

Pesticide Registration (PR) Notice 97-9: Electronic Submission Of Child-Resistant Packaging Test Data For All Pesticides And Child-Resistant Testing Of Prefilled, Nonrefillable Insecticide Bait Stations Not Designed Or Intended To Be Opened Or Activated In A Manner That Exposes The Contents To Human Contact Purpose

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

November 18, 1997

Fax-On-Demand

Telephone: (202) 401-0527

Item: 6105

NOTE: See EPA's instructions for [submitting data electronically](#) on CD-R. (1/11/06)

Notice To: Manufacturers, Producers, Formulators, and Registrants of Pesticide Products

Attention: Persons Responsible For Registration of Pesticides, Manufacturers of Child-Resistant Packaging, and Persons Responsible for the Testing of Child-Resistant Packaging

Subject: Electronic Submission Of Child-Resistant Packaging Test Data For All Pesticides And Child-Resistant Testing Of Prefilled, Nonrefillable Insecticide Bait Stations Not Designed Or Intended To Be Opened Or Activated In A Manner That Exposes The Contents To Human Contact Purpose

This notice will address four separate issues: (1) electronic submission of child-resistant packaging (CRP) test data for all pesticides; (2) unit packaging - individual unit (actual bait station) must be CRP; (3) test procedures clarification on when and how to test prefilled nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact; and (4) exemption from the senior and younger adult test for prefilled nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that

exposes the contents to human contact. Ready-to-use rodenticide bait stations are not a part of this PR Notice. The Rodenticide RED (Registration Eligibility Document) will discuss ready-to-use rodenticide bait stations.

(1) ELECTRONIC SUBMISSION

When the Agency exercises its authority under 40 CFR 157.36 (Recordkeeping) to review child-resistant packaging (CRP) protocol test data for a pesticide it should be available upon request for inspection and copying or submission to the Agency. With this PR-Notice the Agency is specifically requesting that this information, whenever requested, also be made available or submitted in an electronic format. The electronic availability of CRP protocol test data from pesticide registrants is part of an Agency effort to expedite CRP protocol test data review by having the data in a format compatible with computer assisted data analysis. This notice describes the electronic format requirements essential for the computer program to recognize the data for computer analysis.

(2) UNIT PACKAGING

Under 40 CFR 157.27, (Unit Packaging) either the outer retail package or the individual unit package of a pesticide product distributed or sold as an aggregate of one or more unit packages must qualify as CRP, if the pesticide product meets the criteria of 40 CFR 157.22. Prefilled, nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact are placed for prolonged periods of time (e.g. more than 24 hours) in locations that may be accessible to children. Consequently, the individual units themselves (actual bait stations) rather than the outer packaging must comply with the standards in 40 CFR 157.32 to reduce the risk of accidental injury or illness to children. Products for which the outer retail package, but not the individual bait stations meet the standards in 40 CFR 157.32 will be deemed noncompliant.

(3) TEST PROCEDURES CLARIFICATION

This notice also clarifies how the child-resistant packaging protocol test applies to prefilled, nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. This notice will discuss the condition of the package to be tested, how to test the package, the number of units and how they are given to the child at the beginning of the test, whether or not a demonstration of how to open or activate the package is necessary, the definition of a test failure, the

type of information needed, and when a package should be tested.

(4) EXEMPTION

On June 13, 1997 a five year exemption was granted from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) (Ease of adult opening), for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. No action is required to qualify for this exemption. However, the CRP certification for products relying on this exemption must specify that the package is exempt from compliance with the senior and younger adult effectiveness specifications per this exemption. Products qualifying for this exemption must still fully comply with all other CRP effectiveness, compatibility, and durability standards, as well as all other requirements of 40 CFR Part 157. A copy of the Federal Register Notice (*1) on this exemption is attached (attachment 2).

(*1) (62 FR 32223, June 13, 1997), available on the internet at:
<http://www.epa.gov/fedrgstr/EPA-PEST/1997/Day-13/p15565.htm>

EFFECTIVE DATE

This PR Notice becomes effective upon the date of signature by the Agency. These policies (as described in this document) apply to all pesticide products subject to the CRP regulations. The actions discussed in this PR Notice are supplemental to the CRP requirements of PR 96-2 (regarding the senior friendly CRP and recertification to CRP by January 21, 1998).

