

1839-223

6/28/2012

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D C 20460

JUN 28 2012

OFFICE OF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

Mr Thomas W Isaac
Senior Regulatory Specialist
Stepan Company
22 W Frontage Rd
Northfield Illinois 60093

Subject **SCTB Wipe**
EPA Registration Number 1839 223
Application Dated February 8 2012
EPA Received February 8 2012

Dear Mr Isaac

The following amendment submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) as amended is acceptable

Proposed Amendment

- Addition of Duck Hepatitis B Virus (DHBV) and Human Hepatitis B Virus (HBV)

General Comments

Efficacy review see attachment

A stamped copy of the acceptable labeling is enclosed Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling

Should you have any questions or comments concerning this letter please contact Drusilla Copeland at (703) 308 6224

Sincerely

A handwritten signature in black ink, appearing to read "Velma Noble".

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure stamped label and approved revised review 6/28/12

SCTB Wipe

(Optional statements)

CLEANER // NEW // QUICK // EASY // EFFECTIVE // FAST EFFECTIVE
// CONVENIENT

CLEANS DISINFECTS & DEODORIZES

MULTI PURPOSE CLEANER

ANTIBACTERIAL FORMULA CLEANS and DISINFECTS

CITRUS SCENTED // FRESH SCENTED // LEMON SCENTED // MINT SCENTED //

*VIRUCIDAL//TUBERCULOCIDAL//BACTERICIDAL//PSEUDOMONICIDAL

Cleans and Deodorizes in One Easy Step

Kills 99.9% of Bacteria

Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)

ACTIVE INGREDIENTS

Alkyl (60% C₁₄ 30% C₁₆ 5% C₁₂ 5% C₁₈)

dimethyl benzyl ammonium chlorides

0 105%

Alkyl (68% C₁₂ 32% C₁₄) dimethyl

ethylbenzyl ammonium chlorides

0 105%

INERT INGREDIENTS

99.790%

Total

100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side (back) panels for additional precautionary statements

EPA REG NO 1839 223
EPA EST NO 1839 IL 01

STEPAN COMPANY
22 W Frontage Rd
Northfield IL 60093

ACCEPTED
with COMMENTS
in EPA Letter Dated

6/28/12

Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended for the pesticide
registered under EPA Reg No 1839-223

NET CONTENTS X lbs X ozs *(mandatory must be expressed in avoirdupois pounds and ounces)*

(optional can also express as total count and size)

X Pre measured (Pre moistened) (Wipes) (Towelettes) (Cloths) (X) x (X)
(e.g. 40 Pre measured Wipes (7 x 8) (18cm x 20cm)

X Pre measured Single Use (Pre Moistened) (Wipes) (Towelettes) (Cloths) (X) x (X)
(e.g. 40 Pre measured Towelettes (7 x 8) (18cm x 20cm)

U S Patent No 5,444,094

(This product or product name) is bactericidal in the presence of organic soil (5% blood serum) against *Escherichia coli (E coli)* ATCC 11229 *Escherichia coli* O157 H7 ATCC 43895 *Salmonella (choleraesuis) enterica* ATCC 10708 *Pseudomonas aeruginosa* ATCC 15442 Vancomycin Resistant *Enterococcus faecalis* (VRE) ATCC 51575 *Staphylococcus aureus* ATCC 6538 and Methicillin Resistant *Staphylococcus aureus* (MRSA) ATCC 33593 at 5 minutes contact time

(This product or product name) is bactericidal in the presence of organic soil (5% blood serum) against *Escherichia coli (E coli)* (ATCC 11229) *Escherichia coli* O157 H7 (ATCC 43895) *Salmonella (choleraesuis) enterica* (ATCC 10708) *Pseudomonas aeruginosa* (ATCC 15442) Vancomycin Resistant *Enterococcus faecalis* (VRE) (ATCC 51575) *Staphylococcus aureus* (ATCC 6538) and Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33593) at 5 minutes contact time

(This product or product name) is tuberculocidal in the presence of organic soil (5% blood serum) against *Mycobacterium bovis* BCG (Tuberculosis) at 20 C at 5 minutes contact time

