PM 31 60142-1 page 1 of 17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 28 1993

Veridien Corporation
11800 28th Street North
St. Peterburg, FL 33716

Attn: Robert Baker
Vice President Operations

Subject: Virahol
EPA Registration No. 60142-1
Letter dated July 8, 1993

The labeling (brochures) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. On the front page, delete the statement "The world's only patented, User-friendly hospital surface disinfectant". This is a comparative and misleading statement.

b. On the front page, delete the paragraph beginning with "Before VIRAHOL, healthcare practitioners...." and ending with "....food grade substances". This is a comparative and misleading paragraph.

c. On page 5 of the "Product Specifications and Technical Data" sheet, the sentence "The fast, total kill of disease causing..." appears to be an incomplete sentence. Please clarify.

d. Change "Hospital-Grade Disinfectant" to read "Hospital Disinfectant" wherever it appears in the brochure.

e. On the "Product Specifications and Technical Data, delete the words "Full-Strength".

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

f. On page 5 of the "Product Specifications and Technical Data" sheet, delete the sentence beginning with "VIRAHOL must be safe..." and ending "... with those exposed to to it".

g. On page 2 of the "Product Specifications and Technical Data" sheet, delete the sentence "The formulation is completely stable ..." or submit alternate language.

h. On page 3 under Section E, delete the sentences beginning with "These test determine..." and ending with "... to Class IV (the lower category)." This is considered a safe claim.

i. On page 3 under Section E, delete the sentence "These results prove that VIRAHOL is pleasant to use".

j. On page 4, under the subheading "Test: Acute Dermal Toxicity", include the words "when used as directed" after the word "safe".

k. On page 5, under the heading "Toxicology Summary", delete the sentence beginning with "The amazing fact is that VIRAHOL provides ...". This is a misleading sentence.

l. On page 6, under the heading "Viruses", change Herpes simplex" to read "Herpes simplex II".

m. On page 7, under the heading "Section G..." delete or rephrase the entire paragraph beginning with "Due to its unique formulation, ..." and ending with ".... for water-based disinfectants". This is a comparative and misleading statement.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,

John H. Lee
Product Manager 31
Antimicrbial Program Branch
Registration Division H7505C

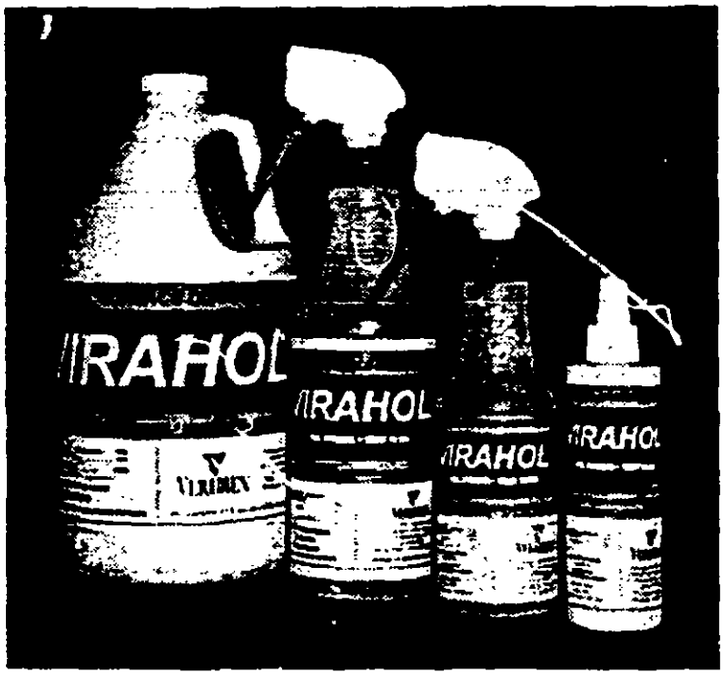
Enclosure

VERIDIEN

VIRAHOL®

The world's only patented, user-friendly hospital surface disinfectant.

Supply proof that no other hospital disinfectant is patented, as claimed.