BACKGROUND

FIFRA 25(c) (3) requires EPA's CRP standards to be consistent with those of the Consumer Product Safety Commission (CPSC). The CPSC is authorized by the Poison Prevention Packaging Act of 1970 (PPPA) to issue requirements that certain household chemical products, prescription drugs, and over the counter pharmaceutical products be sold in CRP.

The CRP protocol test, 16 CFR 1700.20, was designed to measure the child resistance and adult effectiveness of reclosable and nonreclosable (unit-dose) packages. The nonreclosable (unit-dose) packages considered when the CRP protocol test was designed were single packages whose entire contents were intended to be used at the time of initial opening, and packages consisting of one or more individually packaged units intended to be used sequentially (e.g.

nonreclosable flexible packaging (strip/pouch), rigid, or semi-rigid packaging (blister)).

The CRP regulations for pesticides resulted in the development of several different types of nonreclosable packages that were not considered when the CRP protocol test was designed. An example is ant and roach bait stations, which generally use multiple units at one time. Each unit contains the product, which is placed in use for prolonged periods of time (more than 24 hours) in locations that may be accessible to children (e.g. on the floor).

These pesticide packages must comply with the effectiveness standards and protocol testing procedures specified in 40 CFR 157.32 and the Recordkeeping requirements in 40 CFR 157.36. There may still be a number of questions for these packages such as what effectiveness standards apply, should the unit package or the outer retail package be child-resistant; and exactly how should these types of packages be tested? This PR Notice is intended to answer these questions.

(1) ELECTRONIC DATA SUBMISSION

The CRP Recordkeeping requirements in 40 CFR 157.36 prescribe that registrants retain records supporting their CRP certification. Upon request by the Agency, these records should be available for inspection and copying, or submission. The Agency conducts a computer assisted analysis of the CRP protocol test data. In an effort to streamline CRP data analysis and respond expeditiously to pesticide registrants the Agency requests that CRP data be made available to the Agency as both a hard copy and electronically(*2) to eliminate the time necessary to input the data.

(*2) The electronic availability of CRP data is voluntary. Anyone who would like to comply and is unable to provide all the data described in this PR Notice should contact Rosalind L. Gross to ascertain if some type of electronically formatted submission may be arranged.

Appendix A to this notice contains detailed format instructions that should be used. The CRP protocol test data is requested to be in the following format: a hard copy and an electronic version on a 3.5 inch high density computer disk in an IBM compatible electronic dbf, wk1, or wk3 data base format (e.g. dBASE, lotus, paradox, Quattro pro) using the field format specifications in the attached tables (appendix A). Note the dbf format is the preferred format, if a wk1 or wk3 file can be converted to a dbf file, please do so. All fields in the

format specified in Appendix A for the electronic data submission are essential for the computer program to recognize the data for electronic analysis. Additionally, if the file is wk format, the following conditions are integral to data recognition for computer analysis:

Specify whether the file is a wk1 or wk3

One worksheet per file named "sheet 1"

The variables have a maximum length of 20 characters

Column headings in row 1

A maximum of one row for the titles/column headings

Start the actual data at row 3

Alpha and numeric characters should not be mixed in one field

Row 3 may not be blank

(2) UNIT PACKAGING

Under 40 CFR 157.27, (Unit Packaging) either the outer retail package or the individual unit package of a pesticide product distributed or sold as an aggregate of one or more unit packages must qualify as CRP, if the pesticide product meets the criteria of 40 CFR 157.22. Prefilled, nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact are placed for prolonged periods of time (e.g. more than 24 hours) in locations that may be accessible to children. Consequently, the individual units themselves (actual bait stations) rather than outer packaging must comply with the standards in 40 CFR 157.32 to reduce the risk of accidental injury or illness to children.

Prefilled, nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact that are subject to CRP regulations and are packaged and released for shipment on or after January 21, 1998 must be packaged in individual units (actual bait stations) that comply with the standards in 40 CFR 157.32, which requires CRP when tested by the protocol specified in 16 CFR 1700.20 shall meet the effectiveness specifications in 16 CFR 1700.15(b) as well as the compatibility and durability standards (40 CFR 157.32(b) and (c)). Products for which the outer retail package, but not the individual bait stations meet the standards in 40 CFR 157.32 will be deemed noncompliant.

(3) TEST PROCEDURES CLARIFICATION

The testing procedures outlined below are intended to clarify the

procedural requirements described at 16 CFR 1700.20 as they pertain to prefilled, nonrefillable insecticide bait stations(*3) not designed or intended to be opened or activated in a manner that exposes the contents to human contact.

