and pests, Reporting and recordkeeping requirements.

Dated: March 22, 1996.

Stephen L. Johnson,

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 96–8143 Filed 4–3–96; 8:45 am]

**BILLING CODE 6560–50–F02**

**[PF–648; FRL–5359–6]**

## Withdrawal of Feed Additive Petition for Dacthal W75

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

**ACTION:** Notice.

**SUMMARY:** EPA is withdrawing a feed additive petition from ISK Biotech Corp., 5966 Heisley Rd., P.O. Box 8000, Mentor, OH 44061-8000 for residues of (Dacthal W75) in or on bean cannery waste, tomato pomace and potato peels.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne Miller, Product Manager (23) Registration Division (7505C), Office of Pesticide Programs. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, 703–305–6224.

**SUPPLEMENTARY INFORMATION:**

*Withdrawn Petition*

*FAP 4H5688.* Notice of the petition requested by ISK Biotech Corp., 5966 Heisley Rd., P.O. Box 8000, Mentor, OH 44061-8000 was filed by EPA November 2, l994 (59 FR 54907). The Notice stated that ISK Biotech Corp. had proposed to amend 40 CFR part 186 by establishing a feed additive regulation to permit the residues of DCPA (Dacthal W75) in or on bean cannery waste, tomato pomace and potato peels. The Agency's Subdivision O Guidelines were revised June, l994. Bean cannery waste was removed from Table II of that guideline, therefore a feed additive tolerance is no longer required. Tomato pomace is no longer considered to be a significant animal feed, therefore a feed additive tolerance is no longer required. The need for feed additive tolerances on processed potato waste is based on the maximum concentration factor observed for residues in or on wet peel. Concentration was only observed in the dry peel fraction, therefore a feed additive tolerance for dried potato waste is not required. The Agency has withdrawn the subject FAP.

List of Subjects

Environmental protection, Animal feeds, Pesticides and pest.

Dated: March 22, 1996.

Stephen L. Johnson,

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 96–8144 Filed 4–2–96; 8:45 am]

**BILLING CODE 6560–50–F**

**[OPPTS–42186A; FRL–5359–3]**

## Request for Proposals for Enforceable Consent Agreements; Dermal Absorption Rate Testing of Eighty OSHA Chemicals; Solicitation of Interested Parties; Text of Test Protocol

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

**ACTION:** Notice.

**SUMMARY:** This notice addresses all manufacturers and processors of eighty chemical substances of interest to the Occupational Safety and Health Administration of the Department of Labor (OSHA) which were designated for dermal absorption testing in the 31st, 32nd and 35th Reports of the TSCA section 4 Interagency Testing Committee (ITC). These persons are invited to submit to EPA proposals for enforceable consent agreement (ECA) consideration for dermal absorption rate testing of the 80 chemicals. The protocol set forth in this notice is recommended as the test protocol for these proposals. In addition, EPA is soliciting ''interested parties'' to participate in or monitor any ECA negotiations initiated in response to this solicitation.

**DATES:** Written proposals for ECAs and written requests to be designated an interested party must be received by July 2, 1996. EPA may extend the deadline for receipt of testing proposals upon request and a showing of good faith efforts on the part of potential submitters to develop testing proposals by the deadline.

**ADDRESSEES:** Send written submissions, identified by the document control number (OPPTS–42186A) (FRL–5359–3), in triplicate to: TSCA Document Control Office (7407), Rm. ET–G099, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Attn: TSCA section 4. The public record supporting this action, including comments, is available for public inspection from Noon to 4 p.m., Mondays through Fridays, except legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Persons submitting information any portion of which they believe is entitled to treatment as confidential business information (CBI) by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this waiver of any confidentiality claim, and the information may be made available to the public by EPA without further notice to the submitter.

Proposals may be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Proposals in electronic form must be submitted as ASCII files and must avoid the use of special characters and any form of encryption. Proposals will also be accepted on disks in WordPerfect 5.1 (DOS) file format or ASCII file format. All proposals in electronic form must be identified by docket number OPPTS–42186A (FRL–5359–3). Information claimed as CBI should not be submitted via e-mail. Proposals in electronic form may be filed on-line at many Federal depository libraries. Additional information on submissions in electronic form may be found in Unit VI of this notice.

