been imposed at the time the shares were purchased under Article III, section 26(d) of the Rules of Fair Practice Promulgated by the National Association of Securities Dealers;

(3) No amount is charged to shareholders or to the fund that is intended as payment of interest or any similar charge related to a deferred sales load;

(4) No deferred sales load is imposed on an amount that represents an increase in the value of company shares due to capital appreciation;

(5) No deferred sales load is imposed on shares, or amounts representing shares, purchased through the reinvestment of dividends or capital gains distributions;

(6) If all or part of a deferred sales load is payable at the time shares are redeemed, then shares, or amounts representing shares, that are not subject to any deferred sales load are redeemed first, and other shares or amounts are then redeemed in the order purchased, *provided, however,* another order of redemption may be used if such order would result in the redeeming shareholder paying a lower deferred sales load; and

(7) The same deferred sales load is imposed on all shareholders except that scheduled variations in or elimination of deferred sales loads may be offered to particular classes of shareholders or in connection with particular classes of transactions if the conditions contained in paragraphs (a) through (d) of rule 22d–1 under the Act [17 CFR 270.22d–1] are satisfied with respect to such scheduled variations. Nothing in this paragraph shall prevent a company from offering to existing shareholders a new scheduled variation that would waive or reduce the amount of a deferred sales load that has not yet been paid.

(b) Any exempted person, or any affiliated person of such exempted person (or any affiliated person of such affiliated person), who holds a company out to the public, or who, directly or indirectly, causes a company to be held out to the public, as being "no-load" or uses, or who, directly or indirectly, causes the use of, terminology that, given the context and presentation, is likely to convey to investors the impression that no charges for sales or promotional expenses are imposed on shares issued by the company, shall not be entitled to the exemption provided in paragraph (a).

(c) For purposes of this rule:

(1) "Company" means a registered open-end management investment company, other than a registered separate account, and includes a separate series of such a company;

(2) "Exempted person" includes any company and any principal underwriter of, dealer in, or person authorized to consummate transactions in securities issued by such company;

(3) "Deferred sales load" means any amount propely chargeable to sales or promotional expenses that is or may be deducted directly from a shareholder's account in one or more installments during the term of the investment, or upon redemption, or both. This term shall include, but is not limited to, a contingent deferred sales load within the meaning of paragraph (c)(4); and

(4) "Contingent deferred sales load" means a deferred sales load that is paid, if at all, at the time of redemption, the amount of which would decrease to zero if the shares were held for a reasonable period of time specified by the company.

3. By proposing to amend Item 2(a)(i) and Instruction 5 of Item 2(a)(i) of Form N–1A, described in § 239.15A and 274.11A, to read as follows:

Item 2. Synopsis

(a)(i) Include a table furnishing the following information, using the caption provided, in the format illustrated below:

* * * * *

Deferred Sales Load (as a percentage of the net asset value at the time of purchase, and, where applicable, as a percentage of the net asset value at the time of redemption)

* * * * *

Instructions:

* * * * *

Shareholder Transaction Expenses

5. "Deferred Sales Load" includes, but is not limited to, the maximum contingent deferred sales load, expressed as the lesser of a percentage of the net asset value at the time of purchase or of the net asset value at the time of redemption.

(a) The table may not include scheduled variations of a deferred sales load, but, instead, the brief narrative following the table should provide a cross-reference to the narrative portion of the prospectus discussing variations.

(b) If the Registrant permits the sales load to be paid in installments pursuant to rule 6c–10 [17 CFR 270.6c–10], the table should disclose the maximum deferred load, and may disclose the installment amounts (or percentage amounts) and frequency of deduction, which should be described after the caption "Deferred Sales Load," *e.g.,* 2% per year not to exceed 8% of net asset value at the time of purchase. However, if the installment amounts or frequency of deduction vary so that a brief description following the caption is impractical, the Registrant may include a tabular presentation of installments unless such a presentation would be so lengthy as to encumber the larger table. In that case, the Registrant should list only the maximum amount and provide a cross-reference to the narrative portion of the prospectus discussing the sales load.

(c) If the Registrant imposes a contingent deferred sales load as defined in rule 6c–10(c)(4), the table may include a tabular presentation, within the larger table, of the range of the contingent deferred sales load over time.

By the Commission.

Jonathan G. Katz,

Secretary.

November 2, 1988.

[FR Doc. 88–25863 Filed 11–8–88; 8:45 am]

BILLING CODE 8010–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–3445–5]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA is proposing to disapprove a site-specific revision to the Ohio State Implementation Plan (SIP) for ozone. This revision is a request for monthly averaging and a relaxation from Ohio's reasonably available control technology (RACT) requirements for volatile organic compound (VOC) emissions for an architectural aluminum extrusion coating line (K001) at Easco Aluminum Corporation (Easco). This facility is located in Trumbull County, Ohio.

USEPA is proposing to disapprove this SIP revision, because it has not been demonstrated that add-on controls for Easco are economically infeasible, that application of RACT on less than a monthly basis is infeasible, and that a permanent relaxation is warranted.

DATE: Comments on this revision and on the proposed USEPA action must be received by December 9, 1988.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886–6031, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604

Ohio Environmental Protection Agency, Office of Air Pollution Control, 361 East Broad Street, Columbus, Ohio 43210

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.)

Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Chicago, Illinois 60604, (312) 886–6031.

SUPPLEMENTARY INFORMATION: On September 11, 1985, the Ohio Environmental Protection Agency (OEPA) submitted a proposed revision to its ozone SIP, allowing monthly averaging and relaxation from Ohio's RACT [1] VOC regulations for an architectural aluminum extrusion coating line (K001). This operation is located at the Easco Facility in Trumbull County [2] Ohio, a nonattainment area for ozone.

On March 25, 1986, USEPA notified OEPA that the September 11, 1985, submittal requesting a monthly averaging and a RACT relaxation for Easco was deficient as stated in USEPA's technical support documents (TSD) dated February 5, 1986, and March 14, 1986. OEPA submitted supplemental information on July 7, 1986, and August 18, 1986, to support this revision.

