Dated: February 20, 1997.

Matthew Hale,

Acting Director, Office of Solid Waste.

[FR Doc. 97–5419 Filed 3–4–97; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 372

[OPPTS–400101; FRL–5584–9]

RIN 2070-AC00

Polymeric Diphenylmethane Diisocyanate; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of petition.

SUMMARY: EPA is denying a petition to remove polymeric diphenylmethane diisocyanate (PMDI) from the diisocyanates category subject to the reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). EPA has reviewed the available toxicological data on this chemical and has determined that PMDI does not meet the section 313(d)(3) deletion criterion. Therefore, EPA is denying the petitioner's request to remove PMDI from the EPCRA section 313 diisocyanates category.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Acting Petitions Coordinator, 202–260–3882, or e-mail: bushman.daniel@epamail.epa.gov, for specific information regarding this document or for more information on EPCRA section 313, the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 401 M St., SW., Washington, DC 20460, Toll free: 1–800–535–0202, in Virginia and Alaska: 703–412–9877 or Toll free TDD: 1-800-553-7672.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This action is taken under sections 313(d) and (e)(1) of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11023. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) (Pub. L. 99-499).

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using listed toxic chemicals to report their environmental releases of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act of 1990 (PPA), 42 U.S.C. 13106. Section 313 established an initial list of toxic chemicals that was comprised of more than 300 chemicals and 20 chemical categories. Polymeric diphenylmethane diisocyanate (PMDI) is a diisocyanate chemical reportable under the diisocyanates category which was added to the EPCRA section 313 list of toxic chemicals on November 30, 1994 (59 FR 61432) (FRL–4922–2). Section 313(d) authorizes EPA to add or delete chemicals from the list, and sets forth criteria for these actions. EPA has added and deleted chemicals from the original statutory list. Under section 313(e)(1), any person may petition EPA to add chemicals to or delete chemicals from the list. Pursuant to EPCRA section 313(e)(1), EPA must respond to petitions within 180 days, either by initiating a rulemaking or by publishing an explanation of why the petition is denied.

EPCRA section 313(d)(2) states that a chemical may be listed if any of the listing criteria are met. Therefore, in order to add a chemical, EPA must demonstrate that at least one criterion is met, but does not need to examine whether all other criteria are also met. Conversely, in order to remove a chemical from the list, EPA must demonstrate that none of the criteria are met.

EPA issued a statement of petition policy and guidance in the Federal Register of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for submitting petitions. On May 23, 1991 (56 FR 23703), EPA issued guidance regarding the recommended content of petitions to delete individual members of the section 313 metal compound categories. EPA has also published a statement clarifying its interpretation of the section 313(d)(2) and (3) criteria for adding and deleting chemical substances from the section 313 list (59 FR 61432).

II. Description of Petition

On August 15, 1995, EPA received a petition from the Polyurethane Division of the Society of the Plastics Industry (SPI) to delete PMDI (Chemical Abstracts Service Registry Number (CASRN) 9016–87–9) from the list of chemicals reportable under EPCRA section 313 and PPA section 6607. Specifically, the petitioner requested that PMDI be removed from the EPCRA section 313 diisocyanates category. The petitioner contends that PMDI should be delisted because: (1) PMDI does not independently meet the EPCRA section 313 toxicity criteria since it is a mixture that contains approximately 50 percent 4,4'-methylenediphenylene isocyanate (MDI), and it is the MDI that dominates the toxicity of the mixture; (2) PMDI is not a diisocyanate and does not meet the molecular weight criterion of the diisocyanates category that the petitioner claims was set by EPA; (3) MDI, which is the constituent of toxic concern, is listed in the diisocyanates category and its releases would continue to be reported by users of PMDI; and (4) the higher molecular weight oligomers that make up the other 50 percent of PMDI have low volatility relative to other members of the diisocyanates category which prevents significant environmental exposures.

Because the petitioner does not dispute the listing of MDI and acknowledges that the MDI component of PMDI is a source of the toxicity of PMDI, this petition is limited to the issue of whether the higher molecular weight oligomers in PMDI can reasonably be anticipated to add to the toxicity of PMDI such that PMDI should be included as a separate chemical in the diisocyanates category.

