subchapter R**

[EPA-HQ-OPPT-2007-0392; FRL-8798-9]

RIN 2070-AJ21

**Final Clarification for Chemical Identification Describing Activated Phosphors for TSCA Inventory Purposes**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final clarification.

**SUMMARY:** This is a clarification under which certain activated phosphors that are not on the Toxic Substances Control Act (TSCA) section 8(b) Chemical Substance Inventory (TSCA Inventory) will be considered to be new chemical substances under TSCA section 5, and thus will be subject to applicable notification requirements under TSCA section 5. In certain letters and other statements issued by EPA from 1978 to 2003, the Agency erroneously indicated that activated phosphors (otherwise known as doped phosphors) constitute mixtures of phosphors and dopants for purposes of the TSCA Inventory, and thus that they were not separately reportable as chemical substances under TSCA section 5(a) new chemical notification requirements. This clarification is necessary because EPA's statements in this area have not been consistent.

**DATES:** EPA's clarification is effective August 24, 2011.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2007-0392. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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**SUPPLEMENTARY INFORMATION:****I. Does this Action Apply to Me?**

You may be affected by this action if you are, or may in the future be, a manufacturer or importer of an activated phosphor that requires submission of a premanufacture notification (PMN) or

exemption request under TSCA section 5. Special procedures will apply to persons who manufactured these chemical substances after the publication of the Initial TSCA Inventory and before the effective date of this final chemical identification clarification document in the **Federal Register**. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers or importers (NAICS codes 325, 3251), e.g., anyone who manufactures or imports, or who plans to manufacture or import, an activated phosphor for a non-exempt commercial purpose.
- Electric lighting equipment manufacturing, electric lamp bulb and part manufacturing (NAICS codes 3351, 33511), e.g., anyone who manufactures or imports, or who plans to manufacture or import, lighting equipment containing an activated phosphor for a non-exempt commercial purpose.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

**II. Background****A. What Action is the Agency Taking?**

EPA is clarifying that certain previous EPA statements which indicated that activated phosphors are mixtures rather than chemical substances in their own right were erroneous, and that TSCA Inventory listing may be required for these materials. This action provides a clarification in the approach used for the chemical identification of activated (doped) phosphors for purposes of listing on the TSCA Inventory. This clarification was proposed in the **Federal Register** issue of January 16, 2008 (73 FR 2854) (FRL-8131-8) and a reopening of comments on the proposed clarification was announced in the **Federal Register** issue of May 2, 2008 (73 FR 24187) (FRL-8360-7).

An activated phosphor is a substance resulting from the 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. Dopants can include such substances as

yttrium, europium, germanium, gallium, strontium, antimony, manganese, or magnesium. When an activated phosphor is electrically excited, it emits light. The color and electrical efficiency of light emission is a function of the parent phosphor and of the dopant which is present.

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current an inventory of chemical substances manufactured (which includes import) or processed for commercial purposes in the United States. This inventory is known as the TSCA Chemical Substance Inventory (TSCA Inventory). EPA promulgated a rule in the **Federal Register** issue of December 23, 1977 (42 FR 64572) under TSCA section 8(a), 15 U.S.C. 2607(a), to compile an inventory of chemical substances in commerce at that time. Building on several earlier interim policies, EPA promulgated a rule in the **Federal Register** issue of May 13, 1983 (48 FR 21722) setting forth procedures for the submission, receipt, and health and safety review of PMNs covering chemical substances not yet in commerce when required under TSCA section 5, 15 U.S.C. 2604. Section 8(b)(1) of TSCA, 15 U.S.C. 2607(b)(1), instructs EPA to add a PMN substance to the TSCA Inventory as of the earliest date on which it is manufactured or processed in the United States.