Before VIRAHOL®, healthcare practitioners were forced to use disinfectants formulated with toxic chemicals. Not only were the users put at risk from those chemicals, but others were exposed to those same dangers from residues on surfaces, on equipment, and in the environment. These harsh chemicals also release unpleasant odors and stain or damage the equipment they are meant to disinfect. VIRAHOL® is unique among disinfectant formulations because it is organic (isopropanol-based) instead of aqueous (water-based). VIRAHOL® combines its non-aqueous isopropanol base (a known disinfecting agent itself) with propylene glycol, a maskant and other inert ingredients that are food grade substances.

- ***Hospital surface disinfection that is quickly efficacious against many organisims, including Tuberculosis.***
- ***A non-aqueous, non-conducting formulation to prevent damage caused by electrolic action.***
- ***Wetting ag t with action that penetrates organic material more quickly and completely.***
- ***Nontoxic* formulation that is convenient to use & co·npletely sta[illegible] periods wihout loss of efficacy.***
- ***A pleasant fragrence that freshens the areas where used.***

ACCEPTED
[illegible] Label
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

*Nontoxic - OSHA - 29 CFR 1910.1200

All testing on Virahol® has been confirmed by outside independent laboratories to further confirm the published results...

A Material Safety Data Sheet (MSDS) has been prepared for Virahol® in accordance with federal regulations after sucessful completion of following battery of tests:

TOXICOLOGY

- Inhalation Toxicology
- 14 Day Oral Toxicology
- Primary Ocular Eye Irritation
- Allergic Contact Dermatitis
- Primary Skin Irritation
- Acute Dermal Toxicity

MICROBIOLOGICAL EFFICACY

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Streptococcocus species
- Herpes simplex Type II
- HIV (Associated with AIDS)
- Fungi (athlete's foot)
- Poliovirus
- Tuberculosis

CHEMICAL SAFETY

- Specific Gravity
- Conductivity
- pH
- Viscosity
- Flash Point
- Boiling Point
- Vapor Pressure
- Separation
- Evaporation
- Stability
- Gas Chromatography
- Spectrophotometric Analysis

These tests are also normally used on all products in assigning a toxicity category rating which may range from Class I (Dangerous Substances) to Class IV (Nontoxic Substances). Extensive independent laboratory testing has confirmed that Virahol® is rated in the lowest category (Nontoxic Substances).

Virahol® is should be allowed to remain moist on a surface in excess of 10 minutes to provide a safety margin and to allow hidden or protected pathogens to be exposed and killed. The 10 minute contact time is the same as that recommended by the Centers for Disease Control (CDC).

VIRAHOL® IS COMPATABLE IN CONTACT WITH THESE MATERIALS:

- Aluminum
- Buna N Rubber
- Cast Bronze
- Epoxy
- Natural Rubber
- Neoprene
- Nylon
- Polypropylene
- PVC
- Silicone
- Stainless Steel (304, 316, 440)
- Teflon
- Titanium
- Tygon
- Viton

VERIDIEN Corporation
11800 28th Street North
St. Petersburg, Florida 33716
(813) 572-6636

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

PRODUCT SPECIFICATIONS & TECHNICAL DATA

TUBERCULOCIDE

BACTERICIDE

VIRUCIDE

FUNGICIDE

FULL-STRENGTH

READY-TO-USE

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

VIRAHOL®

HOSPITAL-GRADE DISINFECTANT

Environmentally Sensitive Solutions For Today's Healthcare Infection Control Challenges

[redacted]

PRODUCT SPECIFICATIONS & TECHNICAL DATA

SECTION A... *BACKGROUND*

VERIDIEN CORPORATION is a technologically-progressive, environmentally-sensitive company concerned with the alarming increase in worldwide epidemics of viral and bacterial infections. **VIRAHOL®** was conceived in 1986 by Paul and Diane Simmons in response to: (a) the dramatic rise of increasingly resistant infectious pathogens; and (b) heightened public awareness of communicable diseases. Their intensive research yielded the proprietary formulation for **VIRAHOL®**. Testing conducted by independent, certified laboratories validated its effectiveness against a long list of disease-causing pathogens.