III. EPA's Technical Review of PMDI

A. Introduction

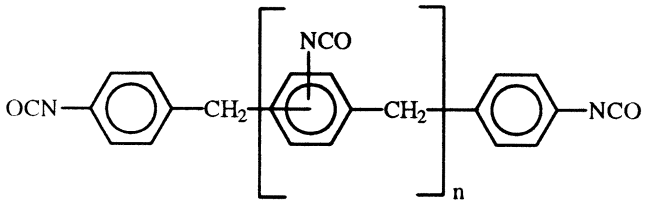
On November 30, 1994 (59 FR 61432), EPA added the diisocyanates category to the EPCRA section 313 list of toxic chemicals based on concerns for chronic pulmonary toxicity. There are no other criteria for defining this EPCRA section 313 category. The diisocyanates category consists of a list of 20 individual diisocyanates, including PMDI. The reference that the petitioner makes to a ''molecular weight criteria set by EPA for the diisocyanates category'' refers to the definition EPA set for the diisocyanates category under review by EPA's Office of Pollution Prevention and Toxics (OPPT) in the existing chemicals program (Ref. 1). The OPPT existing chemicals review was undertaken to determine whether to regulate diisocyanates under the Toxic Substances Control Act (TSCA). The TSCA diisocyanates category was defined as ''monomeric diisocyanates of molecular weight less than or equal to 300, plus polymeric diphenylmethane diisocyanate (which is only 40 to 60 percent polymerized).'' While EPA included all members of the TSCA category in the EPCRA section 313 diisocyanates category, it did not

include any molecular weight criterion or any other criteria other than the list of chemicals included in the EPCRA category. Therefore, molecular weight alone does not exclude a diisocyanate from being included in the EPCRA section 313 diisocyanates category.

The technical review of the petition to delete polymeric diphenylmethane diisocyanate included a review of the chemistry of PMDI (Refs. 2 and 3) and available toxicological data (Refs. 3-16). The focus of EPA's review, however, was on whether the higher molecular weight oligomers in PMDI can reasonably be anticipated to cause chronic pulmonary toxicity.

B. Chemistry

PMDI is manufactured by a process that results in a mixture that contains approximately 50 percent MDI and 50 percent higher molecular weight oligomers (Refs. 2 and 3). PMDI typically contains the following products in the percent ranges indicated in the figure below:



n	MW	Weight %
0 (MDI)	250	40-60
1	381	25-35
2	512	10-20
3	643	<5
4	774	trace

The higher molecular weight oligomers are those where n = 1 or greater in the above figure. As indicated above, less than 5 percent of the compounds in the mixture have a molecular weight greater than 512. The higher molecular weight oligomers contain the diisocyanate moiety; however, they are not formally identified as diisocyanates since they have more than two isocyanate groups. Since the reactive sites in diisocyanates are the isocyanate groups, these extra isocyanate groups are additional reactive sites (both chemically and biologically) within the molecule (Ref. 4). These higher molecular weight oligomers are structurally very similar to MDI, varying only by the sequential addition of an aromatic ring and an isocyanate group.

Since the higher molecular weight oligomers are never isolated as pure compounds, their physical/chemical properties have not been measured and must be estimated. Using data on MDI as a reference point, the estimated melting point range for the higher molecular weight oligomers in PMDI would be 30-50 °C, the estimated boiling point would be > 400 °C and the estimated vapor pressure would be < 1 x 10^{-5} millimeters mercury (mm Hg) (Ref. 2).

C. Toxicity Evaluation

In a 2–year chronic inhalation study (Refs. 12 and 13), Wistar rats (60/sex/exposure level) were exposed whole-body to 0, 0.2, 1.0, and 6.0 milligrams per cubic meter (mg/m^3) of PMDI aerosol for 6 hours/day (hrs/day), 5 days/week (days/wk), for 24 months. The PMDI material tested was a dark brown liquid with an average molecular weight of about 400 that contained 47 percent MDI and 53 percent higher molecular weight oligomers. Ninety five percent of the particles in the aerosols generated were smaller than 5 micrometers.