Manufacture of a non-exempt new chemical substance is prohibited prior to the expiration of the new chemical notice review period. Once EPA receives a PMN, the Agency has 90 days to review the notice (unless for good cause EPA extends the review period); the Agency has 30 or 45 days to complete its review of exemption requests. During the review period, EPA may act under TSCA section 5(e) or 5(f) to regulate the new chemical substance. If EPA has not prohibited manufacture of the chemical substance during the review period, manufacture may begin subject to any restrictions or testing requirements imposed upon the submitter during the review period (these restrictions may be imposed upon others via a Significant New Use Rule (SNUR) and subsequent action under TSCA section 5(e) or 5(f) taken in follow-up to a significant new use notification (SNUN)). When manufacture begins, the notice submitter must provide a Notice of Commencement of Manufacture or Import (NOC), after which EPA adds the chemical substance to the TSCA Inventory. If the Agency receives a new chemical notice submission for a chemical substance which EPA determines is excluded from

consideration as a chemical substance under TSCA (generally because it meets the criteria for one of the excepted categories at TSCA section 3(2)(B), which include mixtures, pesticides, tobacco, food, drugs, etc.) the Agency will not accept the new chemical notice. Similarly, during the period 1978–1979, when EPA was accepting submissions for the Initial TSCA Inventory, and during 1979–1983, prior to promulgation of the May 13, 1983 PMN rule, the Agency rejected notifications for materials which it determined to be excluded.

#### *B. Why is the Agency Taking this Action?*

Partly as a result of the Agency's incomplete information and understanding of the chemistry involved in manufacturing activated phosphors, from 1978 through 2003, EPA was inconsistent in its statements to potential submitters and in its actions regarding whether activated phosphors are considered distinct chemical substances for purposes of the TSCA Inventory. During the period 1978–1979, when EPA received submissions for the Initial TSCA Inventory, it accepted many doped phosphors for listing, but in some cases it sent “problem letters” to the manufacturers of doped phosphors indicating that they were mixtures of the phosphor and dopants and thus ineligible for listing.

In October 1979, the Agency wrote to a lighting manufacturer and stated that such listings could be “unnecessary” and that their continued inclusion on the TSCA Inventory would be “closely examined.” In January 1980, a lighting manufacturer wrote to the Agency to challenge problem letters it had received. The manufacturer stated that the materials it manufactured should be excluded from mixture status because they had characteristic crystal structures and that volatile reaction products given off during their manufacture showed that chemical synthesis was occurring. In March 1982, the Agency wrote to a lighting manufacturer and suggested that certain chlorophosphate activated phosphors could be regarded either as physically altered chlorophosphates or as mixtures, thus not subject to premanufacture notice. In August 1983, the Agency wrote to the lighting manufacturer which had challenged the problem letters and informed it that the materials had, in fact, been placed on the TSCA Inventory, and in addition that a new chemical notice was appropriate for another activated phosphor but that ‘low levels’ of an activator would not require a separate new chemical notice.

In January 1993, a lighting manufacturer submitted a Low Volume Exemption (LVE) Application for an activated phosphor with a letter referencing much of the history as described in this document and asserting that, based on Agency positions, no submission should be necessary, but the Agency did accept the application and granted the LVE. After that LVE was granted, the manufacturer submitted a letter asserting that activated phosphors should, in fact, be considered to be mixtures and requested that the Agency issue a clarifying statement. In response, the Agency met with the manufacturer on the issue and indicated that activated phosphors should be considered chemical substances instead of mixtures, but did not issue a written clarification.

In 1995, EPA issued the publication entitled “Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures (Formulated and Statutory Mixtures),” available at <http://www.epa.gov/opptintr/newchems/pubs/mixtures.txt>, which provided guidance regarding the mixture definition given at 40 CFR 710.2(q) and 720.3(u):

*Mixture* means 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; except “mixture” does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.

“Formulated and Statutory Mixtures” discusses common examples of mixtures, including paints, blended fuels, and solvent combinations. “Mixture” can include, as well, solid solutions—homogeneous crystalline phases composed of several distinct chemical species. Alloys are solid solutions, and are considered mixtures. For the purposes of TSCA, multi-component blends or formulations of chemical substances, or certain reaction product combinations which can be completely characterized as consistently formed definite sets of their constituent chemical substances, are considered to be mixtures of chemical substances. Mixtures are not reportable, although their constituent chemical substances are. Most important in the context of

this document, a mixture can often provide its function over some range of constituent ratios, consequently it is unusual if the ratios of chemical substances which comprise a mixture are necessarily definite or stoichiometric, and if the mixture components are deliberately reacted together to manufacture a chemical substance, EPA does not consider this reaction product to be a mixture for TSCA purposes except in very specialized circumstances which are not present in the case of the activated phosphors.

