12-5-85

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 10-21-85 OUT 12-04-85

Dorothy M Portner 12/5/85

Reviewed By Dorothy M. Portner Date 12-04-85

EPA Reg. No. 5813-EU

EPA Petition or EUP No. None

Date Division Received 10-01-85

Type Product Hospital/General Disinfectant

Data Accession No(s). 259661

Product Manager PM-32 (Castillo)

Product Name Tilex

Company Name The Clorox Company

Submission Purpose Application to register a new product with efficacy data and proposed labeling

Type Formulation Non-pressurized spray (undiluted) and liquid concentrate diluted for use

Active Ingredient(s):	%
Sodium hypochlorite	2.0

200.0 Introduction

200.1 Use

Proposed labels are attached.

200.2 Background Information

The submission, received 10-1-85, is an application to register a new product. Proposed labeling and efficacy data were provided.

201.0 Data Summary (Accession No. 259661)

The submitted data were developed by B.B. Colina and L.C. Hargis of Hill Top Research, Inc., Miamiville, Ohio.

201.1 Description of the Test

A. Test Method: AOAC Spray Products Test
Exposure Period: 1 minute
Organic Soil: 5% horse serum
Spray Time & Distance: 2-3 seconds, 6-8 inches
Subculture medium: Fluid Thioglycollate Medium USP XX
(For both primary & secondary bacterial subcultures)
Glucose Neopeptone Broth + 0.05% Na Thioglycollate + 1.5% Triton X100
(For both primary & secondary fungal subcultures)
Incubation Period: 37°C for 48 hours
(For bacterial growth)
25-30°C for 10 days
(for fungal growth)

B. Test Method: AOAC Use Dilution Test
Exposure Period: 5 minutes at 20°C
Organic Soil: 5% horse serum
Dilution: 1:17
Subculture medium: Fluid Thioglycollate Medium USP XX
(For both primary and secondary bacterial subcultures)
Incubation Period: 37°C for 48 hours
(For bacterial growth)

201.2 Test Results

A. AOAC Spray Products Test

Test Organism	Survival/Slide After Drying	No. Positive/Total 238	232	156*
S. choleraesuis (PR = 1:90)	2.7×10^6	0/60	0/60	0/60
S. aureus (PR = 1:60)	3.1×10^6	0/60	1/60	0/60
P. aeruginosa (PR = 1:80)	3.3×10^6	1/60	0/60	0/60
S. pyogenes (PR = 1:65)	5.5×10^5	0/10	-	0/10
T. mentagrophytes (PR = 1:70)	3.3×10^6	0/10	-	0/10

PR = Phenol Resistance.
- = Not tested.
* 60-day shelf-life sample.

B. AOAC Use Dilution Test

Test Sample	No. Positive*/Total
M-1367, 2004.31-5	1/60
M-1367, 2004.41-1	0/60
M1407, 8/23/83	0/60

* S. choleraesuis: 1.5×10^6/cylinder after drying; Phenol Resistance = 1:90

201.3 Conclusions

1. The data demonstrate a satisfactory performance as a non-pressurized, undiluted, one-step hospital disinfectant-cleaner spray in 1 minute against the bacterial and fungal microorganisms indicated in 201.2 A above.

2. The data demonstrate a satisfactory performance as a limited one-step disinfectant-cleaner against Gram-negative microorganisms in non-medical areas at a 1:17 dilution in 5 minutes.

3. The data submitted to support product efficacy against mildew are not required and were not reviewed.

RIN 3724-95

EFFICACY REVIEW FOR EPA REG. NO. 5813-24

Page_____ is not included in this copy.

Pages 4 through 6 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

✓ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 5813-EU

Data Division Received 10-01-85

Data Accession No(s). 259661

Product Manager No. PM 32 (Castillo)

Product Name Tilex

Company Name The Chlorox Company

202.0 Recommendations

202.1 Efficacy Supported By Data

A. The submitted data developed by the AOAC Products Spray Test support efficacy of the subject product as a one-step disinfectant-cleaner in both medical and non-medical use areas when applied undiluted in a non-pressurized spraying device to thoroughly wet hard, non-porous surfaces having a moderate organic soil load for a 1-minute contact time.