**FOR FURTHER INFORMATION CONTACT:** Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET–543B, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554–1404; TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov. For specific information regarding this solicitation or related matters, contact Roger A. Nelson, Project Manager, Chemical Testing and Information Branch (7405), Rm. ET–729A, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260–8163; e-mail: nelson.roger@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:**

I. Introduction

The ITC has reviewed 658 chemical substances that were presented to the ITC by OSHA in 1991 (58 FR 26898, 26900, May 5, 1993 and 58 FR 38490,

38492–38493, July 16, 1993). OSHA requested the ITC to assess the availability of dermal absorption data for these chemical substances and to determine the need for further testing. (See 58 FR 26898, 26900, May 5, 1993.) The ITC indicated that OSHA needs quantitative measures of dermal absorption in order to evaluate the potential hazard of these chemicals to workers (58 FR 38490, 38492, July 16, 1993).

In its 31st, 32nd, and 35th Reports to the EPA Administrator (published at 58 FR 26898, May 5, 1993; 58 FR 38490, July 16, 1993; and 59 FR 67596, December 29, 1994, respectively) (FRL–4583–4, FRL–4630–2, and FRL–4923–2, respectively), the ITC designated for dermal absorption testing a total of 83 of the chemical substances nominated by OSHA. These chemicals are listed in Table 1.—''Chemicals Designated by the ITC for Dermal Absorption Testing'' in Unit II of this notice. After reviewing additional information, in its 34th and 36th Reports (published at 59 FR 35720, July 13, 1994 and 60 FR 42982, August 17, 1995, respectively) (FRL–4870–4 and FRL–4965–6, respectively), the ITC withdrew the designation for three of the chemicals (noted in table 1 in Unit II of this notice). Eighty of the chemical substances nominated by OSHA are thus currently designated by the ITC for dermal absorption testing.

In the Federal Register notices containing the 31st, 32nd and 35th ITC Reports, EPA solicited proposals for ECAs for dermal absorption testing of the subject chemical substances. In the notices of the 31st, 32nd and 35th Reports, EPA referenced a proposed dermal absorption test protocol for review by potential submitters in developing their submissions (Ref. 1). Public comments on the protocol were received by EPA and were entered into the docket for the 31st, 32nd, or 35th ITC Report, as appropriate (docket nos. OPPTS–41038, OPPTS–41039, and OPPTS–41042, respectively). In addition, the Chemical Manufacturers Association (CMA) submitted a proposal outlining an alternative protocol (Ref. 2). Scientists from EPA and a number of agencies represented on the ITC (including OSHA) reviewed the public comments and the CMA proposal. Based on this review, a protocol entitled ''Recommended Protocol for *In Vitro* Percutaneous Absorption Rate Studies'' was developed, and is set forth in Unit V of this notice.

EPA received no proposals for ECAs for dermal absorption testing of any of the subject chemical substances in response to the above-mentioned solicitations. In today's notice, EPA is soliciting proposals for ECAs which address the chemical substances listed in table 1 in Unit II of this notice and through which dermal absorption rate data would be developed to meet OSHA's needs.

## II. Response to Submissions to EPA

### *A. Response to Public Comments on the ITC Reports*

Comments were received on the 31st, 32nd and 35th ITC Reports and were entered into the docket for the corresponding ITC Report. Comments received on these ITC Reports addressing the proposed test protocol were reviewed as part of the protocol development process, as discussed in Unit I of this notice. EPA and the ITC have reviewed all other comments received on these ITC Reports. The analysis of these comments by EPA and the ITC follows.

In its comments on the 31st ITC Report, Mobil (Ref. 3) asserted that acute dermal toxicity studies would be cheaper and faster than skin penetration studies. EPA and the ITC believe that acute dermal toxicity studies would not meet OSHA's needs since such studies would not provide data on absorption rates.

BASF (Ref. 4) stated that it has been established that tetrahydrofuran (32nd ITC Report) can be rapidly absorbed in lethal amounts through the skin of rats and rabbits. OSHA needs data related to the real measured rate of the absorption of tetrahydrofuran by the skin. The needed data are not provided in the comment.

Aristech (Ref. 5) commented that there is no specific need to test diphenylamine (32nd ITC Report) since this chemical is no different from other regulated substances for which dermal penetration data are not available. EPA and the ITC believe that such data are needed to make determinations concerning the need to alert industrial hygienists, employers, and workers to the potential adverse health effects of dermal exposure to diphenylamine, as explained in Unit III of this notice.