Ohio's SIP

Under the existing federally approved SIP for Ohio, the architectural aluminum extrusion coating line (K001) is subject to the control requirements contained in Ohio Administrative Code (OAC) Rule 3745–21–09(U)(1)(a)(iii) which limits the VOC content of extreme performance coatings applied to miscellaneous metal parts and products to 3.5 pounds of VOC per gallon of coating, minus water. OAC Rule 3745–21–04(C)(28) requires compliance with the limit by December 31, 1982. USEPA approved these rules as meeting the RACT requirement of the Clean Air Act on October 31, 1980 (45 FR 72122), and June 29, 1982 (47 FR 28097).

Summary of SIP Revision

Easco's Girard Extrusion Division is an aluminum extrusions facility which applies paint to extruded parts. Easco operates one electrostatic spray coating line which applies a wide range of coatings (approximately 80 different coating per month) to products in the architectural and transportation vehicles industries. Approximately 30 percent of the paint used is white paint that has been in compliance since October 1, 1984. Bronze and several other colors accont for an additional 30 percent which are now in compliance. The remaining 40 percent of coatings are high performance architectural coatings and flexible recreational vehicle coatings.

Easco's aluminum extrusion paint line is subject to OAC Rule 3745–21–09(U)(1)(a)(iii) which limts extreme performance coatings used on miscellaneous metal parts and products to 3.5 pounds of VOC per gallon of coating, minus water. OAC Rule 3745–21–04(C)(28) requires compliance with this limit by December 31, 1982.

The Ohio Environmental Protection Agency has proposed to specify the following allowable VOC emission limitations to be met by November 30, 1985, for Easco's paint line in lieu of OAC Rules 3745–21–09(B) and 3745–21–09(U)(1)(a)(iii):

(a) The VOC content of each coating employed in this coating line, excluding the high performance aluminum coatings, shall not exceed 3.5 pounds of VOC per gallon of coating, excluding water, as a monthly, volume-weighted

(b) In addition, a VOC emission ceiling (for any coating) is established at 6.2 pounds of VOC per gallon of coating employed, minus water, in order to ensure that maintenance of the ozone NAAQS is not jeopardized.

Extended Averaging Time Criteria

USEPA's January 20, 1984, policy memorandum, entitled "Averaging Times for Compliance With VOC Emission Limits", contains the following criteria for evaluating VOC requests for extended averaging.

Criterion 1

Extended averaging can be permitted where the source operations are such that daily VOC emissions cannot be determined, or where the application of RACT for each emission point is not economically or technically feasible on a daily basis.

Criterion 2

Sources in areas lacking approved SIPs, or in areas with approved SIPs but showing measured violations, cannot be considered for longer term averages until the SIP has been revised demonstrating ambient standards attainment and maintenance of reasonable further progress (RFP) (reflecting the maximum daily emissions from the source with long-term averaging).

Criterion 3

A demonstration must be made that the use of long-term averaging (greater than 24-hour averaging) will not jeopardize either ambient standards attainment or the reasonable further progress (RFP) plan for the area. This must be accomplished by showing that the maximum daily increase in emissions associated with monthly averaging is consistent with the approved ozone SIP.

Criterion 4

Averaging time must be as short as practicable, and in no case longer than 30 days.

Analysis

For a RACT relaxation to be approved, it must be demonstrated that the RACT-level emission limit for Easco is technically or economically infeasible. OEPA determined the cost-effectiveness, based on an 81 percent overall efficiency and fuel costs only, to be reasonable compared to the cost analysis of the miscellaneous metals Control Techniques Guidelines (CTG).

In addition, for an extension of the averaging time to 30 days to comply with the VOC emission limit, Easco must demonstrate that it is not possible to meet the 3.5 pounds of VOC per gallon of coating, excluding water, limit using a shorter averaging period. Easco has failed to make this demonstration.

If the State demonstrates conclusively that complying low-solvent coastings are unavailable, then the USEPA would consider an alternative RACT determination for the existing coastings.

A detailed discussion of the extent of an acceptable investigation is contained in Appendix A of this document.

USEPA is proposing to disapprove this SIP revision because Easco has not demonstrated that add-on control is economically infeasible and that a shorter averaging period is not practicable.

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[1] A defintion of RACT is contained in a December 9, 1976, memorandum from Roger Strelow, former Assistant Administrator for Air and waste Management. RACT is defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available, considering technological and economic feasibility.

[2] Trumbull County is an area that is unmonitored for ozone. Trumbull County adjoins Mahoning County's northern border. The available meteorological data imply that Trumbull County is downwind of Youngstown, Ohio, (Mahoning County), the closest significant source area of ozone precursors and the only adjoining major urbanized area. OEPA submitted a request to revise the attainment status designations, at 40 CFR 81.336, for Mahoning County and Trumbull County from nonattainment to attainment for the ozone national ambient air quality standard (NAAQS). USEPA will propose action on Ohio's request in a separate **Federal Register** notice. Mahoning County and Trumbull County, at this time, are still designated as nonattainment areas. There have been, however, no measured violations of the ozone NAAQS from 1982 through 1985 in Mahoning County.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before December 9, 1988, will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V office address provided at the front of this notice.

Under 5 U.S.C. Section 605(b), I certify that this SIP disapproval will not have a significant economic impact on a substantial number of small entities, because the effect of this disapproval is to leave in effect existing emission limitations. Therefore, there is no change or any impact on any source or community. Additionally, it applies to only one major corporation, Easco.

Under Executive Order 12291, this action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Authority: 42 U.S.C. 7401–7642.

Dated: February 6, 1987.

Valdas V. Adamkus,

Regional Administrator.

Editorial Note.—This document was received at the office of the Federal Register November 3, 1988.

