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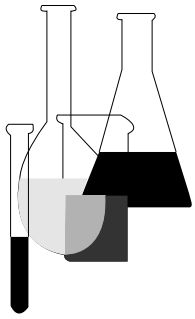
Occupational and Residential Exposure Test Guidelines

OPPTS 875.1300 Inhalation Exposure—Outdoor



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 875.1300 Inhalation exposure—outdoor.

(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 232. This guideline should be used with OPPTS 875.1000.

(b) **Estimation of respiratory exposure by passive dosimetry.** Because of the wide differences in chemical and physical properties of the many pesticides that will be investigated, this guideline will necessarily be more general than the guideline on dermal exposure (OPPTS 875.1100). The specific sampling method, appropriate sampling medium, conditions for storage of samples, and appropriate analytical procedure will largely be dependent on the material being studied. Personal air monitoring will be required and procedures using battery-operated pumps or modified respirators developed by Durham and Wolfe (see paragraph (e)(2) of this guideline) will be described.

(1) **Laboratory studies necessary before field studies are initiated**—(i) **Analytical procedure.** The choice of analytical procedures will depend on the material being studied and is, therefore, left to the discretion of the investigator. The method must be sufficiently sensitive so that, coupled with the trapping and extraction procedures chosen, it is capable of measuring exposure to 1 μg/h (or less, if the toxicity of the material under study warrants greater sensitivity).

(ii) **Choice of personal monitors**—(A) **Trapping efficiency testing.** (*1*) A trapping efficiency test must be documented for the medium chosen. The procedure described by Melcher et al. under paragraph (e)(6) of this guideline is preferred since it can be performed at approximately the relative humidity expected during field studies. The investigator can adapt this procedure, which was designed for solid sorbents, to all types of sampling media by appropriate modification. Gauze pads can be tested by eliminating the solid sorbent and placing a pad holder between the glass tube containing the front glass wool plug (described under paragraph (e)(6) of this guideline) and a pump. A filter support assembly such as that available from Ace Glass, Inc. (catalog no. 7519) may be used to support the pad in the air stream. The gauze pad may have to be trimmed to fit the support, but should be large enough so that all flow is through the pad and no leakage occurs around the periphery. The apparatus used by Melcher will have to be further modified to accommodate the large airflow of this procedure.

(*2*) If a liquid medium is to be tested, the glass tube containing the front glass wool plug is connected directly to the impinger. In all cases, the residue remaining in the front glass wool plug and that trapped in

the medium must be determined to find the trapping and extraction efficiency:

$$\text{percent efficiency} = \frac{\text{(quantity recovered from medium)}}{\text{(quantity added to plug)} - \text{(quantity left in plug)}} \times 100$$

(*3*) Efficiency testing for gauze pads should be conducted using an airflow near the mean minute ventilation of a man doing light work (29 L/min). If a medium to be used with a personal sampling pump is being tested, the airflow must be equal to the maximum that will be used in the field. Tests are to be be conducted with the relative humidity of the airflow through the collection medium held at a level based on a reasonable estimate of what the relative humidity might be during the field study. Each test should be run for a period of time at least as long as the longest exposure time anticipated during field studies. Seven or more separate determinations constitute a test.

(*4*) While it would be desirable to know the trapping efficiency of media using aerosols or particulates, no completely satisfactory procedure is currently available for this type of testing. Registrants are strongly urged to develop an appropriate procedure. Unless aerosols or particulates can be introduced to test the collecting medium when pesticides having very low vapor pressures are used, the investigator will have to determine the retention efficiency of fortified media rather than the trapping efficiency.

(*5*) To ensure that collected material is not lost from the medium during sampling, the investigator should also test for breakthrough. This can be done by analyzing for any residue that is collected by a trap placed downstream to the medium being tested. This is exemplified by the ''back section'' of packing in the sampling train described by Melcher et al. under paragraph (e)(6) of this guideline. Tests must be performed at high enough residue levels to determine the percentage of breakthrough that will occur if high air concentrations of pesticide are encountered in the field. It is recommended that at least one test be carried out where the initial trap contains 10× the highest amount of residue expected in the field.