DuPont (32nd ITC Report) and the CMA Propylene Glycol Ethers Panel (35th ITC Report) (Refs. 6 and 7, respectively) questioned how OSHA planned to use these data. The uses to which the data will be put are explained in Unit III of this notice. Dow (31st ITC Report) (Ref. 8) questioned the appropriateness of the grouping of the subject chemical substances for testing purposes. EPA believes that the identity of testing needs (dermal absorption rate) for these eighty chemicals is sufficient reason for grouping them together in one notice.

The CMA Ketones Panel (Ref. 9) commented on the request contained in the Federal Register notice announcing the 31st ITC Report for a testing consortium to develop ECAs for all designated chemicals. The Panel expressed its belief that such a consortium would not be feasible in light of the number of chemicals designated and the number of companies that would have to participate in ECA negotiations. EPA acknowledges that multiple ECAs may present a feasible approach. (See Unit III of this notice).

Angus Chemicals submitted two dermal absorption studies (Refs. 10 and 11)—one on 1-nitropropane (31st ITC Report) and the other on 2-nitropropane (32nd ITC Report). These studies were submitted by Angus to support its claims that additional testing of these chemicals is not needed. EPA and the ITC have ascertained that the submitted studies are deficient because the recovered amounts (0.5%) of test material rendered the studies inadequate to determine dermal absorption rates for these chemicals.

DuPont (Ref. 6) submitted comments on 14 chemical substances in the 32nd ITC Report claiming that dermal toxicity data for these chemicals (referenced in the comments) are available. EPA and the ITC have determined that the references cited by DuPont do not address the issue of dermal absorption rate.

The CMA Dinitrotoluenes Panel (32nd ITC Report) (Ref. 12) submitted comments on 2,4-dinitrotoluene (2,4-DNT), including literature describing studies of 2,6-DNT and technical grade DNT, a mixture of 2,4-DNT and 2,6-DNT. (The literature on 2,6-DNT was offered on the basis that 2,6-DNT was an acceptable surrogate for 2,4-DNT.) The Panel claimed that existing dermal absorption data are adequate for 2,4-DNT. EPA and the ITC reviewed the literature and determined that since it does not address dermal absorption rates, the literature is not adequate to meet OSHA's data needs.

The CMA Propylene Glycol Ethers Panel (Ref. 13) commented that dermal toxicity data already exist on dipropylene glycol methyl ether (DPGME) (35th ITC Report). EPA and the ITC ascertained that no dermal absorption rate studies were cited by CMA.

SOCMA (Ref. 14) questioned the designation of biphenyl (35th ITC Report), stating that dermal exposure to biphenyl is limited and animal studies indicate that biphenyl does not produce

adverse health effects following dermal application. EPA and the ITC determined that none of the studies cited by SOCMA relate to dermal absorption rate.

Union Carbide (Ref. 15) asserted that the ITC should not have designated isophorone (35th ITC Report) for dermal absorption testing. OSHA needs data related to the dermal absorption rate of isophorone. These needed data are not provided in the comment.

*B. Response to TSCA Section 8(d) Studies*

EPA has screened the health and safety studies on the subject chemical substances that have been submitted to the Agency pursuant to section 8(d) of the Toxic Substances Control Act (TSCA). None of these submitted studies was determined to be relevant to dermal absorption rate.