Note: This appendix will not appear in the Code of Federal Regulations

Appendix A

The Clean Air Act requires that SIPs for areas not in attainment of the NAAQS by August 7, 1977 must provide for the implementation of RACT as expeditiously as practicable. 42 U.S.C. 7502(b)(2). EPA has defined RACT as—

> The lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasiability. 44 Fed. Reg. 53762 Col. 1 (September 17, 1979).

Through the issuance of Control Technique Guidelines (TCGs) EPA has identified pollutant control levels that USEPA presumes to constitute RACT for various categories of sources. Where the State finds the presumptive norm applicable to an individual source or group of sources, the State typically adopts requirements consistent with the presumptive norm. However, the presumptive norm is a recommendation, and States may develop case-by-case RACT determinations independently of EPA's recommendation. EPA will approve these RACT determinations as long as the States shows they will satisfy the Clear Air Act's RACT requirements based on adequate documentation of the economic and technical circumstances of the particular sources being regulated.[1]

In light of these requirements, EPA will approve an alternative RACT requirement only if the State demonstrates that the requirement does in fact constitute RACT. To make this demonstration, the State must show that in fact the current SIP requirements do not represent RACT because pollution control technology necessary to reach the requirements is not—and is not expected to be—reasonably available. EPA will determine whether the State makes this demonstrations on a case-by-case basis, taking into account all the relevant facts and circumstances concerning each case.

In making these demonstrations, the State must make reasonable efforts to determine and adequately document the availability of complying coatings or other kinds of control, as appropriate. The State is free to consult informally with EPA to determine whether EPA has up-to-date information concerning the availability of particular coatings or other kinds of control. If EPA does not have up-to-date information, the State must undertake further efforts. Examples of these efforts include examining information that is or should be reasonably available to the State, including whether sources operating in the State that are in an industry comparable to the source at issue (*e.g.*, within the same CTG category) achieve compliance with the SIP, by the SIP approved compliance scheduel, by using complying coatings, or other kinds of control, that the source could adopt. In addition, if the State participates in a formally established, multi-state pollution control group or commission, EPA presumes that the State has reasonable access to information concerning whether sources operating in the other States that are members of the group or commission use complying coatings, or other controls. Thus, the State must examine available information concerning sources in those other States. Reasonable efforts by the State also include seeking information reasonably available to the source requesting the SIP revision, including, for example, contacting suppliers available to the source to determine if they have complying coatings or other controls; contacting trade associations to determine if they know of complying coatings or other controls; and reviewing trade publications containing information concerning complying coatings or other controls.

It seems appropriate for the source to make a showing that process changes, such as switching to low solvent coatings are not available. If low solvent coatings (or other process changes) meeting the Control Technique Guideline (CTG)—recommended emission level are shown not to be feasible for a particular source, then the source should identify the lowest level of volatile organic compound (VOC) emissions that is available for that source or type of coating.

Assuming that a source has prepared an adequate showing that abatement ("add-on") controls are not feasible, an example of an action that a source might perform to demonstrate to the State that no complying coating is available would be for the company to place two consecutive advertisements in each of three leading paint trade journals (*e.g., Industrial Finishing, Products Finishing, Modern Paint and Coatings, JCT-Journal of Coatings Technology, American Paint and Coatings Journal*) and describe the application and product specifications for a low solvent paint which they are seeking. This advertisement should solicit paint companies to provide a low VOC product meeting those specifications. The responses which the company receives could be provided to EPA as proof that this type of product does or does not exist. The advertisement in a trade journal would reach a wide number of paint producers, some of whom may have developed suitable low VOC products. When reporting the response to the advertisement to EPA, the State should report the lowest VOC content coating that is available for the particular job, even if that coating does not meet the CTG recommended limit.

[1] More specifically EPA has described RACT and the obligations of the States as follows:

Along with information, each CTG contains recommendations to the States of what EPA calls the "presumptive norm" for RACT, based on EPA's current evaluation of the capabilities and problems general to the industry. Where the States finds [sis] the presumptive norm applicable to an individual source or group of sources, EPA recommends that the State adopt requirements consistent with the presumptive norm level in order to include RACT limitations in the SIP.

However, recommended controls are based on capabilities and problems which are general to the industry; they do not take into account the unique circumstances of each facility. In may cases appropriate controls would be more or less stringent. States are urged to judge the feasibility of imposing the recommended controls on particular sources, and adjust the controls accordingly.

The presumptive norm is only a recommendation. For any source or group of sources, regardless or whether they fall within the industry norm, the States may develop case-by-case RACT requirements independently of EPA's recommendation. EPA will propose to approve any submitted RACT requirement that the State shows will satisfy the requirements of the Act for RACT based on the economic and technical circumstances of the particular sources being regulated. 44 FR 53762–63 (September 17, 1979).

Another example of an approach that a metal coater might use in demonstrating the unavailability of complying coatings for a particular product would be to contact a trade association which represents a large number of manufacturers of low VOC coatings (*e.g.*, the Powder Coating Institute). If such an association documents that none of its members can provide a low solvent complying coating for this product, then this trade association reply could be used to show that a reasonable effort had been made to find a complying product and that such a product apparently does not currently exist. If, through efforts such as those described above, the source makes a convincing demonstration that complying products are not available in the industry, State would not be required to make duplicative efforts.

If, after the reasonable efforts described above are expended, and the State finds that no complying coatings or other controls as appropriate are available, EPA itself may make an independent assessment of the availability of such coatings or controls and the compliance status of other sources in the same CTG category.

[FR Doc. 88-25771 Filed 11-8-88; 8:45 am]
BILLING CODE 6560-50-M

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40 CFR Part 761

[OPTS-62059A; FRL-3475-5]

Polychlorinated Biphenyls; Notification and Manifesting for PCB Waste Activities; Extension of Public Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: EPA is announcing that it is extending the period for receipt of written comments on the proposed rule on notification and manifesting for PCB waste activities, which was published in the **Federal Register** on September 26, 1988. The written comment period is being extended until November 25, 1988, to provide additional time to prepare and submit comments. In addition, the date for the informal hearing on the proposed rule is being changed to December 13, 1988.