These data also support specific efficacy claims against the following infectious microorganisms when the product is used as indicated above:

Salmonella choleraesuis
Staphylococcus aureus
Pseudomonas aeruginosa
Streptococcus pyogenes
Trichophyton mentagrophytes

B. The submitted data developed by the AOAC Use Dilution Test support efficacy of the subject product as a as a one-step limited disinfectant-cleaner (against Gram-negative bacteria) in non-medical use areas when applied at a 1:17 dilution to thoroughly wet, hard, non-porous surfaces having a moderate organic soil load for a 5-minute contact time.

202.2 Non-Health-Related Uses

Efficacy claims to control mildew are considered to have aesthetic significance not directly related to human health do not require supporting efficacy data as explained in the DIS/TSS-16 enclosure.

202.3 Labeling

To provide adequate label directions to disinfect hard, non-porous surfaces, the following revisions are required:

1. Removal of gross filth and heavy soil deposits prior to application of the product for disinfecting.

2. Identification of the hard, non-porous surfaces recommended for disinfection.

3. Application of the undiluted product by spraying or with a sponge until the surfaces are thoroughly wet.

4. Identification of the recommended use areas (e.g. homes, schools, motels).

To reflect the supporting efficacy data for a 1:17 dilution of the product, the label must specify that product effectiveness for disinfecting toilet bowls is only against Gram-negative microorganisms.

In lieu of this statement, additional data demonstrating product efficacy at a 1:17 dilution in 5 minutes against S. aureus would be required to support this pattern of use in non-medical use areas; additional data against P. aeruginosa under these use conditions would also be required if usage of this product is recommended in hospitals and other medical use areas.

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 5813-EU

Data Division Received 10-01-85

Data Accession No(s). 259661

Product Manager No. PM 32 (Castillo)

Product Name Tilex

Company Name The Chlorox Company

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These data also support specific efficacy claims against the following infectious microorganisms when the product is used as indicated above:

Salmonella choleraesuis
Staphylococcus aureus
Pseudomonas aeruginosa
Streptococcus pyogenes
Trichophyton mentagrophytes

B. The submitted data developed by the AOAC Use Dilution Test support efficacy of the subject product as a as a one-step limited disinfectant-cleaner (against Gram-negative bacteria) in non-medical use areas when applied at a 1:17 dilution to thoroughly wet, hard, non-porous surfaces having a moderate organic soil load for a 5-minute contact time.

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

OFFICE OF TOXIC SUBSTANCES

REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES:

Determination of Health-Related and Non-Health-Related Uses

According to Section 3 (c) (5) of the FIFRA, as amended by the Federal Pesticide Act of 1978, and the provisions of 40 CFR 162.18-2 of the Regulations for the Enforcement of the FIFRA, products bearing claims for control of microorganisms which pose a threat to human health require specific efficacy data to support such claims and patterns of use; products bearing claims expressly for control of microorganisms not directly related to human health do not require supporting efficacy data.

The following criteria will be utilized to determine whether or not the labeling of an antimicrobial pesticide bears uses of human health significance:

1. Products bearing claims for control of microorganisms infectious for man will be considered as directly related to human health and will require specific and complete efficacy data to support such claims and patterns of use.

2. Unqualified and non-specific claims for products as sterilizers, disinfectants, or sanitizers will be considered to include or imply effectiveness against microorganisms infectious for man. Antimicrobial products recommended for use in hospital or medical environments, including sickrooms in public or private dwellings, will be similarly considered as human health-related. Such claims or recommendations must be expressly qualified or deleted in order to remove implications of human health significance.

3. Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health will not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided in labeling.

4. Since elimination or significant reduction in numbers of microorganisms (sterilization, disinfection, sanitization) must be demonstrated before a product is considered acceptable for claims against microorganisms infectious for man, or for use in medical or sickroom environments, products bearing claims for effectiveness at the bacteriostatic level (inhibition of growth) will not be accepted for such situations. Bacteriostatic claims will only be permitted for products expressly recommended for control of microorganisms of economic or aesthetic significance (e.g. slime-forming bacteria, odor-causing bacteria).