(B) **Criteria of acceptability.** (*1*) The extraction efficiency of laboratory fortified controls will be considered acceptable if the lower limit of the 95 percentile interval is greater than 75 percent, unless otherwise specified by the Agency. *At a minimum, seven determinations should be made at each fortification to calculate the mean and standard deviation for recovery.* Total recovery from field-fortified samples must be above 50 percent for the study.

(iii) **Exposed media and extract storage—**(A) **Storage of exposed media.** If trapping media are to be stored after exposure, a test for the

stability of the compound of interest must be documented. Media are to be charged with a pesticide by the same procedure as was specified under paragraph (b)(1)(ii)(A) of this guideline for efficiency testing. Fortified media must be stored under the same conditions that will be used for field samples. The storage stability samples are to be extracted and analyzed by the same methods that will be employed for field samples. Replicate samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage are to be be chosen so that the longest corresponds to the longest projected storage period for field samples. A decay curve can then be constructed to determine the appropriate length of storage to meet total recovery criteria.

(B) **Storage of extracts.** If extracts from field samples are to be stored prior to analysis, a documented study of stability is to be be made. Portions of appropriate solvent are to be fortified with levels of authentic concentrate of the same formulation that was used in the field studies and at approximately the same concentration that is expected in extracts from field studies. The fortified samples are to be stored under the conditions to be used for storing extracts from field samples. Each sample should be analyzed immediately before and at appropriate times during storage. The periods of storage are to be chosen so that the longest corresponds to the longest projected storage period for extracts from field samples. A decay curve can then be constructed to determine the length of time to store extract analysis to meet recovery criteria.

(2) **Personal monitoring using battery-powered pumps—**(i) **Pumps.** Several brands of battery-powered personal monitoring pumps are satisfactory for use in estimating an applicator's respiratory exposure to pesticides. However, a pump which is capable of producing an airflow of at least 2 L/min should be used and its batteries should be capable of sustaining maximum airflow for at leat 4 h without recharging.

(ii) **Media containers.** Many devices are available for containing the different types of media that may be used for entrapping pesticides during personal air monitoring. These range from elegant spill-proof microimpingers equipped with membrane filters for separate collection of large particulates to simple tubes used to contain solid sorbents. Most of these devices and their uses have been described by Linch under paragraph (e)(5) of this guideline. Polyurethane foam plugs have become popular for monitoring pesticide exposure and several types of devices to hold these plugs have been described under paragraph (e)(1) and (4) of this guideline.

(iii) **Sampling media.** A host of different media are also available for trapping pesticides in air. The most suitable medium for a particular investigation will depend on the chemicals being studied. The medium should entrap a high percentage of the chemical passing through it, and should allow the elution of a high percentage of the entrapped chemical

for analysis. The chemical should be recovered without any conversion to other reaction products, and the medium should not produce a significant restriction of airflow. Various media that have proved effective for trapping pesticides have been reviewed by Van Dyck and Visweswariah under paragraph (e)(8) of this guideline, and by Lewis under paragraph (e)(3) of this guideline.

(3) **Personal monitoring using modified respirators**—(i) **Supplies**—(A) **Respirators.** A tight-fitting dust respirator with a removable filter is used. The Willson Dustite (Model CP–2D), produced by Willson Safety Products Division of WGM Safety Corp., Reading, PA 19603, has been used with good results. However, this model is no longer in production. If a similar respirator is not available, a cartridge-type respirator, such as the Willson Paint Spray and Pesticide Respirator (Model C–122115), may be used.

(B) **Funnels.** Any polyethylene funnel large enough in diameter to cover the dust pad retaining ring of the respirator is satisfactory.

(C) **Respirator filters.** Commercially available dust filters often contain materials that will interfere with chemical analyses, so they should be discarded. Discs the same diameter as the discarded dust filters are cut from a coarse filter paper, such as Whatman No. 4, to serve as backing for the construction of the monitoring pads.