DATES: Written comments must be received by November 25, 1988. If persons request time for oral comment, EPA will hold an informal hearing in Washington, DC, on December 13, 1988. The hearing is presently scheduled to take place in the public auditorium of the Disabled American Veterans Building, 807 Maine Avenue SW., from 9:30 a.m. to 12:30 p.m. Participants are encouraged to call the TSCA Assistance Office at the telephone number listed under **"FOR FURTHER INFORMATION CONTACT"** to verify the exact time and location. Written requests to participate in the informal hearing must be received by the TSCA Assistance Office or postmarked no later than November 22, 1988.

ADDRESSES: Submit written comments, in triplicate, identified by the document control number OPTS 62059, by mail to: TSCA Public Docket Office (TS-793), Rm. NE G004, Office of Toxic Substances, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Information submitted in any comment concerning this proposed rule may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedure set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be disclosed publicly by EPA by placing it in the public record without prior notice to the submitter. All written comments will be available for public inspection and copying at the TSCA Public Docket Office, in Rm. NE G004, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202-554-1404), TDD: (202-544-0557).

SUPPLEMENTARY INFORMATION: In the **Federal Register** published on September 26, 1988 (53 FR 37436), EPA announced proposed amendments to its existing disposal and storage regulations for polychlorinated biphenyls (PCBs). The proposed rule notice published on that date included a proposal to add a tracking system for PCB wastes, a proposal to add to the regulations an approval process for certain commercial storers of PCB wastes, and a proposal to add certain recordkeeping and reporting requirements to facilitate the implementation of the proposed waste tracking system. The proposed rule notice published on September 26, 1988 required that written comments be submitted by no later than October 26, 1988. The previously issued notice also stated that upon request, EPA would hold an informal hearing on the proposed rule in Washington, DC, on November 9, 1988.

Since the publication of the proposed rule notice, EPA has received several written requests asking EPA to grant commentors an additional 30 days to prepare and submit their written comments. These petitioners have alleged in their written requests that the 30-day comment period required under the September 26, 1988 proposed rule notice has caused them hardship, and that they need the additional 30 days to provide EPA with meangingful comments. The associations which filed the written requests for extensions represent many of the generators, storers, transporters, and disposers of PCB wastes which the proposed regulatory amendments would affect, and they assert that a 30-day comment period is insufficient to enable them to survey their membership and to consider all aspects of the proposed amendments. Other commentors have telephoned the TSCA Assistance Office (TAO) to express similar concerns about the 30-day public comment period.

EPA believes that there is merit to the requests for extensions of the public comment period. The proposed rule published on September 26, 1988 is a lengthy and fairly complex document, and EPA appreciates the difficulties involved in circulating, reviewing, digesting, and responding to such a significant document within only 30 days. EPA does not believe that the exigencies of promulgating this regulation promptly merit cutting off the submission of detailed and meaningful comments by the petitioners. In addition, EPA believes that there are other persons who have only recently become aware of the proposal. If EPA were to cut off the receipt of comments after only 30 days, these commentors would not enjoy any real opportunity to participate in the rulemaking. Therefore, to avoid the confusion and potential for any unfairness occasioned by the 30-day comment period, EPA is granting petitioners' requests that EPA extend the period for submitting written comments an additional 30 days. Accordingly, main written comments on this proposed rule are now due by no later than Friday, November 25, 1988.

The extension of the written comment period also requires that EPA modify its plans for the informal hearing on this proposed rule. The regulations governing public comment on rules issued under section 6 of the Toxic Substances Control Act require that the due date for public comments be at least 2 weeks

prior to any informal hearing. See 40 CFR 750.3(c)(3). Therefore, EPA is designating Tuesday, December 13, 1988 as the date for the informal hearing in Washington, DC.

Persons or organizations desiring to participate in the informal hearing must file a written request to participate. The written request to participate must be sent to the TSCA Assistance Office at the address listed under "**FOR FURTHER INFORMATION CONTACT.**" The written request to participate must include: (1) A brief statement of the interest of the person or organization in the proceeding; (2) a brief outline of the points to be addressed; (3) an estimate of the time required; and (4) if the request comes from an organization, a nonbinding list of the persons to take part in the presentation. Organizations are requested to bring with them, to the extent possible, employees with individual expertise in and responsibility for each of the areas to be addressed. Organizations which do not file main comments in the rulemaking will not be allowed to participate at the hearing, unless the Record and Hearing Clerk grants a waiver of this requirement in writing.

All correspondence relating to requests for extensions to the public comment period have been entered in the public record for this rulemaking.

List of Subjects in 40 CFR Part 761

Environmental protection, Hazardous materials, Labeling, Polychlorinated biphenyls, Reporting and recordkeeping requirements.

Dated: October 31, 1988.

Charles L. Elkins,

Director, Office of Toxic Substances.

[FR Doc. 88-26053 Filed 11-7-88; 2:45 pm]

BILLING CODE 6560-50-M

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40 CFR Parts 795 and 799

[OPTS-42084F; FRL 3473-3]

Commercial Hexane; Proposed Pharmacokinetics Test Requirements and Revision of Proposed Test Guideline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is reproposing under section 4(a) of the Toxic Substances Control Act (TSCA) the pharmacokinetics test requirements and the associated test guideline for commercial hexane. This proposed rule complements a final test rule (53 FR 3382; February 5, 1988) issued under section 4(a)(1)(B) of TSCA that requires manufacturers and processors of commercial hexane to test it for subchronic toxicity, oncogenicity, reproductive toxicity, developmental toxicity, mutagenicity, neurotoxicity, and pharmacokinetics.