In June 1998, a lighting manufacturer wrote to the Agency and stated that, in the absence of any negative response by the Agency within 60 days of the letter, it intended to rely on its interpretation of "Formulated and Statutory Mixtures," and that it believed that that interpretation precluded TSCA Inventory listing for activated phosphors. The Agency did not respond to that letter. Based on a 2003 request from a lighting manufacturer, and cognizant of the history described in this document, EPA held a meeting with the manufacturer in September 2003 and as a result has reexamined some earlier assumptions—particularly about non-stoichiometry and non-reaction between chemical substances used to make activated phosphors—which may have led it to believe that activated phosphors could be considered mixtures.

The result of this reexamination is this clarification that EPA generally considers activated phosphors to be distinct chemical substances under TSCA. EPA's clarification on the potential need to report activated phosphor materials is based on its updated understanding about reaction characteristics and stoichiometry in activated phosphor manufacture: Activated phosphors are in general synthesized by means of a solid state reaction at high temperature and typically using precise quantities of the precursor chemical substances, both for the base materials and for the dopants which control the quality of light emitted. Precise ratios of component materials are used to maintain strict stoichiometry in the end product, and component materials are thoroughly blended before reaction for uniformity of the product. Heat may be absorbed or released by the reactant mixture at certain temperatures, typically by the release of water; this is often an indication of chemical substance synthesis. During the manufacture of activated phosphors, other volatile reaction products are often emitted, another indication that chemical

substances are being formed. The phosphor and the amount of dopant added need to be controlled with high precision, and during sintering the doped phosphor undergoes oxidation state changes. Each of these reaction characteristics is a strong indication that a chemical substance is being synthesized. Since most or all of these characteristics are generally present in activated phosphor manufacture, EPA believes that activated phosphors are manufactured for commercial purposes with chemical reaction. Additionally, activated phosphor products have a different function from the material which would be produced by the same synthetic process in the absence of dopant, and which would not emit the characteristic light, which is the primary property sought. Because dopants provide the primary property sought from these materials, small or even trace amounts of dopant are considered to be reactants which must be included in the chemical identity. Therefore, in EPA's view these materials are not "mixtures" of phosphors and dopants.

#### *C. Why is this Chemical Identity Clarification Necessary?*

Because EPA does not view activated phosphors as mixtures, some previous EPA statements that such materials may not need to be reviewed through the new chemicals process were incorrect. As a result of certain past EPA statements, some manufacturers of activated phosphors have not submitted new chemical notices under TSCA section 5 because those statements incorrectly indicated that activated phosphors were covered for TSCA purposes if the phosphors and activators were already on the TSCA Inventory. Other manufacturers have submitted new chemical notices for similar materials, and they have generally been given TSCA Inventory listings. Several industry representatives have asked EPA to clarify the Agency's chemical identity policy for activated phosphors. EPA now agrees that it is necessary to add listings to the TSCA Inventory for activated phosphors which have been manufactured but not listed. This document provides a clarification to previous statements on chemical identity for activated phosphors. On the effective date of this clarification, activated phosphors that are not on the TSCA Inventory will be considered new chemical substances under TSCA section 5.

Because some of the statements provided by the Agency prior to 2003 led some manufacturers to believe that the products they manufactured were

already on the TSCA Inventory if the phosphors and activators were on the TSCA Inventory, some manufacturers of activated phosphor products have not submitted new chemical notices required under TSCA section 5. This chemical identification problem is similar to one involving monomer acid and its derivatives, which was resolved through Agency-industry dialog and a period for submission of new chemical notices (Correction to Chemical Nomenclature for Monomer Acid and Derivatives for TSCA Inventory Purpose published in the **Federal Register** issue of June 27, 2001 (66 FR 34193) (FRL-6784-6)). The Agency is addressing this activated phosphor situation in a similar manner.