(*3) For example ant, roach or termite bait stations.

Testing Procedure for Child Test

Prefilled, nonrefillable insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact must satisfy all the requirements described at 16 CFR 1700.20. The following directions are intended to clarify the child testing procedures for prefilled, nonrefillable insecticide bait stations. Please consult 16 CFR 1700.20 in addition to the specific procedures discussed below to ensure that you have met all requirements.

1. Remove the outer packaging so that the individual units (actual bait stations) are immediately available to the child.

2. All the units in a retail package (*4) are to be given to the child at the beginning of the test (*5). If the units are attached to a removable frame or other units in the retail package, they are given to the child as they are found in the retail package.

(*4) When the label of a pesticide product advocates the use of more than one retail package per single treatment of a residence, EPA recommends that, at the beginning of the child test, the children be given the total number of units in the number of retail packages suggested for a single treatment of the residence.

(*5) When the number of bait stations in the retail package (retail package size) varies a registrant may want to consider a testing scheme as an alternative to testing each retail package size. In those instances, the Agency should be contacted to ascertain whether or not this approach will satisfy the requirements of 40 CFR Part 157.

3. If a component such as a stake or plastic frame is included in the retail package this component is given to the child with the unit packages at the beginning of the test.

4. Each child shall be allowed up to 5 minutes to open/gain access to as many of the units as possible.

5. At the end of the first 5 minutes, the tester shall not demonstrate how to open the package because the package is not designed or intended to be opened or activated in a manner that exposes the contents to human contact.

6. A second 5 minutes is allowed for all subjects to open/gain access to as many of the unit packages as they can. If one or both children have not used their teeth to try to open the unit packages during the first 5 minutes, the tester shall instruct the children, before the start of the second 5 minute period, that they are permitted to use their teeth if they so desire. (See 16 CFR 1700.20(a) (2) (iv) (25) for details.)

7. A test failure is defined as any child who gains access to an amount of the pesticide product that may produce serious personal injury or illness, or a child who opens or gains access to the contents of more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The determination of the amount of a substance that may produce serious personal injury or illness shall be based on a 25 pound (11.4 kg) child.

8. In addition to the recommendations in 16 CFR 1700.20(d), the test data report should include information regarding:

whether or not the children were told to use their teeth

the total number of unit packages opened or accessed for the full ten minute (two 5 minute) time period.

the method used to open or access each unit

for each unit was the package damaged and how

for each unit was the product exposed or accessed and quantify amount exposed or accessed.

9. Retesting of the unit package is required if there is a change in the package or pesticide formulation which could affect its child-resistance e.g., film thickness, package materials, package seal, package or formulation color change, pesticide formulation more crumbly, pesticide formulation more fluid, etc.

10. The compatibility and durability standards in 40 CFR 157.32 still apply to prefilled, nonrefillable insecticide bait stations. If the bait stations are used outdoors, registrants are reminded to take into consideration the effects of weather and temperature on the ability of the pesticide product as packaged to continue to meet the effectiveness and compatibility

standards for the lifetime of the package.

(4) EXEMPTION

A registrant requested an exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. The registrant argued that it was unnecessary to test the ability of adults to open and resecure a package that is not designed or intended to be opened. Such packages do not present the risk associated with difficult to open packages of being disabled or left unsecured by an adult to avoid the need to reopen them. It is unlikely that the contents of such packages will be left accessible to children due to the actions of an adult. Instead, from a child safety standpoint, the only relevant question regarding such packages is whether they can prevent a child from gaining access to the bait.

The Agency has authority under 40 CFR 157.24 (b) (3) to grant an exemption from any CRP requirement, including the testing requirements, based on technical considerations. EPA has granted a five year exemption(*6) from the senior-adult test and younger-adult test effectiveness specifications described in 16 CFR 1700.15(b)(2) for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. The Agency has granted the exemption because it is unnecessary to test the ability of a senior-adult or younger-adult to open and properly resecure a package not designed or intended to be opened or activated. No benefits in terms of improved child safety would be gained by such testing. In accordance with 40 CFR 157.24(b), no registrant action is necessary to qualify for this exemption. However, CRP certification for products relying on this exemption must specify that this package is exempt from compliance with the senior and younger adult effectiveness specifications per this exemption. Furthermore, registrants are reminded that pesticides subject to the CRP regulations in 40 CFR Part 157 must still comply with child-resistant effectiveness, compatibility, and durability standards, as well as all other requirements of 40 CFR Part 157.