DATES: Submit written comments on or before December 27, 1988. If persons request an opportunity to submit oral comments by December 9, 1988, EPA will hold a public meeting on this proposed rule in Washington, DC. For further information on arranging to speak at this meeting, see Unit VII of this preamble. The incorporation by reference in this rule shall become effective 44 days after date of publication of the final rule in the **Federal Register**.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42084F) in triplicate to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Room NE-G004, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room EB-44, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is reproposing the pharmacokinetics test requirements and the associated test guideline in 40 CFR 795.323 for commercial hexane (previously proposed May 15, 1986, 51 FR 17854).

Public reporting burden for this collection of information is estimated to average 535 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503

I. Background

On May 15, 1986, EPA proposed pharmacokinetics testing of commercial hexane at 40 CFR 795.232 (51 FR 17854). Prior to issuing the final test rule for commercial hexane (53 FR 3382; February 5, 1988), EPA determined from an internal review that inadequacies in the proposed guideline for pharmacokinetics testing would limit the ability to obtain meaningful data. When the final test rule for commercial hexane was issued, EPA required that test sponsors perform pharmacokinetics testing but stated that it would propose a revised test standard and reporting requirements at a later date. EPA is now proposing a revised test standard and reporting requirements.

II. Proposed Pharmacokinetics Test Standard

EPA is proposing that the required pharmacokinetics testing for commercial hexane be conducted according to the inhalation and dermal pharamcokinetics test guideline described in this rule. Pharmacokinetics testing is necessary to determine the absorption, distribution metabolism, and excretion of commercial hexane by inhalation and dermal routes of administration. Data from these studies will help EPA evaluate whether exposure to commercial hexane presents an unreasonable risk of injury to human health.

The purposes of these studies are to: (1) Compare the pahrmacokinetics and metabolism of commercial hexane after inhalation and dermal administration, (2) compare the bioavailability of commercial hexane after inhalation and dermal administration and (3) examine the effects of repeated doses on the pharmacokinetics and metabolism of commercial hexane.

EPA proposes that investigators use 7- to 9-week old rats and 5- to 7-week old female guinea pigs for these studies. Both species have been used extensively for percutaneous absorption studies. Two doses would be required in these studies, a "low" dose and a "high" dose. The "high" dose should ideally induce some measurable toxicity such as weight loss. The "low" dose should correspond to a no observed effect level (NOEL). If possible, the same "high" and "low" doses would be administered by inhalation and dermal contact. The proposed studies would measure blood concentrations, urinary and fecal excretion, and metabolites of the test substances.

As stated in the February 5, 1988 preamble, EPA agrees with the American Petroleum Institute (API) that isotopically labelling all component of commercial hexane would be excessively burdensome. Consequently, EPA is proposing that each pharmacokinetics test described in this document be performed separately with commercial hexane containing two different radiolabeled test substances.

As suggested by API, one test mixture would contain ^{14}C methycyclopentane (MCP) and the other would contain ^{14}C *n*-hexane. (Ref. 1). An intravenous test has also been added to the protocol to obtain baseline information on the metabolism and excretion of the test substances when it is completely absorbed. This data would permit comparisons of absorption and metabolic processes operating via dermal and inhalation routes of exposure by monitoring excretion (urine, feces, expired air) of test substances during the study and tissue distribution of test substances at the end of the study.

EPA believes that this test methodology will provide the basis for a valid and scientifically acceptable test. EPA is proposing that the test guideline described in this document be adopted as the test standard for the pahrmacokinetics studies on commercial hexane. All persons conducting tests would submit plans and conduct tests in compliance with the TSCA Good Labaratory Practice (GLP) Standards found in 40 CFR Part 792.

III. Reporting Requirements

All data developed under this proposed rule would be reported in accordance with TSCA GLPL Standards.

As described in 40 CFR 790.50 under single-phase rulemaking procedures, test sponsors would submit a study plan no later than 45 days before the initiation of pharmacokinetics testing.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. EPA is proposing that the test sponsors complete the pharmacokinetics testing and submit the final report to EPA within 18 months of the effective date of the final test rule establishing pharmacokinetics tests standards and reporting requirements. Interim progress reports would be provided to EPA at 6-month intervals, beginning 6 months after the effective date of the final rule establishing test standards and reporting requirements for the required pharmacokinetics testing, until the final report has been submitted to EPA.

IV. Issues for Comment

EPA is soliciting comments on the suitability of the revised inhalation and dermal pharmacokinetics test standard proposed by the Agency for the testing of commercial hexane.

V. Economic Analysis

To assess the potential economic impact of the final test rule for commercial hexane published in the **Federal Register** of February 5, 1988, EPA has estimated the cost of the testing regimen. Total test costs for the final test rule were estimated to range from $2.2 to $2.9 million. As a result of these costs, EPA determined that the likelihood of significant adverse economic impact was low for the manufacturers of commercial hexane.

In accordance with the specifics of this new protocol, EPA has reevaluated the cost of conducting pharmacokinetics testing on commercial hexane. This procedure is estimated at $208,000 to $262,000. This revised estimate is discussed in more detail in a memorandum in the rulemaking record (Ref. 2).

On the basis of the costs estimated in the economic analysis for the final commercial hexane test rule, and the incremental cost of this pharmacokinetics procedure, the additional testing cost will not result in any change from the conclusions of the prior economic analysis. Refer to the economic impact analysis of the final test rule for commercial hexane for a complete discussion of potential economic impact.

VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "* * * the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (PB 82–140773). On the basis of this study, EPA believes that there will be test facilities and personnel available to perform the testing proposed in this rule.

VII. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting in Washington, DC subsequent to the close of the public comment period. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): (202) 554–1404, by December 9, 1988. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to public, active participation will be limited to those persons who arrange to present comments and to designated EPA participants. Persons wishing to attend should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, EPA would transcribe the meeting and include the written transcript in the rulemaking record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VIII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS–42084F). This record includes the basic information considered by EPA in developing this rule and appropriate **Federal Register** notices.