TABLE 1.—CHEMICALS DESIGNATED BY THE ITC FOR DERMAL ABSORPTION TESTING

| CAS No. | Chemical Name |
|---|---|
| 31st ITC Report: | |
| 60-29-7 | Ethyl ether |
| 75-65-0 | *tert*-Butyl alcohol |
| 76-22-2 | Camphor |
| 78-92-2 | *sec*-Butyl alcohol |
| 79-20-9 | Methyl acetate |
| 97-77-8 | Disulfiram |
| 100-25-4 | *p*-Dinitrobenzene |
| 105-46-4 | *sec*-Butyl acetate |
| 106-42-3 | *p*-Xylene |
| 107-31-3 | Methyl formate |
| 107-66-4 | Dibutyl phosphate |
| 108-03-2 | 1-Nitropropane |
| 108-87-2 | Methylcyclohexane |
| 109-66-0 | Pentane |
| 110-83-8 | Cyclohexene |
| 111-84-2 | Nonane |
| 123-92-2 | Isoamyl acetate |
| 142-82-5 | *n*-Heptane |
| 287-92-3 | Cyclopentane |
| 532-27-4 | *a*-Chloroaceto-phenone |
| 540-88-5 | *tert*-Butyl acetate |
| 628-63-7 | *n*-Amyl acetate |
| 7631-90-5 | Sodium bisulfite |
| 7681-57-4 | Sodium metabisulfite |
| 32nd ITC Report: | |
| 61-82-5 | Amitrole |
| 74-96-4 | Ethyl bromide |
| 75-15-0 | Carbon disulfide |
| 75-25-2 | Bromoform |
| 75-34-3 | 1,1-Dichloroethane |
| 77-78-1 | Dimethyl sulfate |
| 79-46-9 | 2-Nitropropane |
| 80-62-6 | Methyl methacrylate[1] |
| 84-66-2 | Diethyl phthalate[1] |
| 88-72-2 | *o*-Nitrotoluene |
| 89-72-5 | *o*-*sec*-Butylphenol |
| 90-04-0 | *o*-Anisidine |
| 95-13-6 | Indene |
| 95-49-8 | *o*-Chlorotoluene |
| 99-65-0 | *m*-Dinitrobenzene |
| 100-00-5 | *p*-Nitrochlorobenzene |
| 100-01-6 | *p*-Nitroaniline |
| 100-44-7 | Benzyl chloride |
| 100-63-0 | Phenylhydrazine |
| 106-49-0 | *p*-Toluidine |
| 108-44-1 | *m*-Toluidine |
| 108-90-7 | Chlorobenzene |
| 109-99-9 | Tetrahydrofuran |
| 121-14-2 | 2,4-Dinitrotoluene |
| 122-39-4 | Diphenylamine |
| 126-99-8 | *beta*-Chloroprene |
| 150-76-5 | *p*-Methoxyphenol |
| 528-29-0 | *o*-Dinitrobenzene |
| 540-59-0 | 1,2-Dichloroethylene |
| 626-17-5 | *m*-Phthalodinitrile |
| 768-52-5 | N-Isopropylaniline |
| 1300-73-8 | Xylidine |
| 6423-43-4 | Propylene glycol dinitrate |
| 25013-15-4 | Vinyl toluene |
| 35th ITC Report: | |
| 75-05-8 | Acetonitrile |
| 75-12-7 | Formamide |
| 75-35-4 | Vinylidene chloride |
| 77-73-6 | Dicyclopentadiene |
| 78-59-1 | Isophorone |
| 78-83-1 | Isobutyl alcohol |
| 78-87-5 | Propylene dichloride |
| 91-20-3 | Naphthalene |
| 92-52-4 | Biphenyl |
| 95-50-1 | *o*-Dichlorobenzene |
| 96-18-4 | 1,2,3-trichloropropane |
| 98-29-3 | *t*-Butylcatechol |
| 99-08-1 | *m*-Nitrotoluene |
| 99-99-0 | *p*-Nitrotoluene |
| 106-46-7 | *p*-Dichlorobenzene |
| 107-06-2 | Ethylene dichloride |
| 108-93-0 | Cyclohexanol |
| 108-94-1 | Cyclohexanone[2] |
| 110-12-3 | Methyl isoamyl ketone |
| 120-80-9 | Catechol |
| 121-69-7 | Dimethylaniline |
| 123-42-2 | Diacetone alcohol |
| 127-19-5 | Dimethyl acetamide |
| 542-92-7 | Cyclopentadiene |
| 34590-94-8 | Dipropylene glycol methyl ether |

[1] Removed by the ITC in its 34th Report.

[2] Removed by the ITC in its 36th Report.

III. Request for Proposals

No proposals for ECAs for dermal absorption testing of any of the subject chemical substances were received by EPA as a result of the solicitations in the Federal Register notices containing the 31st, 32nd and 35th ITC Reports. EPA has revised the test protocol and is now seeking proposals that will provide for the development of dermal absorption rate data on the eighty chemical substances listed in table 1 in Unit II of this notice. EPA has reason to believe that industry now has an interest in proposing dermal absorption rate testing schemes for at least some of these chemical substances.

EPA encourages submitters to work together to develop proposals for ECAs that address all eighty subject chemical substances or significant subsets thereof. The Agency, however, will also accept proposals for ECAs providing for the testing of individual chemicals. All proposals should set forth offers to test specific chemicals for the endpoint of interest (dermal absorption rate); expressions of interest in ECA negotiations do not, in and of themselves, constitute proposals.