### **III. Activated Phosphors Under the TSCA Inventory and Implications for TSCA Section 5 Reporting**

EPA is clarifying that those of EPA's earlier statements which indicated that activated phosphors are mixtures rather than chemical substances in their own right were erroneous, and that TSCA Inventory listing or TSCA section 5(h)(4) exemption will be required for these materials. Pursuant to TSCA section 5(a)(1), 15 U.S.C. 2604(a)(1), new chemical notices will be required for activated phosphors not on the TSCA Inventory (and for which a TSCA section 5(h)(4) exemption has not been granted) and which are manufactured on or after the effective date of the clarification. See EPA PMN regulations at 40 CFR part 720 for details regarding when reporting is required. Consistent with TSCA Inventory correction guidelines published in the **Federal Register** issue of July 29, 1980 (45 FR 50544), EPA does not consider activated phosphors that were never reported for the Initial TSCA Inventory to be eligible for TSCA Inventory correction as an alternative to new chemical notice submission.

#### *A. What are the Nature and Scope of this Clarification?*

EPA does not believe that activated phosphors are mixtures rather than chemical substances in their own right. Thus listing on the TSCA Inventory established under TSCA section 8(b) may be required for these chemical substances. This clarification will affect anyone who manufactures, or who plans to manufacture, an activated phosphor not currently listed on the TSCA Inventory and for a TSCA-covered use.

#### *B. What are the Key Dates and Provisions of this Clarification?*

The effective date for this clarification, described in Unit II.B., will

be 18 months after date of publication of this final document in the **Federal Register**. After the effective date, any person manufacturing an activated phosphor for a non-exempt commercial purposes and who has not met the new chemical substances requirements of TSCA section 5 will not be considered in compliance with TSCA. By that date, companies required to submit PMNs or exemption notices must have done so at least 90 days (for PMNs, less for exemption notices) before the effective date, to ensure that Agency review is completed before this clarification takes effect.

By that date, companies required to submit premanufacture notices or exemption applications must have done so at least 90 days (for PMNs, less for exemption applications) before the effective date, to ensure that Agency review is completed before this clarification takes effect. New chemical notice review may entail suspension of the notice review period (either by EPA or at the request of the submitter). If a new chemical notice seeking an exemption is rejected, a PMN may need to be filed. Because manufacture may not continue after the 18-month period provided in this notice, companies are advised to submit any required new chemical notices well before the effective date to ensure that all issues are resolved in a timely fashion.

EPA will work closely with manufacturers to resolve chemical identity issues for any specific material that the manufacturer believes should be viewed as a mixture.

To facilitate the new chemical notice process for activated phosphors currently being manufactured but which are not listed on the TSCA Inventory as distinct chemical substances, EPA will allow an exception to its TSCA new chemicals program policy limit of six chemical substances per consolidation notice for these chemical substances. EPA encourages persons intending to manufacture activated phosphors to file new chemical notices using the proper chemical identity immediately instead of delaying their submissions to near the effective date of this document.

New chemical notices filed in response to this chemical identification clarification shall, as specified in 40 CFR 720.50, include all information normally included with a new chemical notice submission, such as 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.

*C. Will a New Chemical Notice Be Required for Persons Who Did Not Submit One Due to an Incorrect EPA Statement, Regardless of Whether They Still Manufacture the Chemical Substance?*

Where required by TSCA section 5 and in accordance with 40 CFR part 720, a new chemical notice must have been submitted for any manufacture for a non-exempt commercial purpose that takes place on or after August 24, 2011. No new chemical notice need be submitted for manufacture taking place before that date. For example, if you manufactured such a phosphor in 1986 but will not be resuming manufacture after August 24, 2011, you are not required to submit a new chemical notice at this time. However, if you later form an intention to manufacture the activated phosphor on or after the effective date of this clarification and the chemical substance has not in the interim been placed on the TSCA Inventory due to another company's manufacture or import, you will need to submit a new chemical notice (and the review period must be completed) before commencing manufacture. Activated phosphors manufactured before August 24, 2011 can be used or processed after the effective date, whether a new chemical notice has been filed or not.

*D. Discussion of Public Comments on the Proposed Clarification*

The Agency reviewed and considered the comments submitted on the proposed clarification published in the **Federal Register** issue of January 16, 2008. Copies of all submitted comments are available in the docket for this action.