(This product or product name) is virucidal in the presence of organic soil (5% blood serum) against Human Immunodeficiency Virus Type 1 Strain HTLV III_B (HIV 1) (associated with AIDS) at 2 minutes contact time and Influenza A (H1N1) Virus (ATCC VR 1469 Strain A/PR/8/34) Hepatitis B Virus (HBV) Duck Hepatitis B Virus (DHBV) Hepatitis C Virus (HCV) and Bovine Viral Diarrhea Virus (BVDV) at 5 minutes contact time

(This product or product name) are (is a) non woven disposable (towelette(s)) (wipe(s)) pre saturated with a quaternary disinfectant cleaner

(This product or product name) are (is) intended for use in

- hospitals and healthcare settings ambulances anesthesia CAT labs CCU Central Supply Clinics Dental Offices Dialysis Clinics Doctor's office(s) Emergency Rooms ER Home health care Hospices ICU Laboratory Laundry rooms Neonatal Intensive Care Units (NICU) Newborn nursery Nursing homes Operating rooms Pediatrics Pediatric Intensive Care Units (PICU) Physical therapy Physician's office(s) Ophthalmic offices Radiology Recovery Room Rehabilitation Respiratory therapy Surgery Transport vehicles X Ray

(and/or)

- Critical Care Areas CCU Emergency Rooms ER ICU Neonatal Intensive Care Units (NICU) Operating Rooms Pediatric Intensive care Units (PICU) Surgery Ophthalmic offices
- Veterinary clinics animal hospitals animal life science laboratories kennels pet animal kennels breeding establishments grooming establishments pet animal quarters zoos pet shops tack shops
- Animal holding areas veterinary waiting rooms veterinary examination rooms veterinary X ray rooms veterinary operating rooms animal transportation vehicles
- Beauty salons barber shops correctional facilities funeral homes mortuaries
- Schools health clubs gyms athletic facilities airports transportation terminals
- Grocery stores Shopping Centers Delicatessens Catering facilities Banquet halls
- Nursery Daycare centers

ACCEPTED
with COMMENTS
in EPA Letter Dated:

6/28/12

Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended or hereinafter amended
No. 1839-223

4/10

(This product or product name) will clean and disinfect hard non porous surfaces of bed railings cabinets carts chairs counters exam tables gurneys isolettes IV poles stethoscopes stretchers tables telephones toilet seats toilets bathtubs bathroom fixtures shower stalls sinks tiles vanity tops hospital beds traction devices MRI CAT scales paddles wheelchairs ultrasound transducers and probes

(This product or product name) will clean and disinfect hard non porous surfaces of grocery cart handles grocery carts shopping carts grocery cart child seats

(This product or product name) will clean and disinfect hard non porous surfaces of changing tables cribs diaper pails trashcans garbage cans

(This product or product name) will clean and disinfect hard non porous surfaces of cabinets chairs computers countertops desks desktops doorknobs fax machines garbage cans headsets keyboards railings seats sinks tables tabletops telephones trashcans

(This product or product name) will clean and disinfect hard non porous surfaces of gym equipment exercise machines wrestling mats gymnastic equipment

Use (this product or product name) to clean and disinfect non porous personal protective safety equipment protective headgear hard hats half mask respirators full face breathing apparatus gas masks goggles spectacles face shields silicone rubber or PVC hearing protectors and vinyl covered ear muffs Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120 F) and allow to air dry (Caution Cleaning at the 120 F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement)

(This product or product name) is formulated to disinfect hard non porous inanimate environmental surfaces such as floors walls metal surfaces stainless steel surfaces glazed porcelain glazed ceramic tile non polycarbonate plastic surfaces bathrooms shower stalls bathtubs and cabinets

**ACCEPTED
with COMMENTS
in EPA Letter Dated.**

4/26/12

Under the Federal Insecticide, Fungicide and Rodenticide Act, this product is registered under

1839-223

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

(For labels that list medical premises and metal and/or stainless steel surfaces one of the following statements must be used)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body

or

This product is not for use on critical and semi critical medical device surfaces

CLEANING/DEODORIZING Use one (product name) (wipe) (towelette) to deodorize and completely remove of all gross debris from surfaces to be treated

DISINFECTING To disinfect hard non porous surfaces thoroughly wet the surface to be treated Treated surface must remain visibly wet for 5 minutes for disinfection