(D) **Gauze.** Any 4–inch (10.2 cm) square gauze surgical sponges that do not contain material that will interfere with analysis are satisfactory. Interfering materials must be preextracted.

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

(ii) **Construction details—**(A) **Respiratory exposure pads.** A disc of filter paper backing is overlaid with 32 plies of gauze, and this combina-

tion is stapled around the periphery of the filter. Excess gauze is trimmed away to conform to the original filter circumference.

(B) **Respirator modification.** The ordinary dust filter is replaced by the gauze fronted filter described under paragraph (b)(3)(iii)(A) of this guideline, and the respirator is fitted with an inverted funnel to eliminate direct drift onto the gauze filter. The spout of a plastic funnel is cut off above the intersection of the spout with the beginning of the conical portion so that a 17 mm hole is produced (if using a single-unit respirator) or a 12 mm hole (if using a double-unit respirator). Durham and Wolfe, under paragraph (e)(2) of this guideline, plugged the hole and drilled simulated nares in the bottom side of the cone. Their original design presented some problem in attaching the funnel because the holes must point downward. Satisfactory results are obtained using a single hole in the end of the funnel.

(4) **Field operations—**(i) **Use of personal monitors.** The intake tube of any pump-powered sampler unit should be positioned so that the opening is downward, to avoid collection of large droplets, which are not normally drawn into the nostrils, via direct drift. The intake tube should be placed as near as possible to the nose level of the test subject. The height of the intake tube is especially important when taking samples indoors where walls or ceilings are being sprayed. For the study subject's comfort and safety, it is necessary to ensure that the pumps, hoses, and samplers are secured to minimize movement and the potential for snagging.

(ii) **Field calibration of personal monitors.** When personal sampler pumps are used, it is necessary to check the flow at the beginning and the end of the exposure period. A convenient flow meter for this operation is battery-operated and will measure flow without disturbance (Model 541 or 543 portable flow calibrators, fitting this criterion, are available from Kurt Instruments, Inc., Carmel Valley, CA 93940). If the flow has been found to change, the mean flow should be used for all calculations.

(iii) **Use of respirators.** The gauze side of the pad must face out, and the mask should be snug. It is advisable to observe workers periodically. Workers may remove the mask to wipe off sweat and inadvertently contaminate the exposure pad by wiping the inside of the mask with a contaminated rag. They may pull the mask down around the neck if it becomes uncomfortable, thus allowing direct drift onto the inside of the exposure pad. Since respiratory exposure is normally quite low, even slight contamination will lead to the introduction of large errors.

(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*) Field-fortified samples will be needed to ascertain total recovery of residues under conditions of the studies. These samples should be fortified at the expected residue levels of actual field samples prior to the start of the monitoring period. Field-fortified samples should be subjected to the same conditions as actual field samples. 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 collected on the same day. 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) **Handling exposed monitoring media.** Respirator pads are to be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. They are to be stored in a chest containing ice or an appropriate plastic-encapsulated frozen gel coolant until they are returned to the laboratory, where they should be stored in a freezer prior to extraction. It is usually convenient to detach the media container from personal monitors and to store the intact container inside a Mason jar in the ice chest until it is returned to the laboratory, whereupon the unit can be disassembled to recover the exposed media.

(vi) **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. 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.

(vii) If personal monitoring pumps are being used, the airflow must also be recorded at the beginning and end of the exposure period. A sample form which can be adapted for use in recording these data in the field is provided.

(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 should 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, names of those responsible for the task. The lower portion of the sheet should contain spaces for recording the condition of storage for pads, other media, extracts, andthe extraction and analytical procedures used. A suggested form for a sample history sheet is included.