VIRAHOL® is the world's first and only fully patented hard surface disinfectant. It ushers in an entirely new era in the critically important field of infection control. The development of **VIRAHOL®** was based on three simple, but powerful principles:

- **VIRAHOL®** must act quickly and totally against a broad spectrum of pathogens to assure maximum protection.
- **VIRAHOL®** must be safe and pleasant to work with. Its use cannot lead to unpleasant working conditions or pose a risk of injury or illness for those exposed to it.
- **VIRAHOL®** must be safe for use on all hard surfaces. It must not discolor, degrade, or damage when used properly.

VIRAHOL® meets all of these objectives completely. This monumental accomplishment resulted from a high level of dedication which is the hallmark of the team that developed **VIRAHOL®**. That same dedication drives the continuing effort both to expand the uses of **VIRAHOL®**, and to expand the family of its companion products.

SECTION B... *THE VIRAHOL® FORMULATION*

VIRAHOL® is unique among disinfectant formulations because it is organic (isopropanol-based) instead of aqueous (water-based). Aqueous disinfectants have highly toxic active ingredients (glutaraldehyde, phenols , etc.) that provide the killing action. But **VIRAHOL®** combines its non-aqueous isopropanol-base (a known disinfecting agent itself) with a blend of food-grade substances.

As stated on the label, **VIRAHOL®** has a deceptively simple formula. It contains 70% isopropanol (isopropyl alcohol) 10% Propylene Glycol, .25% maskant and 19.75% inert ingredients by weight. Together, the isopropanol and the other ingredients provide important benefits for the users:

- Hospital-grade disinfection that is quickly efficacious against pathogenic organisms, including Tuberculosis
- A non-aqueous formulation that is non-conducting to prevent damage caused by electrolytic action
- The wetting agent action penetrates organic material more completely

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

- The formulation is completely stable so it can be stored for long periods of time without losing efficacy
- Pleasant fragrance that freshens the areas where used

Other disinfectants can be supplied as a concentrate and require the addition of water onsite. This procedure presents major problems because the accuracy of the dilution step and the quality of the water used determine the effectiveness of the product. **VIRAHOL®** is carefully manufactured by rigid quality control standards. It is supplied, and is to be used, at full strength to assure absolute, repeatable efficacy and quality while eliminating the possibility of onsite dilution errors.

SECTION C... *INDEPENDENT LABORATORY TESTING*

Submissions to federal agencies (FDA, EPA, USDA) require tremendous amounts of laboratory testing, but confirmatory testing by outside independent laboratories is not required in all cases. Many products currently on the market, therefore, have passed government inspection with test results from their own laboratories only. Testing on **VERIDIEN** products has been confirmed by outside independent laboratories to strengthen the published results of each claim.

It is important that the independent laboratories chosen are reputable and objective, therefore, the selection process is critical and includes an investigation of their track record with the federal agencies. **VERIDIEN** has selected independent laboratories for microbiological, toxicological, and safety testing. The selections were stringent and provided a primary and alternate laboratory in all categories. Each regulatory filing includes extensive testing by the **VERIDIEN** laboratories, with confirmation testing by one or more of the independent laboratories.

A Material Safety Data Sheet (MSDS) has been prepared for **VIRAHOL®** in accordance with federal regulations after successful completion of the battery of tests shown on the following page.

TOXICOLOGY

- Inhalation Toxicology
- 14 Day Oral Toxicology
- Primary Ocular Eye Irritation
- Allergic Contact Dermatitis
- Primary Skin Irritation
- Acute Dermal Toxicity

MICROBIOLOGICAL EFFICACY

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Streptococcus species
- Herpes simplex II
- HIV (Associated with AIDS)
- Fungi (athlete's foot)
- Poliovirus
- Tuberculosis

CHEMICAL SAFETY

- Specific Gravity
- Conductivity
- pH
- Viscosity
- Flash Point
- Boiling Point
- Vapor Pressure
- Separation
- Evaporation
- Stability
- Gas Chromatography
- Spectrophotometric Analysis

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 6014-74

SECTION D... *CHEMICAL SAFETY*

During the R&D phase of a product, many formulations are tested in many ways to find the optimum product formulation. The three major areas of chemical testing are (a) formulation accuracy, (b) product safety, and (c) stability. Each product must always perform according to its label claims, but must also pass all of these test categories to be a **VERIDIEN** product.

