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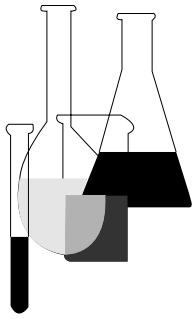
Occupational and Residential Exposure Test Guidelines

OPPTS 875.1200 Dermal Exposure—Indoor



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

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OPPTS 875.1200 Dermal exposure—indoor.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline are OPP guidelines 230 and 233. This guideline should be used with OPPTS 875.1000.

(b) **Estimation of dermal exposure by passive dosimetry—**(1) **Construction of dermal exposure pads and storage envelopes of exposed pads—**(i) **Dermal exposure pads for sprays.** Pads to be used for estimating dermal exposure to sprays are to be constructed from papermaking pulp or a similar material, referred to as α-cellulose, approximately 1 mm thick. A good grade of α-cellulose will absorb a considerable amount of spray without disintegrating. Further, it should not typically require preextraction to remove substances that interfere with residue analysis. This should be determined before using such pads in exposure tests. Acetanier P-FA, produced by ITT Rayonier, Inc., Chemical Cellulose Sales Department, 1177 Summer St., Stamford, CT 06904, has been found to be satisfactory for this use. It is available only in 500 lb bales, but 4 lb samples of 10 inch square sheets are available at no charge (shipping not included) if an investigator wishes to compare it to other potential dermal dosimeter materials before choosing an appropriate pad material. Another material, which is satisfactory and more readily available in small lots, is preparative chromatography paper (17 Chrom) available in sheets from Whatman, Inc., 9 Bridewell Place, Clifton, NJ 07014. The large sheets available form the manufacturer are cut into approximately 4 inch (10.2 cm) squares which are stapled to a protective backing of glassine paper or aluminum foil. Glassine powder-weighing paper precut into 4 inch (10.2 cm) squares is produced by Schleicher and Schuell, Inc., and is available through most laboratory supply companies. The glassine paper or aluminum foil backing prevents contamination of the exposure pad by material deposited on the subject's clothing during a previous spraying.

(ii) **Dermal exposure pads for dry residues.** Pads to be used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulations, are to be constructed from layers of surgical gauze. A piece of heavy filter paper backing approximately 4 inch (10.2 cm) square is overlayed with approximately 32 plies of surgical gauze and the components are bound together with masking tape along all four edges. The finished pad should be bound so that an area of gauze at least 2.5 inch (6.4 cm) square is left exposed. The gauze must be checked for material that would interfere with analysis and be preextracted if necessary.

(iii) **Storage envelopes to contain exposed pads.** If exposed pads are to be stored prior to extraction, envelopes cut from heavy filter paper

my be used. The same white crepe filter paper that is used for backing the dust exposure pads is suitable for this use. It is also necessary to check the envelope for material that will interfere with analysis, since that portion of the envelope that will be in contact with a stored exposure part must also be extracted to obtain any residues that may have been transferred from the pad. A 5×10 inch (12.6×25.2 cm) rectangle cut from the large sheet of filter paper is folded once across the long dimension so that approximately 0.75 inch (2.2 cm) of the lower portion projects above the upper portion. This projection provides a convenient space to record the sample number of the exposed pad contained in the envelope. The filter paper envelopes are contained in individual unwaxed sandwich bags approximately 6.5×8×1 inch (16.5×20.3×2.5 cm). The sandwich bags keep the exposed pads within the protective envelopes and help protect against contamination.

(2) **Preparation of hand rinses.** (i) Hand rinses are prepared by placing solvent in freezer bags or other plastic bags strong enough to withstand vigorous shaking. A satisfactory bag is designed to contain 0.5 gal (1.9 L) of frozen food. Bags less that 1 mil (0.025 mm) inch thickness will puncture too easily to be useful. Use the heaviest available material that is still pliable enough to be wrapped in a tight seal around the wrist.

(ii) During preliminary studies, plastic bags must be shaken with the solvent to be used for field studies to ensure that material which may interfere with analysis is not present. This procedure must be followed regardless of the type of bag used.

(iii) Ethanol (95 percent) has been found to be satisfactory for the removal of most pesticide residues without undue damage to the skin. If the material under study is unstable or insoluble in ethanol, it may be necessary to remove residues using a detergent solution rinse followed by partition of the residue into a suitable solvent for analysis.