(*6) (62 FR 32223, June 13, 1997), available on the internet at:
<http://www.epa.gov/fedrgstr/EPA-PEST/1997/Day-13/p15565.htm>

REGISTRANT ACTION, COMPLIANCE DATE, AND APPLICABILITY

This PR Notice becomes effective upon the date of signature by the Agency. These policies (as described herein) apply to all pesticide products subject to the CRP regulations. Ready-to-use rodenticide bait stations are not a part of this PR Notice. The Rodenticide RED (Registration Eligibility Document) will discuss ready-to-use rodenticide bait stations. Note the actions discussed in this PR Notice are supplemental to the CRP requirements of PR Notice 96-2 (regarding the senior friendly CRP and recertification to CRP by January 21, 1998).

(1) ELECTRONIC SUBMISSION

Within 90 days of the effective date of this PR Notice CRP protocol test data made available to the Agency is requested to be in the following format: a hard copy and an electronic version (*7) on a 3.5 inch high density computer disk in an IBM compatible electronic dbf, wk1, or wk3 data base format using the field format specifications in the attached tables (appendix A). All fields in the format specified in Appendix A for the electronic data submission are essential for the computer program to recognize the data for electronic analysis.

(*7) The electronic availability of CRP data is voluntary. Anyone who would like to comply and is unable to provide all the data described in this PR Notice should contact Rosalind L. Gross to ascertain if some type of electronically formatted submission may be arranged.

(2) UNIT PACKAGING & (3) TEST PROCEDURES CLARIFICATION

Prefilled, nonrefillable insecticide bait stations subject to the CRP regulations that are not designed or intended to be opened or activated in a manner that exposes the contents to human contact, which are packaged and released for shipment on or after January 21, 1998 must be packaged in individual units themselves (actual bait stations) rather than outer packaging that comply with the standards in 40 CFR 157.32. Products for which only the outer retail package, but not the individual bait stations meet the standards in 40 CFR 157.32 will be deemed noncompliant.

(4) EXEMPTION

A five year exemption from senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b) (2) for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to

be opened or activated in a manner that exposes the contents to human contact became effective June 13, 1997 ((62 FR June 13, 1997, p32223), Internet: <http://www.epa.gov/fedrgstr/EPA-PEST/1997/June/Day-13/p15565.htm>). No action is required to qualify for this exemption. However, a CRP certification or CRP recertification per PR Notice 96-2 for products relying on this exemption must specify that the package is exempt from compliance with the senior and younger adult effectiveness specifications per this exemption. The statement:

"I certify that the individual unit packaging used for this product meets the standards of 40 CFR 157.32, including the revised effectiveness specifications in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20. The packaging used is a prefilled, nonrefillable ant or roach insecticide bait station that is not designed or intended to be opened or activated in a manner that exposes the contents to human contact and as such is exempt from compliance with the senior-adult test and younger-adult test effectiveness specifications as described in 16 CFR 1700.15(b) (2), (Ease of adult opening)."

will suffice for this purpose. It should be noted that products relying on this exemption must still fully comply with all other child-resistant packaging effectiveness, compatibility, and durability standards, as well as all other requirements of 40 CFR Part 157.

Applications for amendment, EPA Form 8570-1, and new CRP certification in response to this notice must be sent to:

Postal Service Personal/Courier Service
Document Processing Desk (AMEND) Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C) Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency U. S. Environmental Protection Agency
401 M St., S. W. Room 266A, Crystal Mall 2
Washington, D. C. 20460-0001 1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Comments or questions regarding one or more of these policies should be clearly identified as pertaining to PR 97-9 and state each issue discussed in this PR Notice to which the submission pertains. Comments or questions should be accompanied by supporting data. These comments and/or questions should be addressed to Rosalind L. Gross (see address below) within 60 days of this PR Notice.

Failure to comply with the terms of 40 CFR 157.32 is a violation of FIFRA because the pesticide product is misbranded pursuant to FIFRA Section 2(q)(1)(B). It shall be unlawful under FIFRA Section 12(a) (1) (E) for any person to sell or distribute a misbranded pesticide product that does not comply with 40 CFR Section 157.32. Such an unlawful act may subject the person to a civil penalty under FIFRA Section 14. It is a violation of 18 U.S.C. Section 1001 to knowingly and willfully make a false statement or representation in any matter within the jurisdiction of any department or agency of the United States.