Formulation Accuracy: *Specific Gravity, Conductivity, Viscosity, Gas Chromatography*
These must be checked by the VERIDIEN Quality Control Department to make sure the formula is strictly adhered to at all times during manufacturing.

Product Safety: *pH, Flash Point, Boiling Point, Vapor Pressure*
These tests make sure that the product is as safe and user-friendly as it should be.

Stability: *Separation, Evaporation, Spectrophotometric Analysis*
To insure maximum shelf-life and longevity of use, these tests are conducted on the stability samples at six month intervals.

SECTION E... *TOXICOLOGY*

A complete series of toxicology tests are required for EPA registration of all disinfectants. These tests determine whether the products are safe to use around humans and domestic animals. The results of each test will result in its assignment to a toxicity category from Class I (Dangerous Substances) to Class IV (the lower category).

Extensive independent laboratory testing has confirmed **VIRAHOL®** to be in Class IV, the lowest category. These results prove that **VIRAHOL®** is pleasant to use.

The following pages detail the independent laboratory tests that have been conducted to validate the efficacy of **VIRAHOL®** as well as its user-friendly characteristics.

Test: Acute Oral Toxicity

This test measures the possibility of harm from swallowing a given substance because there is always the possibility of accidental ingestion. **VIRAHOL®** was tested at the equivalent of an average adult male human drinking a full pint. **VIRAHOL®** was found to be non harmful at this level. Ten tests were conducted with equal results. Accidental ingestion of a small quantity of **VIRAHOL®** is not a medical emergency or a life threatening situation.

Test: Acute Dermal Toxicity

This test measures the possibility of harm from contact of a disinfectant on unprotected skin. It is extremely important in evaluating a disinfectant because opportunities exist for frequent and prolonged contact between unprotected skin and disinfecting solutions. To simulate the worst possible case, this test measures the effect if such contact took place continually for 24 hours. The test was conducted at a level that would be sufficient to saturate the front of a garment. Ten separate tests were conducted. In each case, **VIRAHOL®** was found to be nontoxic. Thus,

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

VIRAHOL® is safe to use without having to take precautions to protect exposed skin. Accidental splashes and even extended contact will not cause injury.

Test: Acute Inhalation

This test was designed to determine what effects might take place if the fumes from VIRAHOL® were breathed over a long period of time in a confined space or at a high concentration. This test is especially important because good ventilation conditions are not always available in the rooms where disinfectants are used. The use of a disinfectant that emits toxic vapors can lead to injury, sickness, or even death. This test was of a continuous exposure over a five hour period of the highest concentration that could be reached. Ten tests were conducted, and in all ten cases VIRAHOL® was found to be nontoxic. These results prove that VIRAHOL® can be used in normal settings with no special ventilation. In addition, users report that the fragrance is pleasant and acts as an air freshener to overcome offensive odors from other sources.

Test: Skin Irritation

Skin irritation is a significant problem for disinfectants. The frequent and prolonged contact by persons using disinfectants made from toxic chemicals has led to significant problems of skin irritation. VIRAHOL® has been subjected to three series of six tests each. The first series measured erythema (redness). The second measured skin drying. The third measured the probability of swelling. For each test, four observations were made and scored on a scale of 0 (no irritation of any kind) to 5 (primary irritation). Thus, a total of seventy two separate observations were made and scored. Each test simulated a continuous skin contact of four hours duration. On the basis of these tests, VIRAHOL® was certified as non-irritating.

Test: Dermal Sensitization

Dermal sensitization measures the tendency of skin to develop a sensitivity or allergic reaction to a substance after frequent or prolonged exposure.

To demonstrate that prolonged contact with VIRAHOL® would not lead to skin sensitization, a rigorous and complex series of tests was conducted. Forty two separate tests were conducted with a total of 360 measurements. VIRAHOL® was found to be totally non-sensitizing.

Test: Eye Irritation

The eye is one of the most delicate structures in the human body. In order to validate the safety of VIRAHOL®, comprehensive tests were conducted to determine any reaction in the event that it was splashed (or even sprayed) into the eyes. In conducting the tests, a total of 288 measurements were taken.