1. *Comment.* Commenter OSRAM Sylvania questions the Agency's authority for requiring new chemical reporting for chemical substances that have been in production for some time. The commenter states that "EPA lacks the authority to extend the scope of the TSCA Inventory and PMN requirements to the regulations of these existing chemicals." The commenter suggests that the Agency use TSCA Inventory correction procedures to deal with activated phosphors, and argues that the clarification as to the TSCA Inventory status of activated phosphors constitutes rulemaking, as "it would impose new, substantive legal obligations upon a class of chemicals and companies."

*Response.* EPA disagrees with the comment. TSCA section 3(2) defines "chemical substance" in relevant part as "any organic or inorganic substance of a particular molecular identity." Two

chemicals with differing molecular identities are therefore considered different chemical substances under TSCA. TSCA section 3(9) defines a "new chemical substance" as "any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title" (i.e., the TSCA Inventory). TSCA section 5(a)(1) applies PMN reporting requirements (or applicable exemptions) to new chemical substances. Thus, regardless of the fact that an activated phosphor may have been in commerce for years, if it has not been reported for the TSCA Inventory or added to the TSCA Inventory via PMN and NOC per 40 CFR part 720, it constitutes a new chemical substance subject to TSCA section 5.

This clarification does not create obligations under TSCA. Requirements for new chemical notice reporting are self-executing in TSCA, flowing from TSCA section 5(a)(1) (with "chemical substance" being defined in TSCA section 3(2) and "mixture" defined in TSCA section 3(8)). The purpose of this document is simply to provide notice of how EPA intends to enforce these provisions with respect to activated phosphors. EPA does not believe that this action constitutes rulemaking, but if it were rulemaking it would be interpretive rulemaking not subject to notice and comment under the Administrative Procedure Act (APA).

The TSCA Inventory correction guidelines published in the **Federal Register** issue of July 29, 1980 indicate that materials that were never reported for the Initial TSCA Inventory are not eligible for TSCA Inventory correction as an alternative to premanufacture notice submission. The guidelines describe three main categories as appropriate for correction: Corrections to the identity of previously reported materials, corrections identifying previously unrecognized isolated intermediates, and corrections made in response to Agency communications which identify reporting errors and request corrections. For the first category, the TSCA Inventory correction procedures are appropriate when errors may have been made in reporting the identity ("(1) corrections of typographical or transcriptional errors in recording chemical identity on the Inventory reporting forms..") or when new information improving a previously reported identity can be developed because improvements in analytical methods and equipment regarding a previously reported chemical substance indicate that the accurate description of the chemical substance is different from what was previously reported ("(2)

refinement of the identity of a reported substance, e.g., by narrowing the range of the values for a polymer; (3) identification of new components in the material, e.g., finding that a chemical substance reported as A is actually a mixture of A and B; and (4) discovery that a chemical substance is different from that reported previously, e.g., determining that a substance reported as A is actually C or that a substance reported as D is actually a mixture of E and F.”) Manufacturers’ failure to report activated phosphors for the TSCA Inventory under the first category is covered by none of the four eligibility criteria listed in this unit, which cover improved information about a previously reported chemical rather than failure to report it. Neither the second nor the third category is applicable here.

Under these guidelines, a blanket exclusion from TSCA section 5 reporting, and inclusion on the TSCA Inventory by correction, for all activated phosphors including those first manufactured subsequent to the reporting period for the Initial TSCA Inventory, would be inappropriate. EPA believes such an exclusion would prevent these materials from receiving the environmental, workplace safety, and consumer safety review contemplated by TSCA.

2. *Comment.* Commenter Color Pigment Manufacturers Association (CPMA) stated that because the EPA made its initial error in 1978, when materials were being entered into the TSCA Inventory by survey, EPA should allow for listing of the materials which are the subject of the action by survey and correction to the TSCA Inventory.

*Response.* CPMA has raised three issues here: Addition to the TSCA Inventory by survey for materials which were first manufactured before the end of the Initial TSCA Inventory reporting period, addition to the TSCA Inventory by survey for materials which were first manufactured after the end of the Initial TSCA Inventory reporting period, and use of the TSCA Inventory correction mechanism to enter non-TSCA Inventory materials onto the TSCA Inventory. CPMA’s comment provides no apparent rationale for allowing survey addition to the TSCA Inventory for materials first manufactured after the Initial TSCA Inventory reporting closed in 1979. We have responded to the suggestion that the corrections procedure be used for activated phosphor materials in our response to the comment by OSRAM Sylvania, in Unit III.D.1.