5. When no pesticidal purpose or function is known or shown to exist for a proposed claim or pattern of use for an antimicrobial product, registration will not be considered.

6. Hospital sterilizers and disinfectants, swimming pool water disinfectants, human drinking water disinfectants and purifiers, and food contact surface sanitizers are, by their very nature, human health-related and will require efficacy data whether or not control of specific infectious microorganisms are claimed.

7. Veterinary and animal premise disinfectants will require efficacy data to support claims against those microorganisms which are infectious for both man and animals. Efficacy data will not be required for those microorganisms which are solely pathogenic for animals.

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 10/21/85 OUT 12/04/85

Reviewed by James E. Wilson, Jr. Date 12/03/85

EPA Reg. No. or File Symbol 5813-EU

EPA Petition or EUP No. NONE

Date Division Received 10/01/85

Type Product(s): I,(D), H, F, N, R, S

Data Accession No(s) 259660,31

Product Mgr. No. 32 (Castillo)

Product Name(s) Tilex

Company Name (s) The Clorox Company

Submission Purpose New Application

Chemical & ~~Formulation~~ Liquid

Active Ingredient(s):	%
Sodium hypochlorite	2.0

BACKGROUND

This product will be used as a household mildew and stain remover.

RECOMMENDATIONS

The data submitted are adequate to place the product in the following toxicity categories:

Acute Oral	- x
Acute Dermal	- x
Acute Inhalation	- 4
Eye Irritation	- x
Skin Irritation	- x

✗ Unsigned and undated summaries of these studies were submitted. They are not acceptable. Please have the registrant to submit the studies. Also have the registrant to indicate if Tackle has essentially the same formulation as tilex.

LABELING

No changes required at this time.

DATA REVIEW

Report by Gulf South Research Institute, submitted to Clorox Company, Pleasanton, CA 94566, dated October 7, 1983. (Accession No. 259660).

Acute Inhalation

Report dated March 22, 1985

Method - Five male and five female rats were placed in a 0.5M^3 chamber to test the effects of the undiluted aerosolized test material. The air flow rate was approximately 185.0 liters per minute for 4 hours. Both nominal and actual exposure aerosol concentations were calculated. Four samples were taken near the breathing zone. Particle sizes were also determined. The animals were observed during the exposure period for 14 days after exposure. All animal were weighed on the day of dosing and weekly thereafter.

Results - The nominal concentration was calculated to be 15.67 mg/l and the gravimetric concentration was reported as 5.09 mg/l. The mass median diameter was determined to be 4.5μ(50%). Eighty-three percent of the particles were determined to be 10 u or less Lethargy, red nasal discharge and lacrimation were observed in all animals during the four-hour exposure. Lethargy persisted for 1-2 days after the exposure. Rough coats were seen after exposure; all cleard by day 12. No mortality was reported. Gross necropsy findings were unremarkable.

Conclusion - The product does not produce mortality at 5.09 mg/l during a four-hour exposure.

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN Aug 22 88 OUT Aug 22 88

Reviewed by Alex Arce 8/24/88 Date Aug 22 88

EPA Reg. No. or File Symbol 5813 -EU

EPA Petition or EUP No. None

Date Division Received 8-16-88

Type Product(s): I, (D) H, F, N, R, S

Data Accession No(s). 407775

Product Mgr. No. Jeff Kempter (32)

Product Name(s) Milex

Company Name(s) Clorox Company

Submission Purpose Re- review of data (Original data; eye irritation study was "illegible ". . This is an application for Registration

Chemical & Formulation Liquid

Active Ingredient(s):	%
Sodium Hypochlorite	1.65 %

pH- 13.1

BACKGROUND

The product will be used as a Disinfectant

RECOMMENDATIONS

The data submitted are adequate to place the product tested in the following toxicity category:

STUDY	TOX CATEGORY
Acute Oral	IV
Acute Dermal	IV
Acute Inhalation	
Skin Irritation	III
Eye Irritation	II