(iv) Alcohol hand rinses are prepared by placing 200 mL of 95 percent ethanol in a freezer bag, performing the hand rinse, placing the bag in a wide-mouth 1–pt Mason jar, twisting (or zipping) the top of the bag shut to contain the solvent, and sealing the jar with a lid and a ring. A sheet of aluminum foil inside the lid will help to prevent contamination of the sample. Record the sample number of the hand rinse on a piece of masking tape on the outside of the lid. The sample bottles and caps should be labeled to avoid mix-ups. Stainless steel or other appropriate containers may be substituted for Mason jars.

(3) **Laboratory studies necessary before field studies are initiated.** The total recovery from field-fortified samples must be at least 50 percent. Field-fortified samples should reflect the total sample monitoring and analysis process. Applicable good laboratory practices must be followed at all times. Refer to 40 CFR 160.

(i) **Analytical procedure.** The specific analytical procedure to be used will depend on the material being studied. The procedure chosen must be capable of quantitative detection of residues on exposure pads at a level of 1 μg/cm^2 (less if the dermal toxicity of the material under study warrants a greater sensitivity).

(ii) **Stability of the compound of interest on damp stored pads.** (A) Two options will be offered under paragraph (b)(4)(ii) of this guideline on treatment of exposed pads used with sprays prior to extraction. If the investigator elects to store exposed pads pending extraction, a study must be documented for the stability of the material on moist exposure pads.

(B) Exposure pads are to be fortified with a pesticide product diluted to use concentration, at approximately the levels that are expected to impinge on pads during field studies. The same formulated pesticide product which will be used in the field study must be used as spray material for pad fortification. The pads and their protective envelopes are to be extracted and analyzed by the methods that will be employed for field studies. The time periods for storage of fortified pads should be chosen so that the longest corresponds to the longest projected storage period for field samples. Construction of a decay curve will allow extrapolation of residue levels found in field samples. Results from this study can also be used to determine the length of storage which will be acceptable for the pesticide formulation to be monitored in the field study.

(iii) **Efficiency of extraction.** (A) The method chosen by the investigator to extract residues from exposure media must be studied efficiency of extraction and this study must also be documented. The appropriate type of exposure media must be fortified with simulated spray solution prepared using the same formulation that will be studied in the field and at approximately the same levels as are expected for field samples. The mean plus or minus the standard deviation for recovery must be determined. If the lower limit of the 95 percent confidence interval is less that 70 percent, the extraction procedure is unsatisfactory unless approved by the Agency prior to commencing the study. *At a minimum, seven determinations should be made to calculate the mean and standard deviation for recovery for each fortification level tested.* Studies should always be designed so that extraction efficiencies are the highest possible.

(B) If hand rinses are to be carried out using a particular solvent with subsequent partition into a second solvent for analysis, a study similar to that described under paragraph (b)(3)(iii) of this guideline are to be carried out to determine the efficiency of extraction. The same criteria for acceptability also applies to hand rinse extractions.

(iv) **Estimation of expected stability during the monitoring study.** (A) If the stability of the material of interest is unknown, or if the material is volatile or subject to degradation, investigators must undertake and doc-

ument a study to ascertain loss while pads are worn to determine the length of the monitoring period and to allow for correction for residues lost from collection devices during the monitoring period. Because no standard procedure has been developed for this type of study, it is left to the investigators to develop their own.

(B) It is recommended that collection devices be fortified with simulated spray solution or dust, depending on the material being studied, at approximately the same levels expected to occur during field studies. These dosimeters should be exposed to weather condition similar to those expected during field studies and for the same period of time as will be employed in the field.

(4) **Field operations—**(i) **Attachment of exposure pads.** (A) According to the exposure situation, pads are to be attached to collect residues representative of those impinging on all regions of the body. Normally, a complete set of pads for each exposure period will consist of 10 to 12 pads (see paragraph (b)(3) of this guideline).

(B) The pads are attached to the outside of a worker's clothing or skin at the following locations: Top of the shoulders, in back of the neck just below the lower edge of the collar, on the upper chest near the jugular notch, in back of the forearms, and in front of the thighs and lower legs. If workers are engaged in some activity that is likely to result in extraordinary exposure to regions of the body that are not well represented by the usual pad locations, extra pads must be included to assess such exposure.

(C) If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Since workers often wear upper and lower outer garments made from different types of cloth, pads should also be attached under both garments, particularly in regions expected to receive maximum exposure. Care must be taken to ensure that any pads under clothing are near, but not covered by, pads on the outside of the clothing.