PAPERWORK REDUCTION ACT NOTICE

The annual public burden for the collection of information associated with the CRP requirements at 40 CFR Part 157 are approved by the Office of Management and Budget (OMB) under OMB Control No. 2070-0052 (EPA ICR #616), and is estimated at 1.7 hours per response. The revised burden to accommodate the voluntary electronic submission of CRP data as described in this PR-Notice, is estimated to be 1.9 hours per response. The Agency has therefore adjusted the burden hours under OMB Control No. 2070-0052 to account for the slight increase in burden associated with making this information available electronically. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; acquire CRP in compliance with the regulations, certify to CRP, collecting, verifying, and maintaining information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street, S.W., Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information to this address. The requested information should be submitted in accordance with the instructions in this PR Notice.

ADDITIONAL INFORMATION

For further information about this notice, please contact:

Rosalind L. Gross
Technical Review Branch
Registration Division (7505C)
EPA
401 M Street, SW
Washington, D.C. 20460-0001
(703) 308-7368
Internet Gross.Rosalind@EPAMAIL.EPA.GOV

signed by James J. Jones
James J. Jones, Acting Director
Registration Division (7505C)

=====
=====

APPENDIX A

NOTE CRP TEST DATA ELECTRONIC SUBMISSION

The Environmental Protection Agency (EPA) does a computer assisted analysis of the child-resistant packaging (CRP) protocol test data. In an effort to streamline CRP data analysis and respond expeditiously to pesticide registrants the Agency requests that CRP data be submitted as a hard copy and electronically to eliminate the time necessary to input the data. Electronic retention of CRP data is not mandatory at this time. The EPA regulates pesticide registrants and not CRP manufacturers and CRP testing organizations. Nonetheless, pesticide registrants, CRP manufacturers, and CRP testing organizations are requested to store CRP protocol test data in the following format: a hard copy and an electronic version on a 3.5 inch high density computer disk in an IBM compatible electronic dbf, wk1, or wk3 data base format (e.g. dbase, lotus, paradox, quattro pro) using the field format specifications in the attached tables. Note the dbf format is the preferred format, if a wk1 or wk3 file can be converted to a dbf file, please do so. All fields in the format specified on the attached sheets for the electronic data submission are essential for the computer program to recognize the data for electronic analysis. Additionally, if the file is wk format, the following conditions are integral to data recognition for computer

analysis:

Specify whether the file is a wk1 or wk3

One worksheet per file named "sheet 1"

The variables have a maximum length of 20 characters

Column headings in row 1

A maximum of one row for the titles/column headings

Start the actual data at row 3

Alpha and numeric characters should not be mixed in one field

Row 3 may not be blank

If two child tests are done on the same subjects the second test should be a separate data file. The adult and child tests should be submitted as separate files, rather than using the sample field to identify them.

SENIOR ADULT TEST

Note: when numeric codes are assigned to variables that are words (e.g. test area, sex, tester) a list of the numbers assigned to each value (e.g. male = 1 female = 2) must also be included. The adult and child tests should be submitted as separate files rather than using the sample field to identify them.

Variable Type Size Format Contents

Data

Docno character 9 test id=column 4-6; package id=column 7-9

Sample character 12 identify the pkg for the five minute test.

subj id adult=A, child=C in column 9

Testsite numeric 4

Testarea numeric 2

Testdate numeric 6 MMDDYY

Tester numeric 2

Brthdate numeric 6 MMDDYY

Age numeric 2 years The age of senior adults is calculated by subtracting the test date year from the birth date year. If the test date month and day is less than the birth date month and day, then one is subtracted from the age. For example, if the birth date is 11/28/40 and the test date is 11/20/95 the age is 54 [95-40 = 55, 11/20<11/28 so 55-1 = 54]

Sex numeric 1 male=1, female=2

Timeday numeric 4 use 24 hour clock

Openone numeric 3 seconds time to open package #1; the 5 minute test-a failure is 301

Methone numeric 2

Rscone numeric 3 seconds time to resecure package #1; the 5 minute test-a failure is 301 (NOTE a failure to resecure pkg #1 should not be construed as a senior adult test failure see 16 CFR 1700.20(a)(3)(iii))

Sample2 character 12 identify the pkg for the one minute test.
subj id adult=A, child=C in column 9