The results of these tests show that a person who manages to get a significant amount of VIRAHOL® directly in the eyes could expect to experience a temporary redness, but most substances, even those that are totally nontoxic, will irritate eyes and cause temporary redness. It is therefore advisable for users to take precautions to keep VIRAHOL® out of their eyes and, in the event of accidental contact, to flush the eyes as soon as possible with water or an eyewash solution.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 10142-1

TOXICOLOGY SUMMARY

VIRAHOL® is not dangerous to use. The amazing fact is that VIRAHOL® provides a total kill beyond the minimum requirements for a hospital-grade disinfectant, yet is not toxic.

SECTION F... *MICROBIOLOGICAL EFFICACY*

The fast, total kill of disease causing microorganisms by a disinfectant is what the concept that makes **VIRAHOL®** a truly valuable product. Numerous laboratory and clinical tests have already been conducted to validate the efficacy of **VIRAHOL®**, and further testing is underway against additional microorganisms.

Often, the ability to kill a given organism indicates that a product will be effective against a large variety of like or less resistant organisms. For example, the ability to control Tuberculosis is often considered evidence that a disinfectant is effective against all but bacterial spores because Tuberculosis is extremely difficult to kill.

The **VERIDIEN** policy in this area is cast in stone. No claim of efficacy is made that has not been conclusively proven in the laboratory and confirmed by independent laboratory testing. Most recently, that process has confirmed **VIRAHOL®** as efficacious against Polio and Tuberculosis.

Kill Times

When evaluating a disinfectant, extreme attention is paid to establishing the kill time. A disinfectant that requires an hour to be effective would be of little use, as would one that has a fast kill time because it is fatally toxic to humans. Also, the fact that a formulation can kill a given pathogen in a short time may be unimportant if it requires a very long time to kill others. Usually, extremely fast kill times apply to only one or a few organisms. **VIRAHOL®** is extremely fast acting and has achieved remarkably impressive kill and inactivation times. The ten minute contact time is the same as is recommended by the Centers for Disease Control (CDC).

Index Organisms

To be considered a hospital-grade disinfectant , **VIRAHOL®** had to successfully demonstrate its ability to consistently kill the three index organisms: Pseudomonas aeruginosa, Staphylococcus aureus, and Salmonella choleraesuis. These organisms have been widely accepted as important benchmarks for several reasons: (a) they are very common, (b) they represent three different types of challenges to the killing power of a disinfectant, and (c) they are all causes of serious diseases or infections in humans.

To assure that **VIRAHOL®** effectively controlled these organisms, 60 surfaces contaminated with each of these were run against each of three different batches of **VIRAHOL®**. For each of these samples, a positive control was run to assure the viability of the organism. This resulted in a total of 1,080 separate tests. In 100% of the samples, **VIRAHOL®** completely killed all test organisms, and in each case, the organism was exposed to **VIRAHOL®** for a maximum of only ten minutes.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

VIRUSES

HIV (AIDS virus): Three batches of **VIRAHOL®** manufactured at different times were each subjected to four separate tests for efficacy against the HIV virus. This series of tests required a total of 540 assays. Included in this were controls to assure that the effectiveness of **VIRAHOL®** would not be reduced by the presence of organic material or hard water. In all three cases, **VIRAHOL®** completely inactivated a three log concentration of HIV in less than 60 seconds to prove it is exceptionally effective against that important pathogen.

NOTE ABOUT PATHOGEN CHALLENGE: This is an excellent example of the magnitude of the challenge in these tests. HIV, as well as other pathogens, will normally be found in concentrations of a few organisms (called CFU or Colony Forming Units). Even serious contamination is limited to several hundred CFU. These tests are run against concentrations in the thousands or millions.

Herpes simplex: Of widespread concern, it is one of the current viral epidemics sweeping America. Tests similar to the ones for HIV were conducted utilizing three different batches of product and included controls for different and challenging conditions. **VIRAHOL®** achieved complete control in less than one minute.