(D) If the proposed label specifies that the pesticide can only be used by workers using protective garments, place the pads where it is possible to assess exposure to unprotected regions. For example, if the workers are wearing full protective suits, pads would be needed on the outside of the garments at the back, chest, and shoulders, to assess facial, head, and neck exposure. Additional pads will be necessary under the protective suit at all previously specified locations to assess penetration. Inside pads must be centered under seams as well as under unseamed material, since seams are often areas of maximum penetration. Registrants are encouraged to discuss exposure studies involving protective clothing with Agency personnel when developing a protocol and before submittal for approval.

(E) Pads may be attached to the skin or clothing by using strips of masking tape along two edges of a pad. Some investigators have utilized specially designed harnesses or lightweight vests fitted with open-fronted pockets to hold the shoulder, chest, and back pads. Others have simply attached the pads on clothing with safety pins. These alternative attachment methods and others have been used successfully and are acceptable.

(ii) **Removal and handling of exposed pads.** The procedure for handling exposed pads will depend on the stability of the material being studied. If the laboratory study described under paragraph (b)(3)(ii) of this guideline indicates that the material is stable on moist exposure pads, the method under paragraph (b)(4)(ii)(A) of this guideline may be used. This method is advantageous since it requires less time-consuming manipulation of the exposed pads in the field. If the material is found to be unstable, or if the investigator elects not to perform the stability testing with moist pads, the method under paragraph (b)(4)(ii)(B) of this guideline are to be employed. The latter method may also be employed by choice.

(A) **Stable residues.** Remove the tape used to attach the pad to the test subject and also remove the protective backing from the pad. Slide the prelabeled protective envelope just far enough out of the sandwich bag to insert the pad, and carefully move the envelope back into the plastic bag. Staple all bags containing exposed pads from one exposure of a single test subject together without puncturing the area of the bag containing the samples and store in a chest containing ice or an appropriate frozen plastic-encapsulated gel. Refrigerate the bags until reaching the laboratory.

(B) **Unstable residues.** Remove the tape used to attach the pad to the test subject. Place a template of convenient size (25 cm^2 has been employed with success) in the center of the pad and trim away the excess material around the template. Discard the protective backing and place the sample obtained from the center of the pad in a wide-mouth jar or other appropriate container filled with a convenient volume of a suitable solvent. Store this sample in the same manner as the pads with stable residues.

(iii) **Hand rinses.** A double hand rinse must be performed on each hand. These rinses must be done even on workers who wore protective gloves. A plastic bag containing an appropriate solvent is removed from its Mason jar (or other container) and is tightly applied just below the wrist bone. The hand is shaken vigorously in the solvent, and allowed to drain into the bag for a few seconds, after which the bag is returned to its container. This procedure is repeated on the same hand with a fresh bag of solvent before performing the process on the other hand. These rinses should also be stored under the conditions used for exposed pads until reaching the laboratory.

(iv) **Field-fortified samples and blanks.** (A) Inclusion of field-fortified samples in a study is vital because it will allow data to be corrected

for any residue losses that may occur during the exposure period, during storage in the field, and during transportation to the laboratory. The need for a study of the stability of residues on damp stored pads is eliminated if field-fortified samples are extracted on the same day as are the samples which have been collected.

(B) Because a standard procedure to assess losses from field-fortified samples has not been developed, it is left to the investigator to propose such a procedure. However, the Agency recommends the following as a guide:

(*1*) Pads should be fortified at approximately the levels expected for actual exposure samples. The fortified pads should be exposed to the weather concurrently with the pads being worn by the workers. A member of the monitoring team who is careful to position him or herself where inadvertent exposure cannot occur may wear the fortified pads, or they may be placed in a fixed location that is upwind and a sufficient distance from the application site to avoid contamination. However, investigators are cautioned that upwind locations can quickly become downwind locations, and such occurrences will ruin a set of fortified samples.

(*2*) There should be at least one field-fortified sample per worker per monitoring period for each fortification level. These samples should be stored and analyzed along with the exposure samples. Field blanks of exposure collection media such as pads are also required in order to account for any possible contamination which may occur while collecting, transporting, or handling field samples prior to extraction in the laboratory. Field blanks should be handled in the same manner as exposed pads.

(v) **Field data collection.** The type of field data that must be reported will vary with the operation being studied. A set of data must be compiled for each set of exposure pads and hand rinses. These data must be indexed so that they can easily be related to any particular exposure value. Two examples of the type of data needed in a particular exposure situation are presented as a general guide.