Opentwo numeric 3 seconds time to open package #2; the 1 minute test-a failure is 61

Methtwo numeric 2

Rsctwo numeric 3 seconds time to resecure package 2; the 1 minute test a failure is 61

Screen character 5 do screen yes or no

Scroneto numeric 3 seconds time open screen pkg one; a failure is 61

Scronetc numeric 3 seconds time close screen pkg one; a failure is 61

Scrone numeric 2 pass=1 fail=2, screen pkg one

Scrtwoto numeric 3 seconds time open screen pkg two a failure is 61

Scrtwotc numeric 3 seconds time close screen pkg two a failure is 61

Scrtwo numeric 2 pass=1 fail=2, screen pkg two

Order numeric 1

Easyhrd numeric 1 very easy to use=1, easy to use=2, no opinion=3, hard to use=4, very hard to use=5

Testcom character 3 tester comment

Adltcom character 3 adult comment

Zcodpar numeric 12 zip code participant

Zcodta numeric 12 zip code test area

ADULT TEST

Note: when numeric codes are assigned to variables that are words (e.g. test area, sex, tester) a list of the numbers assigned to each value (e.g. male =1 female = 2) must also be included. The adult and child tests should be submitted as separate files rather than using the sample field to identify them.

Variable Type Size Format Contents

Data

Docno character 9 test id=column 4-6; package id=column 7-9

Sample character 12 subj id adult=A, child=C in column 9

Testsite numeric 4

Testarea numeric 2

Testdate numeric 6 MMDDYY

Tester numeric 2

Brthdate numeric 6 MMDDYY

Age numeric 2 years The age of younger adults is calculated by subtracting the test date year from the birth date year. If the test date month and day is less than the birth date month and day, then one is subtracted from the age. For example, if the birth date is 11/28/60 and the test date is 11/20/95 the age is 34 [95-60 = 35, 11/20<11/28 so 35-1 = 34]

Sex numeric 1 male=1, female=2

Timeday numeric 4 use 24 hour clock

Time_Ope numeric 3 seconds time to open pkg; a failure is 301

Method numeric 2

Resecure numeric 3 seconds time to resecure; a failure is 301

Easyhrd numeric 1 very easy to use=1, easy to use=2, no opinion=3, hard to use=4, very hard to use=5

Testcom character 3 tester comment

Adltcom character 3 adult comment

Zcodpar numeric 12 zip code participant

Zcodta numeric 12 zip code test area

CHILD TEST

Note: when numeric codes are assigned to variables that are words (e.g. test area, sex, tester) a list of the numbers assigned to each value (e.g. male =1 female = 2) must also be included. If two child test are done on the same subjects the second test should be a separate data file. The adult and child tests should be submitted as separate files rather than using the sample field to identify them. (A number of variables are only applicable to the unit dose test and would be left blank for a reclosable package. These variables are marked with an * in the contents column of this table.)

Variable Type Size Format Contents

Data

Docno character 9 test id= column 4-6; package id=column 7-9

Sample character 12 subj id adult=A, child=C in column 9

Testsite numeric 4

Testarea numeric 2

Testdate numeric 6 MMDDYY

Tester numeric 2

Brthdate numeric 6 MMDDYY

Age numeric 2 months (see 16 CFR 1700.20 for calculation method)

Sex numeric 1 male=1 female= 2

Partners numeric 2 # of children in test group (should be 2)

Testpkg numeric 2 package=1 or 2. Indicates whether the child

tested the package first or second (a child

may test 2 different packages per 16 CFR

1700.20(a) (2) (iv) (29)). If only one package

is tested, package=1

Timeday numeric 4 use 24 hour clock

Time_Ope numeric 3 seconds time to open package [time for first unit if

unit dose package] regardless of before or

after demonstration. A failure is 601

Method numeric 2

Amount numeric 3 *Total amt of prod access (# g prod/pkg

multiplied by the total No. pkges

open/access)

Dose numeric 3 *Total No. pkges open/access and indicate

with submission the amount of product and

A.I. that represents

Amtbdemo numeric 3 *No. pkges open/access before demo

Amtademo numeric 3 *No. pkges open/access after demo

Demo numeric 1 demonstration given; yes=1 no=2

Teeth numeric 1 told to use teeth; yes=1 no=2

Result numeric 2 *for each test subject pass=1 fail=2 based on

tox and # pkges open/access

Testcom1 character 3 Tester Comment 1

Order numeric 1

Zcodpar numeric 12 zip code participant

Zcodta numeric 12 zip code test area

=====
=====

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 157

[OPP-250123; FRL-5720-5]

Ant or Roach Insecticide Bait Stations;
Exemption From Adult Portion of Child-Resistant Testing Specifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Rule related notice.