There were no treatment-related deaths, changes in body weights, clinical signs or effects on serum chemistry, hematology or urinalysis parameters. There was a significant increase in lung weights in both males and females exposed to 6.0 mg/m^3 after 1 and 2 years. In the 2–year study, males exposed to the highest dose had increased incidence of spotted and discolored lungs. At the interim sacrifices at 1 year, males and females in the highest dose group had treatment related histological changes in the nasal cavity, lungs and mediastinal lymph nodes. The incidence and severity of degeneration and basal cell hyperplasia of the olfactory epithelium and Bowman's gland hyperplasia were increased in males of the 1.0 and 6.0 mg/m^3 groups and in females of the high dose group following the 2 year exposure period. The lungs from the rats of the 1.0 and 6.0 mg/m^3 group had similar changes to, but more severe than, those found after 1 year of exposure. There were significant increases in alveolar duct epithelialization, accumulation of macrophages containing PMDI associated yellow pigment and focal fibrosis in males and females of the mid and high dose groups. Pulmonary adenomas were found in 6 males and 2 females and 1 male had pulmonary adenocarcinoma in the 6.0 mg/m^3 group. The data obtained in this chronic inhalation study identifies a no-observed-adverse-effect-level (NOAEL) of 0.2 mg/m^3 (duration-adjusted concentration = 0.036 mg/m^3) and a lowest-observed-adverse-effect-level (LOAEL) of 1.0 mg/m^3 (duration-adjusted concentration = 0.18 mg/m^3) based on hyperplasia of the olfactory epithelium.

In a 90-day inhalation study (Ref. 14), Wistar rats (15/sex/dose) were exposed to 4, 8, and 12 mg/m^3 of PMDI aerosol for 6 hrs/day, 5 days/wk, for 13 weeks. The content of the PMDI was approximately 52 percent MDI and 48 percent higher molecular weight oligomers and 95 percent of the particles in the aerosols had aerodynamic diameters of < 5 micrometers. Mortality and severe respiratory distress occurred in the 12 mg/m^3 dosed group, and less severe symptoms occurred in the 8 mg/m^3 dosed group. A dose related increase in lung weight was noted in the 8 and 12 mg/m^3 dose groups for both males and females. Degenerative lesions occurred

in the olfactory epithelium of the nasal cavity of both males and females in the 12 mg/m^3 groups. There was a significant increase in macrophages in the lungs and lymph nodes of all exposed animals (4 mg/m^3 or higher) compared with control groups. This study demonstrated adverse effects in the lungs and nasal cavity at levels of 4 mg/m^3 and above.

Although there are no toxicological studies available on the higher molecular weight oligomers of PMDI in the absence of MDI, there is indirect evidence, from studies of diisocyanates other than PMDI, to support the conclusion that the higher molecular weight oligomers can cause chronic pulmonary toxicity. For some other diisocyanates, the higher molecular weight oligomers rather than the monomeric form may induce adverse pulmonary effects. In one study (Ref. 15), subjects exposed to a prepolymer of toluene diisocyanate (TDI) in wood varnish exhibited an asthmatic reaction, but exposure to monomeric TDI did not elicit the same response. Another prospective study (Ref. 16), was conducted among 10 workers with occupational asthma caused by spray paints which contained both monomeric hexamethylene diisocyanate (HDI) and polymeric HDI. In the study, four workers developed asthmatic reactions only after exposure to polymeric HDI and not after exposure to monomeric HDI.

In the chronic inhalation studies discussed above, the test animals where exposed to aerosols of PMDI which should have contained a representative sample of all of the components of PMDI. From these chronic inhalation studies, it is not possible to separate out the adverse health effects caused by MDI from those caused by the higher molecular weight oligomers and EPA is aware of no studies on the higher molecular weight oligomers themselves. However, given the structural similarities between MDI and the higher molecular weight oligomers, it is reasonable to anticipate that their toxicological properties will be similar to those of MDI and upon exposure will result in the adverse health effects observed in the PMDI studies. In addition, the indirect evidence discussed above also supports this conclusion.

D. Technical Summary

The technical review of the petition to delete polymeric diphenylmethane diisocyanate from the diisocyanates category focused on the chronic toxicity of the higher molecular weight oligomers contained in PMDI. Animal studies conducted on aerosolized PMDI have demonstrated that PMDI can cause chronic pulmonary toxicity. Because of the structural similarities between MDI and the higher molecular weight oligomers of PMDI, there is no basis to conclude that the toxicity observed in these studies is due only to the MDI present in PMDI. Based on a review of the available data on PMDI and other diisocyanates, EPA has determined that there is sufficient evidence to reasonably anticipate that the higher molecular weight oligomers of PMDI can cause chronic pulmonary toxicity.