This record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this proposed test standard consisting of:

(a) Notice of final rule of EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(b) Notice of proposed test rule on methylcyclopentane and commercial hexane (51 FR 17854; May 15, 1986).

(c) Notice of final test rule for commercial hexane and methylcyclopentane (53 FR 3382; February 5, 1988).

B. References

(1) American Petroleum Institute (API). Letter from Steven M. Swanson, Director, Health and Environmental Affairs Department, to USEPA, transmitting comments on the MCP and commercial hexane proposed test rule (September 15, 1986).

(2) USEPA. Internal memorandum from Mark Dreyfus, Regulatory Impacts Branch, to Catherine Roman, Test Rules Development Branch, discussing the cost of the new pharmacokinetics testing protocol for commercial hexane (August 2, 1988).

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the TSCA Public Docket Office, NE–GOO4, 401 M St. SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

IX. Other Regulatory Requirements

A. Executive Order 12291

EPA has judged that the final test rule for commercial hexane was not subject to the requirement of a Regulatory Impact Analysis under Executive Order 12291. EPA has determined that this proposed test rule for pharmacokinetics testing does not alter this determination.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (5 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA has certified that the final test rule for commercial hexane would not have a significant impact on a substantial number of small businesses. The proposed pharmacokinetics test standard and reporting requirements do not change this determination.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 535 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Parts 795 and 799

Chemicals, Environmental protection, Hazardous substances, Laboratories, Recordkeeping and reporting requirements, Testing.

Dated: November 1, 1988.

Susan F. Vogt,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I, Subchapter R, be amended as follows:

1. In Part 795:

PART 795—[AMENDED]

a. The authority citation would continue to read as follows:

Authority: 15 U.S.C. 2603.

b. By adding new § 795.232 to read as follows:

§ 795.232 Inhalation and dermal pharmacokinetics of commercial hexane.

(a) *Purposes.* The purposes of these studies are to:

(1) Determine the bioavailability of the test substances after dermal and inhalation administration.

(2) Compare the pharmacokinetics and metabolism of the test substances after intravenous, dermal, and inhalation administration.

(3) Examine the effects of repeated doses on the pharmacokinetics and metabolism of the test substances.

(b) *Definitions.* (1) "Bioavailability" refers to the rate and relative amount of administered test substance which reaches the systemic circulation.

(2) "Metabolism" means the study of the processes by which a particular substance is absorbed, distributed, biotransformed, stored, and excreted by the body.

(3) "Percent absorption" means 100 times the ratio of the total radioactivity excreted following dermal or inhalation administration and total radioactivity excreted following intravenous administration of the test substance.

(4) "Pharmacokinetics" means the study of the rates of absorption, tissue distribution, biotransformation, and excretion.

(5) "Low dose" should correspond to the no-observed-effect level (NOEL).

(6) "High dose" should induce some measurable effect such as weight loss.

(7) "Test substance" refers to the nonradioactive and both radiolabeled mixtures (^{14}C *n*-hexane and ^{14}C methylcyclopentane) of commercial hexane used in the testing.

(c) *Test procedures*—(1) *Animal selection*—(i) *Species.* The rat shall be used for pharmacokinetics testing because it has been used extensively for metabolic and toxicological studies. The female guinea pig shall be used for dermal bioavailability tests.

(ii) *Animal strains.* Adult male and female rats and female guinea pigs shall be used for testing. The rats shall be 7 to 9 weeks old and their weight range should be comparable from group to group. The female guinea pigs shall be 5 to 7 weeks old, and their weight range should be comparable from group to group. The animals shall be purchased from a reputable dealer and shall be permanently identified upon arrival. The animals shall be selected at random for the testing groups, and any animal showing signs of ill health shall not be used.

(iii) *Animal care.* (A) Animal care and housing shall be in accordance with DHEW Publication No. (NIH)–86–23, revised 1985, "Guide for the Care and Use of Laboratory Animals."

(B) The animals shall be housed in environmentally controlled rooms with at last 10 air changes per hour. The rooms shall be maintained at a temperature of 24 ± 2 degrees centigrade and humidity of 50 ± 10 percent with a 12-hour light/dark cycle per day. The animal subjects shall be kept in a quarantine facility for at least 7 days prior to use, and shall be acclimated to the experimental environment for a minimum of 48 hours prior to treatment.

(C) During the acclimatization period, the rats and guinea pigs shall be housed in suitable cages. All animals shall be provided with certified feed and tap water *ad libitum.* The guinea pig diet shall contain adequate amounts of ascorbic acid.

(2) *Administration of test substances*—(i) *Test substances.* The study will require the use of nonradioactive and radioactive test substances. These test substances shall be identical in chemical composition, and shall contain at least 40 liquid volume percent but no more than 55 liquid volume percent *n*-hexane and no less than 10 liquid volume percent methylcyclopentane (MCP) and otherwise conform to the specifications prescribed in the American Society for Testing and Materials Designation D 1836–83 (ASTM D 1836), "Standard Specification for Commercial Hexanes", published in the *1986 Annual Book of ASTM Standards: Petroleum Products and Lubricants,* ASTM D 1836–83, pp. 966–967, 1986, which is incorporated by reference. ASTM D 1836 is available for public inspection at the Office of the Federal Register, Room 8301, 1100 L Street NW., Washington, DC. and copies may be obtained from the EPA, TSCA Public Docket Office, Room NE G–004, 401 M Street SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Office of the Federal Register in

accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This material is incorporated as it exists on the date of approval, and a notice of any change in this material will be published in the **Federal Register.** Two kinds of radioactive test substances shall be tested. ^{14}C *n*-hexane shall be the only radioactive component of one, and ^{14}C MCP shall be the only radioactive component of the other radioactive test substance.

(ii) *Dosage and treatment*—(A) *Intravenous.* The low dose of each test substance, in an appropriate vehicle, shall be administered to four rats of each sex.