The dermal absorption rate data obtained under this testing program will be used to support development of OSHA's ''skin designations'' for the subject chemical substances. Skin designations for specific chemicals alert industrial hygienists, employers, and workers to potential adverse health effects resulting from dermal exposure to these chemicals in the workplace. OSHA assigns a skin designation to a chemical if it determines that cutaneous exposure (through the skin, eyes, and mucous membranes) to that chemical in the workplace represents a potential significant contribution to overall workplace exposure. Cutaneous exposure is a function of, among other things, the rate of absorption of the chemical substance. One methodology under consideration for developing and assigning skin designations is discussed in Walker et al. (Ref. 17).

EPA has developed a protocol, set forth in Unit V of this notice, that is recommended as the test protocol for all proposals for ECAs. The Agency believes that testing conducted in accordance with the protocol will provide data of use to OSHA, is consistent with EPA and OSHA testing policies, and provides the most economical approach to address a large number of diverse chemical substances. If a submitter chooses not to use the recommended protocol but instead submits an alternative protocol, an explanation should be given as to how this alternative protocol will provide comparable data and achieve the same goals as the recommended protocol.

IV. Solicitation of Interested Parties

Negotiations on ECAs for dermal absorption rate testing of the subject chemical substances will be conducted pursuant to the procedures described in 40 CFR 790.22. All persons who respond to this notice on or before July 2, 1996 will be given the status of interested parties and will be afforded an opportunity to monitor or participate

in the negotiations. All such persons should indicate the chemical substance(s), by name and CAS number, in which they are interested. Those persons who have already given notice in their response(s) to the 31st, 32nd, or 35th ITC Report that they wish to be designated interested parties with regard to ECA negotiations on specific chemical substances will be considered automatically to be interested parties on such chemicals. Interested parties do not incur any obligation by being so designated.

Upon making the appropriate findings under section 4 of the Toxic Substances Control Act (TSCA), EPA has the authority to require dermal absorption rate testing of some or all of these chemical substances through formal rulemaking. If an ECA-based approach does not prove viable, EPA will proceed with rulemaking to require industry to conduct the needed testing.

## V. Recommended Protocol for In Vitro Percutaneous Absorption Rate Studies

### *A. Introduction*

This recommended protocol was developed to provide percutaneous absorption rate data for the Occupational Safety and Health Administration (OSHA) chemicals designated in the 31st, 32nd and 35th Reports (published at 58 FR 26898, May 5, 1993; 58 FR 38490, July 16, 1993; and 59 FR 67596, December 29, 1994, respectively) of the TSCA section 4 Interagency Testing Committee (ITC), as modified by the 34th and 36th ITC Reports (published at 59 FR 35720, July 13, 1994 and 60 FR 42982, August 17, 1995, respectively). The protocol was developed by a group of scientists from agencies represented on the ITC (the Consumer Product Safety Commission, the Department of Defense, EPA, the Food and Drug Administration, the National Institute for Occupational Safety and Health, and OSHA) based on the methods of Bronaugh and Collier (Ref. 16), and modified in response to comments.

The protocol outlines procedures for measuring a permeability constant (Kp) and a short-term absorption rate for chemicals in liquid form. Measurement of short-term absorption rates is only required when a Kp cannot be obtained using the protocol described. For most chemicals, a Kp is most useful in estimating skin permeation. However, for harsh chemicals that may damage the skin more severely with prolonged contact, a short-term absorption rate is more relevant. The permeability constants and short-term absorption rates measured will be used by OSHA to give more specific guidance to employers on whether a chemical used in a particular process warrants changes in engineering controls or use of personal protective equipment to reduce the hazard of systemic toxicity after dermal absorption of the chemical.

OSHA expects that this would be accomplished by using a semi-quantitative procedure such as estimating time required to absorb a toxic dose compared to the inhalation permissible exposure limits (Ref. 17). It is not contemplated that the values developed using this protocol would be used for quantitative risk assessment because of the limitations of the methods used to collect the data and the variability of individual exposure scenarios present in workplaces.

The protocol utilizes established *in vitro* diffusion cell techniques which allow absorption studies to be conducted with human skin. The *in vitro* method is chosen for practical considerations. It is efficient in terms of labor and materials and can be easily performed using a standard method by different laboratories. *In vitro* diffusion cell studies are necessary for measuring a Kp.