- To disinfect against *Escherichia coli (E coli)* *Escherichia coli* O157 H7 *Pseudomonas aeruginosa* *Salmonella (choleraesuis) enterica* and Vancomycin Resistant *Enterococcus faecalis* (VRE) allow the treated surface to remain wet for 5 minutes
- To disinfect against *Mycobacterium bovis* BCG (Tuberculosis) allow the treated surface to remain wet for 5 minutes
- To disinfect against *Staphylococcus aureus* and Methicillin Resistant *Staphylococcus aureus* (MRSA) allow the treated surface to remain wet for 5 minutes

A potable water rinse is required for surfaces in direct contact with food

For plastic and painted surfaces spot test on an inconspicuous area before use

For heavily soiled surfaces clean before following disinfecting instructions

***VIRUCIDAL ACTIVITY** (This product or product name) is an effective virucide on hard non porous surfaces against

- Influenza A (H1N1) Virus (ATCC VR 1469 Strain A/PR/8/34) Hepatitis C Virus (HCV) Hepatitis B Virus (HBV) Bovine Viral Diarrhea Virus (BVDV) and Duck Hepatitis B Virus (DHBV) when the treated surface is allowed to remain wet for 5 minutes
- Human Immunodeficiency Virus Type 1 (HIV 1) when the treated surface is allowed to remain wet for 2 minutes

(optional statements to appear anywhere on the label)

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus This product (Product Name) is a broad spectrum hard surface disinfectant that has been shown to be effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)
- This product (Product Name) has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus
- This product (Product Name) has demonstrated effectiveness against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)
- Kills Pandemic 2009 H1N1 Influenza A virus

Use additional (wipe(s)) (towelette(s)) if needed to assure that the treated surface remains continuously wet for the prescribed time

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in EPA Letter Dated

4/28/12

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For Ultrasound Transducers and Probes

Use only on external surfaces of ultrasound transducers and probes

With a clean washcloth clean gel from external surface of the ultrasound transducer or probe to be disinfected Then thoroughly wet probe with (wipe(s)) (towelette(s)) Treated surface must remain wet for 5 minutes Use additional (wipe(s)) (towelette(s)) if needed to assure continuous 5 minute wet contact time Let air dry

Veterinary Practice/ Animal Care Animal Laboratory/ Zoos/ Pet Shop/ Kennels/ Grooming Establishments Disinfection Directions

For cleaning and disinfecting the following hard non porous surfaces equipment not used for animal food or water utensils instruments cages kennels countertops tables etc Remove all animals and feed from premises cages crates etc Remove all litter droppings and manure from equipment to be disinfected Thoroughly clean all surfaces with soap or detergent and rinse with water Thoroughly wet all surfaces to be treated with (wipe(s)) (towelette(s)) Treated surfaces must remain wet for 5 minutes Use additional (wipe(s)) (towelette(s)) if needed to assure continuous wet contact time of 5 minutes Let air dry Ventilate buildings and other closed spaces Do not house animals or employ equipment until treatment has been absorbed set or dried

KILLS HIV 1 HBV and HCV ON PRE CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS

in health care settings (Hospitals Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV 1) (associated with AIDS) Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV 1 and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

PERSONAL PROTECTION When handling items soiled with blood or body fluids use disposable latex gloves gowns masks and eye coverings

CLEANING PROCEDURES Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product (This product or product name) (wipe(s)) (towelette(s)) can be used for this purpose

CONTACT TIME Thoroughly wet surface with a new (product name) (wipe) (towelette) Allow surface to remain wet for 5 minutes and air dry

DISPOSAL OF INFECTIOUS MATERIALS Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal

Not for personal cleansing

This is not a baby wipe!

Do not flush in toilet

ACCEPTED
with COMMENTS
in EPA Letter Dated

4/28/12

Under the Federal Insecticide
Fungicide and Rodenticide Act as
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registered under EPA Reg No 1839-1-12

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Canister Directions (Use any of the following instructions – can also use with canister icon)

TO OPEN

- Remove lid from canister
- Lift flap in center of lid
- Pull up corner of center (wipe) (towelette) (cloth) twist to a point and thread through dispenser hole in lid DO NOT PUSH FINGER THROUGH OPENING
- Replace lid Pull out exposed (wipe) (towelette) (cloth) and snap off The next (wipe) (towelette) (cloth) pops up automatically Dispose of used (wipes) (towelettes) (cloths) in trash receptacle Snap center flap down when finished to retain moisture
- Do not flush