(A) **Agricultural applications, yards, and gardens** (*1*) Pesticide identification—chemical name, formulation, EPA registration number, lot number, and type of concentrate container.

(*2*) Investigator’s name.

(*3*) Description of the area—crop, plot size, and row spacing.

(*4*) Application data—rate, tank capacity, type of carrier, final mix concentration, total pounds applied or mixed.

(*5*) Equipment data—type, model.

(*6*) Weather data—relative humidity, wind speed, wind direction, and temperature.

(*7*) Work activity monitored.

(*8*) Location of exposure pads on the subject and sample numbers corresponding to these pads.

(*9*) Exposure observations—direction of travel of applicator in relation to wind direction, and any special situation observed that might alter normal exposure, such as splashing concentrate directly on a particular pad while filling tank.

(*10*) Exposure time—presented in such a way that total exposure can be calculated per amount of pesticide (or other chemical) handled for the time interval of each work activity.

(B) **Structural pest control, greenhouse, indoor residential applications** (*1*) Pesticide identification—chemical name, formulation, EPA registration number, lot number, and type of concentrate container.

(*2*) Investigator's name.

(*3*) Description of area—linear feet of baseboard treated, size of rooms.

(*4*) Indoor environmental conditions—ventilation, air exchange rate, if known.

(*5*) Application data—rate, tank capacity, type of carrier, final mix concentration, total pounds applied or mixed.

(*6*) Equipment data—type, model.

(*7*) Weather data—relative humidity and temperature.

(*8*) Work activity monitored.

(*9*) Location of pads on the subject and sample numbers corresponding to these pads.

(*10*) Exposure observations—special situations observed that might alter normal exposure, such as adjusting nozzle or rinsing hands after filling tank.

(*11*) Exposure time—presented in such a way that total exposure can be calculated per amount of pesticide (or other chemical) handled for the time interval of each work activity.

(5) **Laboratory operations subsequent to exposure.** As soon as the investigator returns to the laboratory from the field, all samples held in ice chests must be stored in a freezer pending further treatment. A sample

history sheet is to be prepared to document laboratory operations. A convenient sheet of this type contains columns labeled: Sample number, date sample was collected, date of extraction, date of analysis, and the names of the responsible individuals for each laboratory procedure. The lower portion of the sheet contains spaces for recording the conditions of storage for pads and extracts, the extraction procedure employed, and the analytical procedure used. A suggested form for a sample history sheet is provided.

(i) **Extraction of residues from exposed pads.** (A) If exposed pads are returned to the laboratory intact, portions of the pads along with their protective envelopes are cut out as described under paragraph (b)(4)(ii) of this guideline. These samples are extracted according to the procedure that was determined as appropriate by earlier laboratory studies under paragraph (b)(3)(iii) of this guideline. If portions of the pad were cut out and placed in solvent in the field, no further manipulation is necessary before extraction. The data and method of extraction are to be entered on the sample history sheet and the extracts either analyzed immediately or stored under appropriate conditions (under paragraph (b)(3)(iv) of this guideline) for later analysis. If stored, the method of storage must be specified on the sample history sheet.

(B) To reduce laboratory work, pads from opposite sides of the body can be combined prior to extraction. However, if residue values from particular pads are needed for calculations, these pads must be extracted separately. Examples of pads that may not be combined are those from the chest and back and exterior pads adjacent to pads under clothing, which will be used to estimate penetration.

(ii) **Hand rinses.** After returning to the laboratory, both right hand rinses are combined into one sample. The same is true for both left hand rinses. Entries are necessary on the sample history sheet for date and method of extraction. If the samples are to be stored, then the method of storage must be noted.

(iii) **Analysis of samples.** All samples must be analyzed by the methods meeting the criteria specified under paragraph (b)(3)(i) of this guideline. The date and method of analysis are to be entered on the sample history sheet. Fortified substrates should be analyzed along with exposure samples to determine whether total recovery criteria have been met.