Although maintaining the viability of skin more closely simulates *in vivo* conditions, this protocol allows use of static diffusion cells and cadaver skin. This protocol also requires the use of radiolabeled chemicals unless it can be demonstrated that alternative, non-radiolabeled methods provide sufficient sensitivity to detect the parent chemical (and its major skin metabolites in those cases where skin viability is maintained). The first five protocol parameters that are discussed (choice of membrane, preparation of membrane, diffusion cell design, testing hydrophobic chemicals and vehicle) are similar for determination of either of the two percutaneous absorption values. In contrast, the remaining two protocol parameters (i.e., dose and study duration) are different for the two percutaneous absorption values.

### *B. Conduct of Test*

#### 1. Choice of Membrane

i. *Skin selection.* The most accurate absorption data for regulatory concerns related to human health would be obtained with human skin. Since this protocol allows use of the static cell, maintenance of viability of skin is not necessary. Human cadaver skin is required for these studies.

ii. *Number of subjects.* Data from a total of at least six samples obtained from at least three human subjects should be averaged to allow for biological variation between subjects. Replicates are not required. The variability can be up to 5-fold in different samples of normal human skin.

iii. *Regional variability.* Variability in skin permeation is well known to occur in different anatomical regions. The trunk and the extremities have reasonably similar barrier properties (less than 2-fold differences). Enhanced absorption can be observed in regions of the face (4-fold) and the scrotum (20-fold). Small differences in regional absorption may not be significant compared to intersubject variability. However, to minimize the variability in skin absorption measurements, for these tests all samples of human skin shall be obtained from the abdominal region of human subjects of known source and disease state. The time elapsed between death and harvest of tissue shall be reported.

iv. *Validation of human skin barrier.* Barrier properties of human skin shall be pretested with a standard compound such as tritiated water prior to conducting an experiment with the test chemical because barrier alteration can result from surgery or topical scrubbing (Ref. 18).

#### 2. Preparation of Membrane

Full thickness skin should not be used. Since absorbed chemicals are taken up by blood vessels directly beneath the epidermis *in vivo*, an *in vitro* study should use a membrane with most of the dermis removed. This is particularly important for hydrophobic chemicals that would diffuse slowly through the dermis. A suitable membrane shall be prepared from fresh skin with a dermatome at a thickness of 200 to 500 mm. The microtomed skin samples can be stored frozen for up to two weeks, if necessary, if they are frozen quickly and the barrier properties of the samples are confirmed.

#### 3. Diffusion Cell Design

Flow cells or static diffusion cells shall be used in these studies. Flow cells are useful for maintaining the viability of the skin (in the case that live skin is used) because nutrient media must be continually replaced. Also, these cells are preferable for studies requiring round-the-clock sampling since samples can be collected automatically in a fraction collector. Flow cells of adequate design will have only small exposed areas of skin for applying test chemicals because the receptor volume must be small so that the cell contents can be rapidly exchanged (Ref. 19). If flow cells are used, the draft ITC protocol describing their use shall be followed. The draft

ITC protocol was first made publicly available with the 31st ITC Report.

If static cells are used, the testing laboratory must verify that there is not an increase in concentration of the test compound in the receptor fluid that would change the penetration rate. Specifically, the concentration difference across the membrane must not decrease by more than 10% during the experiment. Concentration of the neat liquid should be taken as the density of the compound.

4. Temperature

Skin shall be maintained at a physiological temperature which is about 32°C.

5. Testing Hydrophobic Test Chemicals

Chemicals with water solubility less than about 10 mg/L do not freely partition from skin into aqueous receptor fluid. To increase the water solubility of such hydrophobic chemicals, polyethoxyoleate (PEG 20 oleyl ether) shall be added to the receptor fluid at a concentration of 6 percent. To ensure that an increase in concentration of the chemical in the receptor fluid does not alter the penetration rate, the concentration difference across the membrane must not decrease by more than 10% during the experiment.

6. Vehicle

If the test chemical is a liquid at room temperature and does not damage the skin during the determination of Kp, it shall be applied neat. If the chemical cannot be applied neat because it is a solid at room temperature or because it damages the skin when applied neat, it should be dissolved in water. If the concentration of a hydrophobic chemical in water is not high enough so that a steady-state absorption can be obtained, the chemical shall be dissolved in isopropyl myristate. *In vitro* percutaneous absorption experiments with other vehicles of interest may be required for selected test chemicals in order to meet the data needs of individual Federal agencies. A sufficient volume of liquid shall be used to completely cover the skin and provide the amount of test chemical needed as described in section B.7. ''Dose'' of this protocol below. The volume should be sufficient so that the skin surface remains covered by the vehicle during the determination of Kp.