In regard to materials which were in commerce already before the end of the

Initial TSCA Inventory reporting period in 1978, the Initial TSCA Inventory has been closed to survey reporting since the end of TSCA Inventory reporting in 1979, with the only mechanism for changing the Initial TSCA Inventory listings and compilation having been TSCA Inventory corrections. Although there may have been some persons manufacturing activated phosphors during the Initial TSCA Inventory reporting period for TSCA who were confused by EPA guidance at that time, irrespective of the guidance, those persons should have reported for the Initial TSCA Inventory in some manner to account for their manufactured activated phosphor products. For example, in their Initial TSCA Inventory reporting, some persons may have identified their phosphor compounds without including the activators (dopants) in the chemical names. Others may have viewed their activated phosphors to be mixtures of two chemical substances (i.e., the activator and the phosphor host material), and reported both of their perceived mixture components.

EPA believes that a survey process for adding certain activated phosphors which may have been in commerce before 1978 to the TSCA Inventory at this late date would not be warranted. TSCA section 5 reporting for all activated phosphors not on the TSCA Inventory (and for which a TSCA section 5(h)(4) exemption has not been granted) and which are to be manufactured on or after the effective date of this clarification is a practical way to enable the affected manufacturers to come into compliance without undue disruption; it will facilitate the safety and environmental impact review for these materials intended in the statute; and the criteria used to assess these materials will be uniform.

3. *Comment.* Commenter American Chemistry Council (ACC) stated that this is more than a ‘clarification’, but that it is a reversal of a position held for 20 years. Therefore, a public review and comment period, and consultation with stakeholders, is in order.

*Response.* Rather than having stated a consistent position, EPA’s guidance has been inconsistent, as noted in the proposal. This clarification provides the guidance necessary to go forward with one policy about the activated phosphor materials. A significant number of manufacturers have in fact submitted PMNs and exemption notices covering over 200 activated phosphors (this includes reporting forms for the Initial TSCA Inventory) and the Initial TSCA Inventory reporting form and PMN

substances have been given TSCA Inventory listings. The Agency has provided an opportunity for stakeholder input in the comment process via the proposed clarification, and met with one manufacturer before the clarification was written and one during the comment period.

Most of the chemical substances subject to this clarification, and which are reportable, were manufactured after the close of the TSCA Inventory reporting period and new chemical notices would have been submitted had there not been any erroneous guidance from EPA. Therefore, the net new chemical notice reporting burden should be little greater than if EPA had issued accurate guidance on activated phosphors after the publication of the Initial TSCA Inventory. Those who have already reported activated phosphors will not need to do anything, while those who have not yet reported such chemical substances must do so by the effective date of this document. In this way, new chemical notices will finally have been submitted for all of the activated phosphors initially manufactured for a non-exempt commercial use. Due to the confusion caused by EPA’s earlier erroneous guidance, the Agency wishes to minimize any inconvenience to the chemical industry by providing an exception to its TSCA new chemicals program policy of a limit of six chemical substances per consolidation notice for these chemical substances and by setting an effective date for the consistent interpretation at 18 months after date of publication of this document in the **Federal Register**.

4. *Comment.* Commenter ACC said 12 months is not sufficient to do the work required to come into compliance with this clarification. ACC noted that regulated industry is doing a good deal of ongoing work to come into compliance with the European Union REACH program. EPA should lengthen time to come into compliance to 18–24 months.

*Response.* The Agency believes that the number of new chemical notice submissions which will be prepared to conform to the clarification will not be large, nor will they be unusually difficult to write. EPA’s estimate of the total number of premanufacture notices it will receive in response to this clarification is 30. After considering this comment, however, EPA agrees that 1 year could provide insufficient time to complete the new chemical notice review process for all activated phosphors affected by this clarification. Therefore, EPA has extended by 6 months the time that manufacturers and

importers who are currently manufacturing or importing affected activated phosphors would have had under the proposed clarification to complete the TSCA section 5 review process.