TO OPEN PACKAGE Flip open dispensing cap and remove lid by pulling upward Thread center (wipe) (towelette) (cloth) corner through slits in lid center DO NOT PUSH FINGER THROUGH OPENING Replace lid Dispense (wipes) (towelettes) (cloths) by pulling out at an angle Snap flip lid down when finished to retain moisture Dispose of used (wipes) (towelettes) (cloths) in trash Do not flush

TO OPEN PACKAGE Pop open dispensing tab and remove top by lifting upward Pull up corner of center (wipe) (towelette) (cloth) twist to a point and thread through slits in top DO NOT PUSH FINGER THROUGH SLITS Replace top and pull (wipe) (towelette) (cloth) at slight angle The next (wipe) (towelette) (cloth) pops up automatically Snap tab closed to retain moisture Do not flush

DISPENSER to start feed Remove large cover and discard seal from container From center of (wipe) (towelette) (cloth) roll pull up (wipe) (towelette) (cloth) corner twist into a point and thread it through the hole in the container cover DO NOT PUSH FINGER THROUGH HOLE Pull through about one inch Replace cover Pull out first (wipe) (towelette) (cloth) and snap off at a 90 degree angle Remaining (wipes) (towelettes) (cloths) feed automatically ready for next use When through using keep small center cap closed to prevent moisture loss Do not flush

Refillable Package Instructions (Use with product supplied in refillable packages)

TO OPEN PACKAGE Flip open dispensing flap and remove lid by lifting upward Place (pouch) (package) in (container) (tub) Open pouch by peeling back seal Insert (wipe) (towelette) (cloth) through opening in lid Replace lid The next (wipe) (towelette) (cloth) pops up automatically When finished close lid flap to retain moisture

Refill Package Instructions (Use for refill package)

TO OPEN PACKAGE Flip open dispensing flap and remove lid by lifting upward Place refill in (container) (tub) Open in (container) (tub) by peeling back seal Insert (wipe) (towelette) (cloth) through opening in lid Replace lid The next (wipe) (towelette) (cloth) pops up automatically When finished close lid to retain moisture

Resealable Package Instructions (Use for product supplied in resealable pouches/packages)

TO OPEN PACKAGE Slowly peel back label (Pull out) (Remove) (wipes) (towelettes) (cloths) as needed To retain moisture reseal (pouch) (package) by firmly pressing label back on the (pouch) (package)

Single Use Pouch Instructions (Use for product supplied in single use pouches/packets)

TO OPEN PACKAGE Tear pouch open (along dotted line) (at tear notch) (along the top edge of pouch) (Pull out) (Remove) (wipes) (towelettes) (cloth)

For product supplied in a single use pouch with a folded towelette include the following)

Unfold (wipe) (towelette) (cloth) before use

Center Pull Dispenser Instructions (Use for product supplied in plastic bags)

TO OPEN PACKAGE (Open lid of the dispenser) (Cut V out of the top of the (plastic bag) (Tear open (tab on) top of (plastic) bag) (Cut open top of (plastic) bag) (Remove the Styrofoam core from the center of the roll) Pull out the first (wipe) (towelette) (cloth) approximately 6 to 8 inches from the center of the roll (Place entire bag inside of center pull dispenser Thread the (wipe) (towelette) (cloth) through the opening on the dispenser) (Thread the (wipe) (towelette) (cloth) through the opening on the dispenser) Place entire bag inside of center pull dispenser (Close the lid of the dispenser) ((Wipe) (Towelette) (Cloth) dispensing tension may be adjusted on the bottom of the dispenser) (Additional loading directions are listed on the dispenser) Dispenser may be mounted with (wipes) (towelettes) (cloths) (dispensing up) (dispensing down) (dispensing up or down)

AMENDED with COMMENTS in EPA Letter Dated 4/18/12
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg No 1839-223

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION Causes moderate eye irritation Avoid contact with eyes or clothing Wash thoroughly with soap and water after handling and before eating drinking chewing gum using tobacco or using the toilet

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment

IF IN EYES Hold eyes open and rinse slowly and gently with water for 15–20 minutes Remove contact lenses if present after the first 5 minutes then continue rinsing Call a poison control center or doctor for treatment advice

(Optional) You may contact XXX/XXX XXXX for emergency medical treatment information