7. Dose

i. *Permeability constant.* An ''infinite dose'' of the test chemical shall be applied to the skin to achieve the steady-state rate of absorption necessary for calculation of a Kp. The actual concentration required to give an undepletable reservoir on the surface of the skin depends on the rate of penetration of the test chemical. Preliminary studies may be necessary to determine this concentration. If necessary to generate a reliable Kp, the diffusion cell tops should be covered with a stopper or with Parafilm7 to prevent evaporation of the vehicle or test chemical. If damage to the skin is likely due to the nature of the test chemical, the skin barrier integrity shall be verified at the end of the experiment by measuring the absorption of a standard compound such as tritiated water (Ref. 18).

ii. *Short-term absorption rates.* Short-term absorption rates shall be determined for those chemicals for which a Kp cannot be measured. The dose of test chemical applied to the skin shall be sufficient to completely cover the exposed skin surface. Four to six diffusion cells shall be set up using skin from a single subject and two to three of these will be terminated at 10 minutes and at 60 minutes. Skin absorption at each sampling time is the sum of the receptor fluid levels and the absorbed chemical that remains in the skin (Ref. 20). Unabsorbed chemical is removed from the skin surface by washing gently with soap and water. This experiment shall be repeated with skin from two additional subjects. If necessary to generate reliable short-term absorption rates, the diffusion cell tops should be covered with a stopper or with Parafilm7 to prevent evaporation of the test chemical.

8. Study Duration

i. *Permeability constant.* The percutaneous absorption study shall be performed until at least four absorption measurements are obtained during the steady state absorption portion of the experiment. A preliminary study may be useful to establish time points for sampling. The required absorption measurements can be accomplished in an hour or two with fast penetrating chemicals but can require 24 hours or longer for slow-penetrating chemicals. Unabsorbed material need not be removed from the surface of the skin.

ii. *Short-term exposure rate.* The test chemical shall be applied to skin for at least durations of 10 and 60 minutes. At the end of the study, the unabsorbed material shall be removed from the surface of the skin with soap and water and the amount absorbed into the skin and receptor fluid shall be determined (Ref. 20).

*C. Expression of Results*

1. Permeability Constant

The Kp shall be calculated by dividing the steady-state rate of penetration (measured in $\mu g \times hr^{-1} \times cm^{-2}$) by the concentration of test chemical (measured in $\mu g \times cm^{-3}$) applied to the skin. For example, if the steady-state rate is $1\ \mu g \times hr^{-1} \times cm^{-2}$ and the concentration applied to the skin is $1000\ \mu g \times cm^{-3}$, then the Kp value is calculated to be $0.001\ cm \times hr^{-1}$.

2. Short-Term Exposure Rate

The rates of penetration ($\mu g \times hr^{-1} \times cm^{-2}$) shall be determined from the total amount of test chemical found in the receptor fluid and skin after the 10- and 60-minute exposures.

*D. Recordkeeping and Reporting Requirements*

In addition to compliance with TSCA Good Laboratory Practice (GLP) Standards at 40 CFR part 792, the following specific information shall be collected and reported:

1. Description of Test Systems and Test Methods

The report shall include where and when the test was performed, who performed it, a good laboratory practice statement, and where the records of the test are stored. All of this must be certified by the signatures of the individuals performing the work and their supervisors.

The source, identity and purity of the test chemical shall be reported. The source, identity and handling of the test skin shall be described. There shall be a detailed description of the test procedure and all materials, devices used and doses tested. There shall be a detailed description and illustration of flow cell design. There shall be a description of the skin preparation method including measurements of the skin membrane thickness.

The analytical techniques to be used including their accuracy, precision and detection limits (in particular for non-radiolabelled tests) shall be described and if a radiolabel is used, there shall be a description of the radiolabel (e.g., type, location of and radiochemical purity of the label).

All data collected in the course of the experiment must clearly be identified as to dose and specimen. Derived values (means, permeability coefficient, graphs, charts, etc.) are not sufficient.

2. Conduct of Study

Data shall be collected and reported on the following:

1. Monitoring of testing parameters.

2. Temperature of chamber.
3. Receptor fluid pH.
4. Barrier property validation.
5. Maintenance of glucose utilization (if using viable skin).
6. Analysis of receptor fluid for radioactivity or test chemical and metabolites (if using viable skin).

3. Results

The permeability constant (Kp) or short-term absorption rate shall be presented. In addition, all raw data from each individual diffusion cell shall be maintained to support the calculations of permeability constants and short-term exposure rates. When radiolabelled compounds are used, a full balance of the radioactivity shall be presented, including cell rinsings and stability of the test substance in the donor compartment.