Polio virus: This once dreaded killer has been well controlled in recent years but is still of concern in healthcare and other settings where there is risk of infection. Tests were conducted at a three minute exposure. The kill was total.

FUNGI

Trichophyton mentagrophytes is the organism causing athletes foot and is highly resistant to disinfectant control. A disinfectant that will achieve total control of Trichophyton mentagrophytes is considered effective against the other fungi as well. This test was performed with two different samples of **VIRAHOL®**. Two portions from each batch were tested with ten contaminated samples run against each. Thus, a total of 40 individual tests were completed. In addition, the Trichophyton mentagrophytes itself was tested for strength. **VIRAHOL®** exceeded the required test criteria on each of these samples. Thus, it is considered a completely effective fungicide with a ten minute maximum kill time.

TUBERCULOSIS

For decades, Tuberculosis (TB) had been assumed to be under total control in the United States, but during the past several years, it has resumed its position as a pathogen of immense concern. Immunosuppressed individuals such as cancer patients or those with AIDS are extremely susceptible to TB infection. The large number of such individuals in our society today has increased the number of reported TB cases.

Once an immunsurpressed person has contracted TB, it is difficult to diagnose and he/she can infect otherwise healthy individuals before being diagnosed and placed in isolation. A critical requirement for a modern hospital-grade disinfectant is its effectiveness against TB. In addition, Mycobacterium tuberculosis, which is the causative organism, is second only to bacterial spores in resistance to disinfectants. For this reason, many experts cite effectiveness against Mycobacterium tuberculosis as the primary way to separate a high-level disinfectant from an intermediate-level disinfectant.

The test for efficacy against Mycobacterium tuberculosis is one of the most demanding and complex for a disinfectant to pass. It consists of three separate exposures of ten samples each.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 6011 42-1

Each sample is incubated for a full 90 days to assure that the organisms have had ample time to recover in case they were only temporarily inactivated.

Independent laboratory testing has proven that VIRAHOL® passes this test with total success. This demonstrates that it is effective against one of the organisms of greatest concern in today's healthcare settings.

MICROBIOLOGICAL SUMMARY

VIRAHOL® is totally effective against the broad spectrum of pathogens which are of such serious concern in healthcare environments of the 1990's. What is truly remarkable is that, while achieving this excellence in effectiveness, it remains pleasant to use.

SECTION G... *MATERIALS COMPATIBILITY*

VIRAHOL® has been extensively tested in accordance with the concepts of ASTM Standard Test Methodologies against a wide range of materials commonly found in medical and dental settings. The following page lists the materials that have been validated as being compatible with the safe and effective formula of VIRAHOL®.

- Aluminum
- Buna N Rubber
- Cast Bronze
- Epoxy
- Natural Rubber
- Neoprene
- Nylon
- Polypropylene
- PVC
- Silicone
- Stainless Steel (304,316,440)
- Teflon
- Titanium
- Tygon
- Viton

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

Due to its unique formulation, VIRAHOL® leaves no residue when it evaporates from a surface. The formulation is organic and does not contain the harsh substances which usually lead to corrosion, discoloration, or damage. Many disinfectants rely in part on the fact that they are either very acid or very alkaline for their antimicrobial activity, but VIRAHOL® has a neutral pH. It is also non-conducting, to avoid damage by electrolysis, which is a problem for water-based disinfectants.

NOTE: VIRAHOL® is not designed to be used with acrylics.

Section H... *SUMMARY*

AIDS and Herpes are all dangerous diseases once thought limited in transmission to an exchange of blood or other body fluids during intimate contact. It is becoming increasingly clear that any contact with body fluids from an infected person can pose a risk of transmission of these bloodborne pathogens. Aspergillus infections (which can lead to fatal pneumonia in immunosuppressed persons) have emerged as a significant issue related to healthcare facilities. Tuberculosis has re-emerged and is expected to grow to major epidemic proportions by the mid 1990's. The environmentally-transmitted diseases, and those spread through contaminated blood and other body fluids, threaten to kill millions of people each year. VIRAHOL® represents the most responsible and effective solution to the disinfection challenges we face in fighting those diseases.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1

VERIDIEN

11800 28th Street North • St. Petersburg • Florida 33716 • 1-800-638-8592

15 7 17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 28 1993

Veridien Corporation
11800 28th Street North
St. Peterburg, FL 33716

Attn: Robert Baker
Vice President Operations

Subject: Virahol
EPA Registration No. 60142-1
Letter dated April 19, 1993

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to include TB claims, is acceptable, subject to the comments listed below.