DATA REPORT FORM

Exposure Sample History

Sample Series ____________

Sample number	Date Collected	By	Date Extracted	By	Date Analyzed	By
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Preextraction storage:

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Extraction procedures:

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Analysis:

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(6) **Presentation of results—**(i) **Standard body surface areas.** (Refer to paragraph (b)(6)(i) of this guideline.) Calculation of total dermal exposure will be performed by the Agency and are therefore not required of the registrant. For the calculation of adult dermal exposures, the body surface areas given in the following Table 1. will be employed by the Agency:

Table 1. Body Surface Areas for Calculation of Adult Dermal Exposures

Region of the Body	Surface Area of Region (cm^2)
Head (includes face)	1,300
Face	650
Back of Neck	110
Front of Neck	150
Chest/Stomach	3,550
Back	3,550
Upper Arms	2,910
Forearms	1,210
Hands	820
Thighs	3,820
Lower Legs	2,380
Feet	1,310

(ii) **Information for dermal exposure calculations.**—(A) The dermal exposure for any particular body area will be the product of the body surface area given above and the appropriate residue level expressed as micrograms of residue per square centimeter of exposure pad ($\mu g/cm^2$/pad). Information must be reported so that exposure can be calculated as a function of time engaged in the work activity and as a function of the amount of chemical handled in the work activity. In some cases, more than one pad is representative of the area exposed. For these cases, the mean of residues found on the appropriate pads will be used. If any pad is found to contain a level of residue that is below the limit of quantification of the procedures employed, the level of residue on the pad will be considered to be half of this limit. The body areas of interest are related to the appropriate exposure pads in the following Table 2. Refer to paragraph (b)(5)(i)(B) for examples of which pads should not be combined for analysis.

Table 2. Locations of Dermal Exposure Pads That Represent Different Regions of the Body

Body area of concern	Exposure pads representative of the body area
Totally unprotected head[1]	Shoulder, chest, and back[2]
Face	Chest
Neck	Chest and back
Upper arms	Shoulder and forearm/ upper arm
Forearms	Forearm
Hands	Total of residues in the hand rinses or monitoring glovesis used without regard for surface area
Chest	Chest
Back	Back
Thighs	Thigh
Calves	Shins
Feet	If necessary, total of residues in socks can be used without regard for surface area.

[1] Includes face.
[2] Exposure to the head may be estimated by using the mean of the shoulder, back, and chest patches, or by using a head patch.

(B) Final results must be reported in the text of the report submitted to the Agency as the mean of the exposure per square centimeter of the collection pad for each region of the body. These results must be corrected for total recovery. The number of separate exposures giving rise to each mean and the rate of the exposure must be specified. The exposure per square centimeter of the collection pad for each region of the body for each separate exposure must also be submitted to the Agency.

(C) Final results must include pertinent field data such as type of application equipment, formulation, tank mix, application rate, pounds of active ingredient handled, crop, and range of weather conditions. All assumptions used in calculations must be included. Refer to OPPTS 875.1600 for complete instructions for data reporting requirements.

(7) **Alternate methodology for the measurement of hand exposure.** (i) If the investigator finds that the previously described rinsing procedure is not appropriate in a particular situation for monitoring exposure to the hands, the use of absorbent gloves is acceptable. The use of gloves will require that the studies described under paragraph (b)(3) of this guideline to determine stability and extractability of residues performed prior to the field study.

(ii) Lightweight absorbent gloves provide several advantages over rinsing for the assessment of hand exposure. They can be changed very quickly, trap toxicants that normally would be absorbed during the exposure period, and can be used to collect residues that are insoluble in, or are degraded by, water or ethanol. The use of gloves may also have certain disadvantages. Gloves may absorb more material than would be retained by the skin, thus overestimating hand exposure. Gloves often contain foreign materials that may interfere with low level analysis. This can be reduced by preextraction of gloves with an appropriate solvent.

(iii) Two types of lightweight absorbent gloves have proven useful for monitoring had exposure. One is a white cotton ‘‘pallbearer’s’’ glove and the other is a white nylon glove that is often used by handlers for fruit packing.

(iv) Exposed gloves should be processed in the same manner as exposed dermal pads. In the field, each pair of exposed gloves may either be placed directly into a container of solvent, or into a protective envelope inside an unwaxed sandwich bag. Upon returning to the laboratory, both gloves in solvent or both gloves plus their protective envelope are extracted by an appropriate method.

(c) **Indoor sites.** For the purpose of these guidelines, indoor sites include, but not be limited to: Homes and apartments,greenhouses, barns and other farm buildings, commercial buildings and manufacturing facilities, restaurants and food handling and processing facilities, fumigation facilities, warehouses, railroad boxcars, schools, hospitals and other health care facilities, and mushroom houses.

(d) **Postapplication measurements.** Postapplication measurements will be required only on a case-by-case basis depending on the type of pesticide product and its use.

(e) **Number of replicates—dermal exposure.** For exposure during application, a minimum of five replicates each at a minimum of three representative indoor sites are to be employed. It is recommended that as many individuals as practicable be monitored.