VI. Public Docket

*A. Materials Contained in the Docket*

EPA has established a docket for this action (to include paper versions of comments in electronic form) under docket control number OPPTS-42186A (FRL–5359–3). The public record is available for inspection from Noon to 4 p.m., Mondays through Fridays, except legal holidays, in the TSCA Nonconfidential Information Center, Rm. NE–B607, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Information claimed as CBI, while part of the record, is not available for public review. The docket includes the following:

1. USEPA. Proposed Protocol for *In Vitro* Percutaneous Absorption Studies. (May 5, 1993).

2. Chemical Manufacturers Association (CMA). Letter to Charles M. Auer, USEPA. (October 21, 1994).

3. Mobil Oil Corporation. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (July 6, 1993).

4. BASF Corporation. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 13, 1993).

5. Aristech Chemical Corporation. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 29, 1993).

6. DuPont. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 15, 1993).

7. The CMA Propylene Glycol Ethers Panel. Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (February 27, 1995).

8. The Dow Chemical Company. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (June 3, 1993).

9. The CMA Ketones Panel. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (July 2, 1993).

10. Angus Chemical Company. Letter from Allen F. Bollmeier, Jr. to Roger Nelson, USEPA, enclosing study entitled: ''Skin Absorption and Metabolism/Toxicokinetic Study of $^{14}$C-1-Nitropropane in Female Rhesus Monkeys''. (June 16, 1993).

11. Angus Chemical Company. Letter from Allen F. Bollmeier, Jr. to John D. Walker, ITC, enclosing study entitled: ''Skin Absorption and Metabolism/Toxicokinetic Study of $^{14}$C-2-Nitropropane in Female Rhesus Monkeys''. (June 21, 1993).

12. The CMA Dintrotoluenes Panel. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 30, 1993).

13. The CMA Propylene Glycol Ethers Panel. Comment letter on the 35th TSCA Interagency Testing Committee Report from Langley Spurlock to Charles M. Auer, USEPA. (March 31, 1995).

14. Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA). Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (January 30, 1995).

15. Union Carbide Corp. Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (February 24, 1995).

16. Bronaugh, R.L. and Collier, S.W. Protocol for *In Vitro* Percutaneous Absorption Studies, in *In Vitro Percutaneous Absorption: Principles, Fundamentals, and Applications*, (R.L. Bronaugh and H.I. Maibach, Eds.), CRC Press, Boca Raton, 1991, pp. 237–241.

17. Walker, J.D., Whittaker, C. and McDougal, J.N. Role of the TSCA Interagency Testing Committee in Meeting the U.S. Government's Data Needs: Designating Chemicals for Percutaneous Absorption Testing. In: F. Marzulli and H. Maibach (eds.) *Dermatotoxicology*. Taylor Francis, Washington, DC. (In press).

18. Bronaugh, R.L., Stewart, R.F., and Simon, M. Methods for *In Vitro* Percutaneous Absorption VII: Use of Excised Human Skin, *J. Pharm. Sci.*, vol. 75, pp. 1094–1097, 1986.

19. Bronaugh, R.L. and Stewart, R.F. Methods for *In Vitro* Percutaneous Absorption Studies IV: The Flow-Through Diffusion Cell, *J. Pharm. Sci.*, vol. 74, pp. 64–67, 1985.

20. Bronaugh, R.L., Stewart, R.F., and Storm, J.E. Extent of Cutaneous Metabolism during Percutaneous Absorption of Xenobiotics, *Toxicol. Appl. Pharmacol.*, vol. 99, pp. 534–543, 1989.

*B. Submissions to the Docket in Electronic Form*

Proposals in electronic form may be sent directly to EPA at:
ncic@epamail.epa.gov
Proposals in electronic form must be submitted as ASCII files and must avoid the use of special characters and any form of encryption.

The official record of this action, as well as the public version, will be maintained in paper form. Accordingly, EPA will transfer all proposals received electronically into paper form as they are received and will place the paper copies in the official record which will also include all proposals submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Authority: 15 U.S.C. 2603.

Dated: March 26, 1996.

Charles M. Auer,
*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

[FR Doc. 96-8008 Filed 4–2–96; 8:45 am]
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## FEDERAL DEPOSIT INSURANCE CORPORATION

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice and request for comment.

**BACKGROUND:** In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the