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

PESTICIDE STORAGE Store in an area inaccessible to children

(The following Storage/Disposal statements can be used for household and Institutional/Industrial products)

(Optional for product supplied in nonrefillable canisters)

CONTAINER STORAGE/DISPOSAL Wipes Dispose of (wipe) (towelette) in trash after use Do not flush Canister Tightly close lid between uses to retain moisture Nonrefillable container Do not reuse or refill this (container) (canister) Offer empty (container) (canister) for recycling if available or discard in trash

(Optional for Product Supplied in Refillable Containers & Refill Package)

CONTAINER STORAGE/DISPOSAL Wipes Dispose of (wipe) (towelette) in trash after use Do not flush Container Refill only with (this product) (product name) Do not reuse or refill except as described in the directions for use Tightly close lid between uses to retain moisture Offer empty (container) (tub) for recycling if available or discard in trash Refill (Package) (Container) (Pouch) Nonrefillable (package) (container) (pouch) Do not reuse or refill this (package) (container) (pouch) Offer empty (container) (package) (pouch) for recycling if available or discard in trash

(Optional for Product Supplied in Resealable Packages)

CONTAINER STORAGE/DISPOSAL Wipes Dispose of (wipe) (towelette) in trash after use Do not flush Resealable (Package) (Pouch) Reseal label between uses to retain moisture Do not reuse or refill empty (pouch) (package) Offer empty (package) (pouch) for recycling if available or discard in trash

(Optional for Product Supplied in Single Use Pouches/Packets)

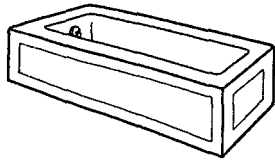
CONTAINER STORAGE/DISPOSAL Wipes Dispose of (wipe) (towelette) in trash after use Do not flush (Pouch) or (Packet) Offer empty (pouch) (packet) for recycling if available or discard in trash

(Optional for Product Supplied in plastic bags for use in Center Pull Dispensers)

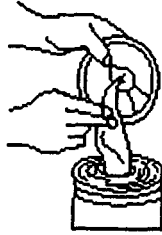
CONTAINER STORAGE/DISPOSAL Wipes Dispose of (wipe) (towelette) (cloth) in trash after use Do not flush Dispenser Refill only with (this product) (product name) Do not reuse or refill except as described in the directions for use Keep dispenser closed to retain moisture Plastic Bag Do not reuse or refill empty plastic bag Offer empty plastic bag for recycling if available or discard in trash

ACCEPTED
with COMMENTS
in EPA Letter Dated
6/28/15
Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended for the pesticide
registered under EPA Reg. No. 1839-223

9/10



Bathtub



Canister Directions



Changing Table



Computer



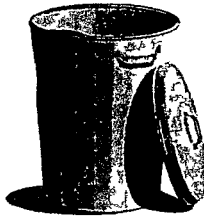
Baby crib



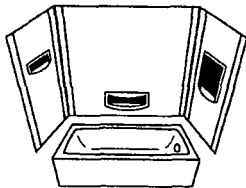
Door Knob



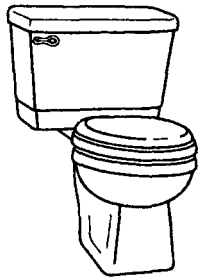
Faucet



Garbage Can



Tub and Shower walls



Toilet

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

4/28/12

Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended for the pesticide
registered under EPA Reg No *1839-223*

10/0

Pouch/Packet Label to be used with Master Container Label

SCTB Wipe

EPA REG NO 1839 223
EPA EST NO 1839 IL 01

Net Contents 1 (Wipe) (Towelette) (Cloth)

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ 30% C ₁₆ 5% C ₁₂ 5% C ₁₈) dimethyl benzyl ammonium chlorides	0 105%
Alkyl (68% C ₁₂ 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0 105%

INERT INGREDIENTS

	<u>99 790%</u>
Total	100 000%

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE (OUTER CONTAINER) (BOX) FOR PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

DISPOSAL DISPOSE (WIPE) (TOWELETTE) (CLOTH) IN TRASH AFTER USE DO NOT FLUSH DISCARD
EMPTY (POUCH) (PACKET) IN TRASH

ACCEPTED
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4/28/12

Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended or the pesticide
registered under EPA Reg No 1839 223