Under the proposed clarification, such manufacturers would have had to submit a premanufacture notice to EPA within 6 months after publication of the final clarification in order for EPA to have had the entire 180 day period authorized by TSCA section 5 (90 days plus opportunity for up to a 90-day extension under TSCA section 5(c)) to complete the PMN review. This time frame may have been too short in some circumstances. Under this final clarification, such manufacturers and importers will have up to 12 months to submit a PMN in order for EPA to have the entire 180-day review period (90 days plus opportunity for up to a 90-day extension under TSCA section 5(c)) to complete the review of a PMN. This approach will allow such manufacturers and importers additional time to compile the information necessary to prepare and submit PMNs or exemption requests. However, EPA encourages manufacturers and importers to submit PMNs or, alternatively, exemption requests as soon as possible after publication of the final clarification. Doing so will provide EPA with more time to complete any consent orders and, if necessary, establish testing requirements for those activated phosphors for which EPA may have concerns of potential unreasonable risk to human health or the environment.

5. *Comment.* Commenter CPMA said this action is onerous and punitive for CPMA members, and results from EPA's mistake. It will be disruptive if it results in materials being unavailable for manufacture during the PMN review process, and will be costly to small businesses.

*Response.* As noted in Unit III.D.1., it is the statute that imposes the requirement for new chemical notice reporting. This document is not punitive; rather it clarifies EPA's views with respect to the chemical identity of activated phosphors. The commenter is correct that the need for this action arises from the Agency's error, and EPA will make a diligent effort to complete the new chemical notice reviews as quickly as possible. We recommend that manufacturers submit as promptly as possible, and well before the effective date of the clarification. As noted in Unit III.D.4., we have lengthened the time period for coming into conformity with the clarification to 18 months from 12 months as proposed, and the effective date of the clarification has

been chosen to enable the reviews to be completed before the effective date. CPMA provided no information to support the claim that there are such small businesses and that the economic impact on them would be significant. EPA estimates that the number of new chemical notices which may be received from small businesses is 10. When EPA receives applications from small business as a result of this clarification we will make every effort to assist these submitters to navigate the process as necessary.

6. *Comment.* Commenter CPMA said the Agency has not provided any evidence in the proposed clarification that the phosphor materials subject to the clarification pose a significant risk to humans or the environment.

*Response.* TSCA compels TSCA section 5 review for new chemical substances, regardless of what information may be available regarding their risks. A TSCA section 5 notice presents information available to the submitter regarding risk for review and assessment by EPA.

7. *Comment.* Commenter CPMA states that EPA rarely meets the statutory 90-day review period for inorganic substances, and that a multi-year review would impose a burden on manufacturers of these materials. Commenter cited several cases.

*Response.* EPA will strive to complete the review of new chemical notices submitted in response to this clarification promptly. For more than 80% of submitted chemical substances, the new chemical notice review process is completed at the EPA Focus meeting, which takes place well before the end of the statutory 90-day PMN review period, and without the chemical substance being restricted or regulated in any way. For those new chemical substances for which EPA determines that regulatory action may be necessary, the new chemical notice review period may be suspended by the submitter to enable the Agency to consider additional information in its review and, if necessary, to develop and negotiate a consent order. The cases cited by the submitter were cases in which TSCA section 5(e) consent orders, which enabled the submitters to commence manufacture subject to certain conditions, were signed within a year of submission. The Agency recommends that affected manufacturers should submit their new chemical notices early in the period following publication of this document, and that they consult prior to submission with EPA's New Chemicals Management Branch ((202) 564-9373) in the New Chemicals Program to

determine what information will facilitate quick review.

8. *Comment.* Commenter CPMA said EPA has not substantiated that activated phosphors are not statutory mixtures and this action relative to activated phosphors is inconsistent with EPA policy on other mixtures.

*Response.* EPA believes that activated phosphors are chemical substances, not mixtures, under TSCA. These chemical substances consist of reaction products resulting from chemical bond formation between the activators and the host materials or precursors. As a result, the Agency considers the activators to be chemically incorporated in the activated phosphors, becoming part of the phosphor structure and composition.

9. *Comment.* Commenter OSRAM Sylvania said the host portion, not the activators, should be used in determining the TSCA Inventory status of phosphors.