IV. Rationale for Denial

EPA is denying the petition submitted by the Polyurethane Division of the Society of the Plastics Industry to delete PMDI from the diisocyanates category on the EPCRA section 313 list of toxic chemicals. This denial is based on EPA's conclusion that, based on available data on PMDI and other diisocyanates, the higher molecular weight oligomers of PMDI can reasonably be anticipated to cause chronic pulmonary toxicity. EPA considers the LOAEL of 1.0 mg/m^3 and the NOAEL of 0.2 mg/m^3 for PMDI to be relatively low doses and thus EPA does not consider PMDI to have low chronic toxicity. Therefore, in accordance with EPA's stated policy on the use of exposure assessments (59 FR 61432, November 30, 1994), EPA does not believe that an exposure assessment is necessary to conclude that PMDI meets the toxicity criterion of EPCRA section 313(d)(2)(B).

V. References

1. USEPA, OPPTS, 1995. Memorandum from Sandra Strassman-Sundy, Existing Chemical Assessment Division, re: Additions to Section 313. (May 6, 1992).

2. USEPA, OPPTS, 1995. Chemistry Report for Delisting of Polymeric MDI by Diana Darling, Industrial Chemistry Branch, Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics. (September 25, 1995).

3. USEPA, OPPTS, 1995. Memorandum from James W. Holder, Effects Identification and Characterization Group, National Center for Environmental Assessment, Office of Research and Development, re: Response to Delist Polymeric MDI (PMDI) from Ongoing MDI Reporting under Section 313, Toxic Chemical Release Reporting of EPCRA (Emergency Right-to-Know Act of SARA of 1986). (September 18, 1995).

4. Dynamac. 1987. Generic Health Hazard Assessment of the Chemical Class Diisocyanates, Final Report May 5, 1987, Appendix 4. EPA Contract No. 68-02-3990, Work Assignment No. 205. Submitted to USEPA, Office of Toxic Substances, Health and Environmental Review Division, Washington, DC Prepared by Dynamac Corporation, Rockville, MD.

5. USEPA, OPPTS, 1995. Memorandum from Nicole Paquette, Health Effects Branch, Health and Environmental Review Division, Office of Pollution Prevention and Toxics, re: Review of the Delisting Petition for Polymeric Diphenylmethane Diisocyanate (PMDI). (September 20, 1995).

6. USEPA, OPPTS, 1995. Memorandum from Daniel Bushman, Industrial Chemistry Branch, Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics, re: Health Effects Review for Polymeric Diphenylmethane Diisocyanate. (October 2, 1995).

7. USEPA, OPPTS, 1995. Memorandum from Nicole Paquette, Health Effects Branch, Health and Environmental Review Division, Office of Pollution Prevention and Toxics, re: Health Effects Review for Polymeric Diphenylmethane Diisocyanate (PMDI). (October 5, 1995).

8. USEPA, OPPTS, 1995. Memorandum from Elbert L. Dage, Analysis and Information Management Branch, Chemical Screening and Risk Assessment Division, Office of Pollution Prevention and Toxics. re: Risk Assessment Review for Polymeric Diphenylmethane Diisocyanate (PMDI). (November 7, 1995).

9. USEPA, OPPTS, 1996. Memorandum from Nicole Paquette, Health Effects Branch, Health and Environmental Review Division, Office of Pollution Prevention and Toxics, re: Health Effects Review for Polymeric Diphenylmethane Diisocyanate (PMDI). (January 16, 1996).

10. USEPA, OPPTS, 1996. Memorandum from Daniel Bushman, Toxics Release Inventory Branch, Environmental Assistance Division, re: EPCRA Section 313 Petition to Delist PMDI. (July 8, 1996).

11. USEPA, OPPTS, 1996. Memorandum from Nicole Paquette, Health Effects Branch, Health and Environmental Review Division, Office of Pollution Prevention and Toxics, re: EPCRA Section 313 Petition to Delist Polymeric Diphenylmethane Diisocyanate (PMDI). (July 9, 1996).

12. Reuzel, P.G.J., Arts, J.H.E., Lomax, L.G., Kuijpers, M.H.M., Kuper, C.F., Feron, V.J., Loser, E., ''Chronic Inhalation Toxicity and Carcinogenicity Study of Respirable Polymeric

Methylene Diphenyl Diisocyanate (Polymeric MDI) Aerosol in Rats,'' Journal of Fundamental and Applied Toxicology, v. 22, (1994), pp. 195-210.

13. Reuzel, P.G.J., Arts, J.H.E., Kuypers, M.H.M., Kuper, C.F., ''Chronic Toxicity/Carcinogenicity Inhalation Study of Polymeric Methylene Diphenyl Diisocyanate Aerosol in Rats (Final Report),'' Prepared by Civo Institute for the International Isocyanate Institute. Report No. V88.122. (March 1990).