1. Change "Hospital-Grade Surface Disinfectant" to read "Hospital Disinfectant" wherever it appears on the label.

2. Revise the statement "Prepare a fresh solution for each use or when solution becomes visibly dirty" to read "Prepare a fresh solution for each use".

The AOAC Tuberculocidal Test data is acceptable to support effectiveness of the product as a Tuberculocide against Mycobacterium tuberculosis when used undiluted on precleaned, hard, non-porous surfaces for a contact time of 10 minutes at 20°C.

The submitted Tubercolocidal Test data have satisfied our requirements to support TB claims. Therefore, no additional TB data are required to be submitted.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,

John H. Lee
Product Manager 31
Antimicrbial Program Branch
Registration Division H7505C

Enclosure

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

HOSPITAL SURFACE DISINFECTA

VIRAHOL

U.S.

FULL STRENGTH ● TUBERCULOCIDE ● VIRUCIDE ● HERPECIDE ● BACTERICIDE ●

ACTIVE INREDIENT - Isopropanol	70%
INERT INGREDIENTS	30%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

1992 VERIDIEN CORPORATION

VERIDIEN

VERIDIEN CO
11800 28TH ST
ST. PETERSBU
(813) 57

EPA Reg. N
EPA Est. No.

NET CONTENTS - 1 U.S. GALLON - (128 Fluid Ou

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 60142-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Avoid contact with eyes, may cause eye irritation.
Wash hands with soap and water after use.

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, immediately flush with plenty of water.
Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE

KEEP AWAY FROM HEAT & OPEN FLAME

STORAGE AND DISPOSAL

STORAGE

Store in a cool, dry place.

CONTAINER DISPOSAL

Do not reuse empty container. Triple rinse container with water. Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. Avoid smoke.

PESTICIDE DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an appropiate waste disposal facility.

EFFECTIVE AGAINST A BROAD RANGE OF PATHOGENS

HIV (Associatedwith AIDS)	Mycobacterium tuberculosis	Pseudomonas aeruginosa
Staphlococcus aureus	Salmonella choleraesuis	Herpes simplex Type II
Poliovirus Type I	Trichophyton mentagrophytes	

COMPATIBLE IN CONTACT WITH THESE MATERIALS

Aluminum	Buna N	Cast Bronze
Epoxy	Natural Rubber	Neoprene
Nylon	Polypropylene	PVC
Silicone	Stainless Steel(304,316,440)	Teflon
Titanium	Tygon	Viton

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with it's labeling.

Virahol® Hospital-Grade Surface Disinfectant is designed for effective deodorizing and disinfection of hard inanimate surfaces such as walls, sink tops, tables, chairs, telephones and bed frames.

TO DISINFECT CONTAMINATED SURFACES AND OBJECTS:

For heavily soiled areas, or surfaces or objects soiled with blood or body fluids, a precleaning step is required. Use a clean sponge or lint-free cloth.

On precleaned surfaces, apply Virahol® Hospital-Grade Surface Disinfectant with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Allow surfaces to remain wet for 10 minutes. Prepare a fresh solution for each use or when solution becomes visibly dirty.

Inactivates HIV on precleaned environmental surfaces & objects previously soiled with blood or body fluids in healthcare settings or other settings in which there is a expected likelihood of soiling 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 (HIV) (Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES AND OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

Personal Protection: When handling items soiled with blood or body fluids use disposable latex gloves, gown, mask and goggles.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of Virahol Hospital-Grade Surface Disinfectant.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to Federal, state, and local regulations for infectious waste disposal.

Contact Time: Apply Virahol® Hospital-Grade Surface Disinfectant with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Allow surfaces to remain wet wet for 1 minute to insure total inactivation of HIV virus. This contact time will not control other common types of viruses and bacteria.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 28 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 60142-1