(B) *Inhalation.* Two concentrations of each test substance shall be used in this portion of the study, a low concentration and a high concentration. The high concentration should ideally induce some overt toxicity, while the low concentration should correspond to the NOEL. In addition, the high concentration should not exceed the lower explosive limit of the test substance. Inhalation treatment shall be conducted using a "nose-cone" or "head only" apparatus to reduce ingestion of the test substance through "grooming."

(C) *Dermal—(1) Dermal absorption studies.* Dermal treatment should be conducted by the methodology of System, A.S., Dames, B.L. and Niemeier, R.W., "*In vivo* percutaneous absorption studies of volatile solvents in hairless mice. I. Description of a skin depot", In: *Journal of Applied Toxicology* 6:43–46, (1986), or by some other suitable modification because the test substances have significant volatility. The high and low doses shall be tested in rats and guinea pigs.

(*2*) *Washing efficacy study.* Before performing the dermal absorption studies, a washing efficacy study shall be conducted to assess the removal of the applied low dose of test substance by washing the exposed skin area with soap and water, and an appropriate organic solvent. The low dose shall be applied to separate groups of four rats and four female guinea pigs in accordance with paragraph (c)(2)(ii)(C)(*1*) of this section. Two to five minutes after application, the treated areas of two rats and two guinea pigs shall be washed with soap and water and the treated areas of the remaining animals shall be washed with an appropriate solvent. The amount of test substance recovered in the washing solutions shall be determined to assess the efficacy of its removal by washing.

(iii) *Dosing and sampling schedule*—(A) *Rat studies.* Each experimental group shall contain at least four animals of each sex. After administration of the test substance, each rat shall be placed in an individual metabolic unit for collection or urine, feces, and expired air. For the inhalation of and dermal studies, excreta from the rats shall also be colleced during the exposure periods. At the end of each collection period, the metabolic cages shall be cleaned to recover any excreta that might adhere to the cages. All studies, except the repeated dose studies, shall be terminated at 7 days, or after at least 90 percent of the radioactivity has been recovered in the excreta, whichever occurs first. All studies described below shall be conducted separately with each radiolabeled test substance.

(*1*) *Intravenous study.* Group A shall be given a single intravenous low dose of the labeled test substance (containing either ^{14}C *n*-hexane or ^{14}C MCP) at the low dose.

(*2*) *Inhalation studies.* A single 6-hour exposure period shall be used for each group.

(*i*) Group B shall be exposed to a mixture of the labeled test substance in air at the low concentration.

(*ii*) Group C shall be exposed to a mixture of the labeled test substance in air at the high concentration.

(*3*) *Dermal studies.* The test substance shall be applied and kept on the skin for a minimum of 6 hours. At the time of removal of the covering apparatus, the treated area shall be washed with an appropriate solvent to remove any test substance that may be on the skin surface. The covering apparatus components and the washing solutions shall be assayed to recover residual radioactivity. At the termination of the studies, each animal shall be sacrificed and the exposed skin area removed. An appropriate section of the skin shall be solubilized and assayed for radioactivity to ascertain whether the skin acts as a reservoir for the test substance.

(*1*) Group D shall be given one dermal, low dose of the labeled test substance.

(*ii*) Group E shall be given one dermal, high dose of the labeled test substance.

(*4*) *Repeated dosing study.* Group F shall receive a series of single daily 6-hour inhalation doses of nonradioactive test substance at the low dose over a period of at least 7 days. A single 6-hour inhalation dose of the radioactive test substance (^{14}C *n*-hexane or ^{14}C MCP) at the low dose shall be administered 24 hours after the last nonradioactive dose. Following administration of the radioactive substance, the rats shall be placed in individual metabolic cages. Excreta shall also be collected during the exposure periods. The study shall be terminated 7 days after the last dose, or after at least 90 percent of the radioactivity has been recovered in the excreta, whichever occurs first.

(B) *Guinea pig studies*—(*1*) *Intravenous study.* The study conducted on group A as specified in paragraph (c)(2)(iii)(A)(*1*) of this section shall be repeated using four guinea pigs per group (group G).

(*2*) *Dermal studies.* The studies conducted on groups D and E as specified in paragraph (c)(2)(iii)(A)(*3*) of this section shall be repeated using four female guinea pigs per group.

(i) Group H shall be given one dermal low dose of test labeled test substance.

(*ii*) Group I shall be given one dermal high dose of labeled test substance.

(*iii*) After administration of the test substance, each guinea pig shall be kept in a separate metabolic unit to facilitate collection of excreta. At the end of each collection period, the metabolic units shall be cleaned to recover any excreta that might adhere to them. All studies shall be terminated at 7 days, or after 90 percent of the radioactivity has been recovered in the excreta, whichever occurs first.

(3) *Types of Studies*—(I) *Pharmacokinetics studies*—(A) *Rat studies.* Groups A, B, C, D, E, and F shall be used to determine the kinetics of absorption of the test substance. In animal subjects administered the test substance intravenously (i.e., Group A), the concentration of radioactivity in blood and excreta shall be measured following administration. In animal subjects administered the test substance by the inhalation and dermal routes (i.e., Groups B, C, D, E, and F), the concentration of radioactivity in blood and excreta shall be measured at selected time intervals during the following exposure period to allow calculations of uptake, half lives, and clearance. In addition, in the groups administered the test substance by inhalation (i.e., Groups B, C, and F), the concentration of test substance in the exposure chamber air shall be measured at selected time intervals during the exposure period.

(B) *Guinea pig studies.* Groups H and I shall be used to determine the extent to which the test substance is metabolized and absorbed through the skin. The amount of radioactivity in excreta shall be determined at selected time intervals that will enable the measurement of kinetic processes.

(ii) *Metabolism studies—Rats.* Groups A, B, C, D, E, and F shall be used to determine the metabolism of the test substance. Excreta (urine, feces, and expired air) shall be collected for identification and measurement of the

quantities of test substance and metabolites.