(i) **Extraction of residues from exposed media.** Samples are to be extracted according to the procedure that was determined as appropriate by earlier laboratory studies under paragraph (b)(1)(ii)(B) of this guideline. The date and method of extraction are to be entered on the sample history sheet and the extracts whether analyzed immediately or stored under appropriate conditions (under paragraph (b)(1)(iii) of this guideline) for later analysis. If stored, the method of storage must be specified on the sample history sheet.

(ii) **Analysis of samples.** All samples must be analyzed by methods meeting the criteria specified under paragraph (b)(1)(i) of this guideline. The date and method of analysis are to be noted on the sample history sheet.

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 breathing rates.** For the sake of standardization in order that results collected by different investigators will be comparable, the Agency will use the values in the following Table 1. for minute ventilation (refer to paragraph (e)(7) of this guideline):

Table 1. Standard Breathing Rates

Level of exertion	Ventilation (L/min)	
	Male	Female
Rest	7.4	4.5
Light work	29	16
Heavy work	60	24

(ii) **Information for inhalation exposure calculations.** (A) The final results for respiratory exposure are to be reported in the text of the report submitted to the Agency as the mean residue per liter of air drawn through the sampling media (if sampling pumps are used). These results must be corrected for losses due to trapping, extraction, and storage. The number of separate exposures giving rise to the mean and the range of the exposures must also be specified. If any exposures are below the quantitative limit of the method used for analysis, the number of such exposures must also be specified. For the purposes of calculating mean residue per liter of air sampled, any samples that contained residues below the limit of quantification should be considered to have contained half this limit. Also, samples should not be considered as valid if the final airflow through the sampling medium was found to be less than 25 percent of the initial airflow. The total time worked and the total quantity of active ingredient handled during the sampling period must be reported. The residue and the total quantity of air drawn through each individual sample are to also be included in the report.

(B) The final results must also include pertinent field data such as type of application, equipment, formulation, tank mix, application rate, crop, and range of weather conditions. Information pertaining to nozzle type and droplet size produced must also be provided. All assumptions used in calculations must be specified. Refer to OPPTS 875.1600 for complete instructions for reporting.

(c) **Number of replicates—respiratory exposure.** For the purposes of these guidelines, a replicate is defined as measuring potential inhalation exposure using a personal monitoring device for an individual over the course of one work cycle or portion thereof.

(1) **Aircraft pilots.** A minimum of three replicates each at a minimum of three sites must be employed. It is recommended that as many different individuals as practicable be monitored.

(2) **Other workers.** A minimum of five replicates each at a minimum of three sites must be employed. It is recommended that as many different individuals as practicable be monitored.

(d) **Combined testing.** When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.

(e) **References.** The following references should be consulted for additional background material on this test guideline.

(1) Davis, J.E. et al., Potential exposure of apple thinners to phosalone. *Bulletin of Environmental Contamination Toxicology* 29:592–598 (1982).

(2) Durham, W.F. and H.R. Wolfe, Measurement of the exposure of workers to pesticides. *Bulletin of the World Health Organization* 26:75–91 (1962).

(3) Lewis, R.G., Sampling and analysis of airborne pesticides. Pp. 51–94 in Air Pollution from Pesticides and Agricultural Processes. R.E. Lee, Jr., ed. CRC Press, Cleveland, OH (1976).

(4) Lewis, R.G. et al., Protocol for Assessment of Human Exposure to Airborne Pesticides. Health Effects Research Laboratory, Office of Research and Development, US EPA. NTIS EPA-600/2–80–180, 46 pp. (1980).

(5) Linch, A.L., Evaluation of Ambient Air Quality by Personnel Monitoring. CRC Press, Cleveland, OH (1974).

(6) Melcher, R.G. et al., Collection of chlorpyrifos and other pesticides in air on chemically bonded sorbents. *Analytical Chemistry* 50:251–255 (1978).

(7) Spector, W.S., Handbook of Biological Data. W.B. Saunders Co., Philadelphia, PA (1956).

(8) Van Dyk, L.P. and K. Visweswariah, Pesticides in air: sampling methods. *Residue Reviews* 55:91–134 (1975).