14. Reuzel, P.G.J., Kuper, C.F., Feron, V.J., Appelman, L.M., Loser, E., ''Acute, Subacute, and Subchronic Inhalation Toxicity Studies of Respirable Polymeric Methylene Diphenyl Diisocyanate (Polymeric MDI) Aerosol in Rats,'' Journal of Fundamental and Applied Toxicology, v. 22, (1994), pp. 186-194.

15. Vandenplas, O., Malo, J.L., Saetta, M., Mapp, C.E., Fabbri, L.M., ''Occupational Asthma and Extrinsic Alveolitis Due to Isocyanates: Current Status and Perspective,'' British Journal of Industrial Medicine, v. 30, (1993), pp. 213-228.

16. Vandenplas, O., Cartier, A., Lesage, J., Cloutier, Y., Perrault, G., Grammar, L.C., Shaughnessy, M.A., Malo, J.L., ''Prepolymers of Hexamethylene Diisocyanate as a Cause of Occupational Asthma,'' Journal of Allergy and Clinical Immunology, v. 91, (1993), pp. 850-861.

VI. Administrative Record

The record supporting this decision is contained in docket control number OPPTS–400101. All documents, including the references listed in Unit V. of this document and an index of the docket, are available to the public in the TSCA Nonconfidential Information Center (NCIC), also known as the Public Docket Office, from noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA NCIC is located at EPA Headquarters, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: February 20, 1997.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 97–5307 Filed 3–4–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 16, 74, 75, and 95

Indirect Cost Appeals

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This NPRM would remove the informal grant appeals procedure for indirect cost rates and other cost issues. The regional HHS Divisions of Cost Allocation have been reorganized into a new Program Support Center and no longer report to the Regional Directors, making the process obsolete. The Department also sees little value in this formal appeals process because it frequently lengthens the time required for appeals. Deletion of this rule will reduce internal management regulations as required by Executive Order 12861.

DATES: Comments must be submitted by May 5, 1997.

ADDRESSES: Comments must be in writing and should be mailed or faxed to Charles Gale, Director, Office of Grants Management, HHS, Room 517–D, 200 Independence Ave. SW., Washington DC 20201; FAX (202) 690–8772. Written comments may be inspected at the identified address during agency business hours from 9:30 a.m. to 5:30 p.m.

FOR FURTHER INFORMATION CONTACT: Ronald Speck, (202) 401–2751. For the hearing impaired only: TDD (202) 690–6415.

SUPPLEMENTARY INFORMATION: We propose to remove 45 CFR part 75, ''Informal grant appeals procedures,'' together with all references to it. Part 75 provides for an informal appeals process to the Regional Directors (prior to formal appeals under 45 CFR part 16) for disputes arising from determinations made by a Director, Division of Cost Allocation (DCA) in the Department's regional offices, concerning indirect cost rates and certain other cost allocation plans. The Department's Divisions of Cost Allocation have been reorganized into a new Program Support Center and no longer report to the Regional Directors. Consequently the procedures in part 75 are obsolete.

In addition, experience has shown that this informal appeals process actually resolves very few of the covered disputes, because most of these informal appeals are subsequently appealed to the Departmental Appeals Board established by 45 CFR part 16. Therefore, this informal appeals process has the effect of lengthening the total time required to finally resolve the subject appeals.

Since the department sees little value in this informal appeals process, and this process is obsolete, we propose to eliminate part 75 and thereby reduce internal management regulations as required by Executive Order 12861.

Regulatory Impact Analyses

Executive Order 12866

In accordance with the provisions of Executive Order 12866, this proposed rule was not reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule before publication and, by approving it, certifies that it does not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

This proposed rule does not contain information collection requirements requiring clearance under the Paperwork Reduction Act.

List of Subjects in 45 CFR Parts 16, 74, 75, and 95

Accounting, Administrative practice and procedure, Grant programs—health, Grant programs—social programs, Grants administration, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number does not apply)

Dated: February 25, 1997.

Donna E. Shalala,

Secretary.

Accordingly, for the reasons set forth above, it is proposed that title 45 of the Code of Federal Regulations be amended as follows:

PART 16—PROCEDURES OF THE DEPARTMENTAL GRANT APPEALS BOARD

1. The authority citation for part 16 would continue to read as follows:

Authority: 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

§ 16.3 [Amended]

2. Section 16.3 would be amended in paragraph (c) by removing the words ''and part 75 of this title for rate determinations and cost allocation plans''.