(4) *Measurements*—(i) *Pharmacokinetics.* Four animals from each group shall be used for these purposes.

(A) *Rat studies*—(*1*) *Bioavailability.* The levels of radioactivity shall be determined in whole blood, blood plasma or blood serum at 15 minutes, 30 minutes, 1 hour, 2 hours, 8 hours, 24 hours, and 96 hours after administration of the intravenous and dermal doses, and at the same intervals after the last inhalation exposure.

(*2*) *Extent of absorption.* The total quantities of radioactivity shall be determined for excreta collected daily for 7 days, or after at least 90 percent of the radioactivity has been recovered in the excreta.

(*3*) *Excretion.* The quantities of radioactivity eliminated in the urine, feces, and expired air shall be determined separately at time intervals that provide accurate measurement of clearance and excretory rates. The collection of carbon dioxide may be discontinued when less than one percent of the dose is found to be exhaled as radioactive carbon dioxide in 24 hours.

(*4*) *Tissue distribution.* At the termination of each study, the quantities of radioactivity shall be determined in blood and in various tissues, including bone, brain, fat, gastrointestinal tract, gonads, heart, kidney, liver, lungs, muscle, skin, spleen, and residual carcass of each animal.

(*5*) *Change in pharmacokinetics.* Results of pharmacokinetics measurements (i.e., biotransformation, extent of absorption, tissue distribution, and excretion) obtained in rats receiving the single low inhalation dose of the test substance (Group B) shall be compared to the corresponding results obtained in rats receiving repeated inhalation doses of the test substance (Group F).

(B) *Guinea pig studies—Extent of absorption.* The total quantities of radioactivity in excreta shall be determined daily for 7 days or until 90 percent of the radioactive dose has been excreted.

(ii) *Metabolism.* Four animals from each group shall be used for these purposes. (A) *Rat Studies*—(*1*) *Biotransformation.* Appropriate qualitative and quantitative methods shall be used to assay urine, feces, and expired air collected from rats. Efforts shall be made to identify any metabolite which comprises 5 percent or more of the dose eliminated.

(*2*) *Changes in biotransformation.* Appropriate qualitative and quantitative assay methods shall be used to compare the composition of radioactive compounds in excreta from rats receiving single inhalation dose (Groups B and C) with rats receiving repeated inhalation doses (Group F).

(B) [Reserved]

(d) *Data and reporting.* The final test report shall include the following:

(1) *Preservation of results.* Numerical data shall be summarized in tabular form. Phamacokinetics data shall also be presented in graphical form. Qualitative observations shall also be reported.

(2) *Evaluation of results.* All data shall be evaluated by an appropriate statistical method.

(3) *Reporting results.* In addition to the reporting requirements as specified in 40 CFR Part 792, the following information shall be reported.

(i) Species and strains of laboratory animals.

(ii) Chemical characterization of the test substances, including: (A) For the radioactive test substances, information on the sites and degree of radiolabeling, including type of label, specific activity, chemical purity, and radiochemical purity.

(B) For the nonradioactive test substance, information on chemical purity.

(C) Results of chromatography.

(iii) A full description of the sensitivity, precision, and accuracy of all procedures used to obtain the data.

(iv) Percent and rate of absorption of the test substances after inhalation and dermal exposures to rats and dermal exposure to guinea pigs.

(v) Quantity and percent recovery of radioactivity in feces, urine, expired air, and blood. For dermal studies with rats and guinea pigs, include recovery data for skin, skin washings, and residual radioactivity in the recovering apparatus as well as results of the washing efficacy study.

(vi) Tissue distribution reported as quantity of radioactivity in blood, in various tissues including bone, brain, fat, gastrointestinal tract, gonads, heart, kidney, liver, lung, muscle, skin, and spleen and in residual carcass of rats.

(vii) Biotransformation pathways and quantities of the test substances and metabolites in excreta collected after administering single high and low doses to rats.

(viii) Biotransformation pathways and quantities of test substances and metabolites in excreta collected after administering repeated low doses to rats.

(ix) Pharmacokinetics models developed from the experimental data.

2. In Part 799:

a. The authority citation would continue to read as follows:

Authority: 15 U.S.C. 2063, 2611, 2625.

b. § 799.2155 by adding paragraph (c)(8) and by revising paragraph (d) to read as follows:

§ 799.2155 Commercial hexane.

* * * * *

(c) * * *

(8) *Pharmacokinetics*—(i) *Required testing.* Pharmacokinetics testing shall be conducted with the test substances specified in paragraph (a)(2) of this section and in § 795.232(c)(2)(i) of this chapter. Two separate tests will be run, one with the test substance labeled with ^{14}C *n*-hexane, and the other with the test substance labeled with ^{14}C methylcyclopentane, in accordance with § 795.232 of this chapter. In addition, the rat strain used shall be the same as the strain used in the other tests required under this section.

(ii) *Reporting requirements.* (A) The inhalation and dermal pharmacokinetics test shall be completed and the final report submitted to EPA within 18 months after [the effective date of the final rule specifying the pharmacokinetics test standard and reporting requirements for commercial hexane].

(B) Interim progress reports shall be submitted to EPA for the inhalation and dermal pharmacokinetics test at 6-months intervals, beginning 6 months after the effective date of the final test rule specifying the pharmacokinetics test standard for commercial hexane, until the final report is submitted to EPA.

(d) *Effective date.* (1) Section 799.2155 is effective on November 17, 1988 except for paragraph (c)(8) which is effective [44 days after publication of the final rule incorporating this amendment].

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of the respective paragraphs of this section.

[FR Doc. 88-25929 Filed 11-8-88; 8:45 am]
BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

48 CFR Part 552

[GSAR Notice No. 5-268]

General Services Administration Acquisition Regulation; Economic Price Adjustment Clause for Multiple Award Schedule Contracts

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Proposed rule.