*Response.* EPA believes that an activated phosphor is appropriately viewed as a chemical substance instead of a mixture under TSCA because the activator species (also known as dopants) are chemically incorporated into the structure of activated phosphors, and because the dopants provide the essential property of luminescence to the materials. Chemical incorporation is consistent with the wording used by the commenter to describe activated phosphors, such as "The activator(s) occupies lattice points at random or interstitial positions in the structure," and "...to form the host materials with the activators incorporated into the crystal structure," and is consistent with EPA's understanding of the nature of the activators' chemical interaction and incorporation during the manufacture of activated phosphors.

#### IV. Statutory and Executive Order Reviews

This document announces a clarification of one aspect of the TSCA Inventory chemical identification policy. This action is not a regulatory action under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866.

This document does not contain any new information collection requirements that would require additional review and approval by OMB under the Paperwork Reduction Act (PRA) 44 U.S.C. 3501 *et seq.* Under PRA, an agency may not conduct or sponsor, and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations are codified in 40 CFR chapter I, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in a list at 40 CFR 9.1.

The information collection activities related to the submission of information pursuant to TSCA section 5 have already been approved by OMB under OMB Control No. 2070-0012 (EPA Information Collection Request [ICR] No. 574). The burden for that ICR is estimated to average 100 hours per respondent, including time for reading the regulations, processing, compiling, and reviewing the requested data, generating the request, storing, filing, and maintaining the data.

This action is not subject to notice-and-comment requirements under the APA or any other statute, and is not subject to the provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Nor does this action significantly or uniquely affect the communities of tribal governments as specified by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 9, 2000).

Executive Orders 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) and 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), do not apply to this action because this action is not "economically significant" as defined by section 3(f) of Executive Order 12866. Nor does this action establish an

environmental standard that may have a negatively disproportionate effect on children, or otherwise have any significant adverse effect on the supply, distribution, or use of energy.

This action does not involve any technical standards that require the Agency's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

This action will not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency is not required to and has not considered environmental justice-related issues.

## V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

## List of Subjects in 40 CFR Subchapter R

Environmental protection, Chemical substances, Hazardous substances, Imports, Manufacturing, Reporting and recordkeeping requirements.

Dated: February 17, 2010.

**James Jones,**

*Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

[FR Doc. 2010-3675 Filed 2-23-10; 8:45 am]

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## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

#### 48 CFR Part 207

[DFARS Case 2009-D014]

**RIN 0750-AG61**

### Defense Federal Acquisition Regulation Supplement; Acquisition Strategies To Ensure Competition Throughout the Life Cycle of Major Defense Acquisition Programs

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Interim rule with request for comments.

**SUMMARY:** DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the Weapon Systems Acquisition Reform Act of 2009, section 202, Acquisition Strategies to Ensure Competition throughout the Lifecycle of Major Defense Acquisition Programs.

**DATES:** *Effective Date:* February 24, 2010.

*Comment Date:* Comments on this interim rule should be submitted in writing to the address shown below on or before April 26, 2010, to be considered in the formation of the final rule.

**ADDRESSES:** You may submit comments, identified by DFARS Case 2009-D014, using any of the following methods:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

*E-mail:* [dfars@osd.mil](mailto:dfars@osd.mil). Include DFARS Case 2009-D014 in the subject line of the message.

*Fax:* 703-602-0350.

*Mail:* Defense Acquisition Regulations System, Attn: Ms. Meredith Murphy, OUSD (AT&L) DPAP (DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301-3060.

*Hand Delivery/Courier:* Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202-3402.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Ms. Meredith Murphy, 703-602-1302.

#### SUPPLEMENTARY INFORMATION:

#### A. Background

On May 22, 2009, The Weapon Systems Acquisition Reform Act (Pub. L. 111-23) was enacted to improve the organization and procedures of DoD for the acquisition of major weapon systems. This law establishes new oversight entities within DoD, as well as new and varied weapon system acquisition and management reporting requirements.

Section 202 directs the Secretary of Defense (SECDEF) to ensure that the acquisition strategy for each MDAP includes: (1) Measures to ensure competition at both the prime contract and subcontract level of the MDAP throughout its life cycle as a means to improve contractor performance; and (2) adequate documentation of the rationale for selection of the