SUMMARY: This document grants a 5-year exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) (Ease of adult opening), for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. Products qualifying for this exemption must still fully comply with all other child-resistant packaging (CRP) effectiveness, compatibility, and durability standards, as well as all other requirements of 40 CFR part 157. CRP certification for products relying on this exemption must specify that the package does not comply with the senior and younger adult effectiveness specifications per this exemption. This exemption was requested by S.C. Johnson & Son, Inc., which argued that a package that does not require opening or activation to put into use should not require adult ease of opening testing.

DATES: This exemption becomes effective on [insert date of publication in the Federal Register] and expires on [insert date 5 years after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Rosalind L. Gross, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number: (703) 308-7368, e-mail: gross.rosalind@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: S.C. Johnson & Son, Inc. requested an exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) (Ease of adult opening), for prefilled, nonrefillable ant or roach insecticide bait stations that are not designed or intended to be opened or activated in a manner that exposes the contents to

human contact.

I. Background

FIFRA 25(c) (3) requires EPA's CRP standards to be consistent with those of the Consumer Product Safety Commission (CPSC). EPA's CRP regulations at 40 CFR 157.32 require that CRP for pesticides meet the CPSC packaging standards (effectiveness specifications) and testing procedures set forth in 16 CFR 1700.15(b) and 17000.20. The CPSC Poison Prevention Packaging Standards in 16 CFR 1700.15(b) provide that CRP, when tested by the method described in 16 CFR 1700.20, shall meet certain child-resistant test, senior-adult test, and younger-adult test effectiveness specifications. In 16 CFR 1700.15(b)(2), the senior-adult test and younger-adult test effectiveness specifications are discussed with reference to the senior-adult panel test of 16 CFR 1700.20(a)(3) and the younger-adult panel test of 16 CFR 1700.20(a)(4), respectively.

The EPA CRP regulations provide that exemptions from compliance may be requested on a case-by-case basis for specific products based on technical factors (40 CFR 157.24(b) (3)). The regulations further provide that any such exemption decision will be published in the Federal Register, will be for a specified length of time, and will be applicable to any product with substantially similar composition and intended uses.

II. Requested Grounds for Exemption

As support for its exemption request, S.C. Johnson & Son, Inc. advanced the following arguments:

The purpose of adult testing is to ensure that CRP is not difficult for adults to use properly. If CRP is difficult for adults to open, the concern arises that the package may be disabled or left unsecured to eliminate the difficulty of reopening it. Under such circumstances the contents would be accessible to children. In the case of prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened, this concern does not arise. There is no risk that an adult will disable or fail to resecure a difficult to open package, because the packages need not be opened or activated in order to function properly. As there is no concern that an adult will disable or fail to resecure such a package, there is also no concern that the contents of disabled or unsecured packages will be accessible to children. Instead, from a child safety standpoint, the only relevant question regarding such packages is whether they can prevent a child from gaining access to the

bait.

III. Agency Determination

The Agency has considered the S.C. Johnson & Son, Inc. exemption request and the basis therefore and agrees that it is unnecessary to test the ability of a senior-adult or younger-adult to open and properly resecure a package not designed or intended to be opened or activated. No benefits in terms of improved child safety would be gained by such testing. Therefore, the Agency hereby grants a 5-year exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. The Agency has authority under 40 CFR 157.24(b) (3) to grant an exemption from any CRP requirement, including the testing requirements, based on technical considerations.

IV. Exemption

A 5-year exemption is granted from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2), for prefilled, nonrefillable ant or roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. Products that qualify for this exemption must fully comply with all other CRP effectiveness, compatibility, and durability standards as well as all other requirements of 40 CFR part 157. CRP certification for products relying on this exemption must specify that the package does not comply with the senior and younger adult effectiveness specifications per this exemption. This exemption becomes effective on [insert date of publication in the Federal Register and expires on [insert date 5 years after date of publication in the Federal Register].

List of Subjects in 40 CFR Part 157

Administrative practice and procedure, Infants and children, Packaging and containers, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: June 4, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-15565 Filed 6-12-97; 8:45 am]

BILLING CODE 6560-50-F