CRP STATUS

This product ~~does~~/does not require special packaging

LABEL

A label has not been submitted with this request

The label should have the following:

Precautionary Statement

Causes eye and skin irritation , do not get in eyes , avoid contact with skin or clothing. Harmfull if swallowed

Statement of Practical Treatment

In case of eye contact wash with pleanty of water for at least 15 minutes. and seek medical attention. For skin flush with water ; if irritation persist get medical attention

DATA REVIEW

Test Laboratory: Mideco. Inc University of Utah

Project # 48991

Acute Oral LD_{50} CFR 81.1

Report date: March 29 88 MRID No. 407775

Method of Testing: CfR 81-1

Species: Pats

Sex: Male and female Levels Tested: 5 gm. /kg

Age: Adults No. Animals/dose: 5 m and 5 f

Weights: Acceptable Via: Oral

Material: Undiluted Observation days: 14 days

Necropsy: all

Procedure

The rats were treated with the material by gavage and observed for changes in body weight and signs of toxicity .

Necropsies were performed at termination

Results:

Signs of Toxicity : Mild sedation of temporary nature

Body Weights : All animals gained

Mortality : None

Necropsy : Unremarkable

Conclusion: The Acute Oral LD_{50} is greater tha 5 g /kg ,. male and fem.

Core Guidelines data

Toxicity Category: IV

20

Acute Dermal LD_{50} CFR 81.2

Report Date: March 20 88 MRID No. 407775

Method of Testing: CFR 81-2

Species: Rabbits Levels Tested 20 g/kg

Sex: Male and female No./animals/dose 5/5

Age: Adults Via: Occluded patch

Weight: Acceptable Observation days: 14

Material: Undiluted Necropsy: All

Procedure

Animals were treated with 20 mg/kg of the material in previously clipped and abraded sites of the back and observed for signs of toxicity and changes in body weights ,

Exposure time 24 hours.

Result

Signs of Toxicity: Drmal irritation

Mortality: None

Body weights: Males and females loss weight by the 7 day and gained at the 14 day

Necropsy: Unremarkable

Conclusions: The Acute Dermal LD_{50} is greater than 20 g/kg

Core Minimum data

Toxicity Category: IV

Primary Eye Irritation CFR 81.4

Report Date: Aug 24 88 MRID No.: 407775

Method of Testing CFR 81-4

Species: Rabbits Observation days: Extended to 21

Dose: 0.1 ml Materials: Undiluted MOTE pH 13.1

No. of animals: 9 Via: Eye instillation

Areas: One Necropsy: None

Procedure The rabbits were treated with the material instilled into one eye , other eye served as control . 3 eyes were washed after application , other 6 eyes were unwashed .

Results: 9/9 showed Corneal opacity for5 days,6/9 Iritis developed

Conjunctival irritation was observed in all eyes

Eyes ~~and~~ cleared~~ed~~ 3/9 in 5 days 4/9 in 6 days 3/9 in 7 days , one eye cleared after 14 days. The results had a large variation in response

Core Minimum data

Toxicity Category: II

Over

Corneal Opacity response table

This table has been extracted from work sheet

Rabbit #	Date July 17-	19	20	21	22	25	28	Aug 3	5
934	0	x	x	x	x				
933	0	x	x	x	x				
941	0	x	x	x	x	x			
944	0	x	x	x	x	x	x	x	x
940	0	x	x	x	x				
904	0	x	x	x	x	x			
916	0	x	x	x					
905	0	x	x	x					
855	0	x	x						

Primary Skin Irritation CFR 81.5

Report Date: March 29 88 MRID No.: 407775

Method of Testing: CFR 81-5

Species: Rabbits Observation days: 7 days

No. of animals 6 Material: Undiluted

Dose: 0.5 ml Via: Occluded patch

Areas: In back Necropsy: None

Procedure

The rabbits were treated with the material under an occluded patch and observed for signs of dermal irritation.

Results: Mild Irritation was found in all animals

Conclusion: The product is a mild skin irritant

The irritation lasted for lasted for 72 hours in all 2 rabbits showed a

Core Minimum data response for 7 days

Toxicity Category: III