

70263-3

07/19/2006

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ana Rodriguez-Koster  
Agent for Microban Systems, Inc.  
Lewis and Harrison  
122 C. Street N.W. Suite 740  
Washington, D.C. 20001

JUL 19 2006

Subject: Microban X-580 Instructional Spray Plus  
EPA Reg. No. 70263-3  
Application Dated: June 15, 2006  
Receipt Date: June 19, 2006

Dear Ms. Rodriguez-Foster,

The following notification submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9 and provisions of PR Notice 98-10, is unacceptable.

**Proposed Notification**

- Addition of alternate marketing language.
- Addition of various indoor, nonfood use sites.
- Addition of the alternate statement "Do not use in medical devices"
- Addition of the non-pesticidal claim "Cleans" and directions for use.
- Re-categorizing of the statement "Test fabric or surface in an inconspicuous area for color fastness or adverse reaction" as alternate marketing language.

**Comments**

Based on a review of the material submitted, the following comments apply:  
The proposed application as a notification is unacceptable. This should be resubmitted as a label amendment. Some of the proposed additions as antimicrobial uses are not compatible with the insecticide uses and require more thorough review. A copy has been placed in our records for future reference.

**CONCURRENCES**

SURNAME	DATE						
M. J. Smith	07-14-06						

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Should you have any questions or comments concerning this letter, please contact  
Velma Noble at (703) 308-6233.

Sincerely,



for

Velma Noble  
Product Manager (31)  
Regulatory Management Branch1  
Antimicrobial Division (7510c)

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# LEWIS & HARRISON

122 C Street, N.W., Suite 740  
Washington, D.C. 20001  
telephone 202.393.3903  
fax 202.393.3906

Consultants in Government Affairs

June 15, 2006

VIA FEDERAL EXPRESS

Document Processing Desk [NOTIF]  
Office of Pesticide Programs (7504P)  
U. S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**ATTENTION: Velma Noble**  
**Product Manager, Team 31**

**SUBJECT: Microban Systems, Inc.**  
**Microban X-580 Institutional Spray Plus (EPA Reg. No. 70263-3)**  
**Notification of Minor Label Changes per PR Notice 98-10**

Dear Ms. Noble:

On behalf Microban Systems, Inc., I am submitting a Notification of minor label changes for their end-use product, **Microban X-580 Institutional Spray Plus (EPA Reg. No. 70263-3)**. The purpose of this Notification is to make the following minor changes to the product label:

1. Addition of alternate marketing language. Please note that the added statements simply rephrase the marketing language present on the latest EPA stamped accepted label dated 9/24/2003.
2. Addition of various indoor, nonfood use sites to page 4 of the label. Please note that these use sites are already present on the latest EPA stamped accepted label dated 9/24/2003 under "General Method of Application" (page 3).
3. Addition of the alternate statement "Do not use on medical devices" for labels that list medical premises and metal/stainless steel surfaces.
4. Deletion of the statement "Shake well before and during use." **Microban X-580 Institutional Spray Plus** is a ready-to-use homogeneous mixture that does not need to be mixed or shaken prior to or during use.
5. Addition of the non-pesticidal claim "Cleaner" and brief directions that pertain to it.
6. Re-categorizing of the statement "Test fabric or surface in an inconspicuous area for color fastness or adverse reaction" as alternate marketing language given that the label already instructs users that the product "should not stain those materials not stained by water."

All additions involve no change in the ingredients statement, signal word, use classification, precautionary statements, first aid, physical/chemical properties, or storage and disposal language. Furthermore, the additions do not substitute for or conflict with label text, and are not false or misleading.

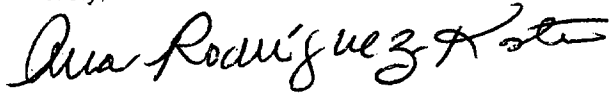
Enclosed please find the following documents in support of this submission:

1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10;
2. One (1) copy of the proposed product labeling, with changes highlighted; and,
3. One (1) clean copy of the proposed product labeling.

Thank you for your assistance with this submission. If you have any questions, please call me at 202-393-3903 x.17 or e-mail me at [alkoster@lewisharrison.com](mailto:alkoster@lewisharrison.com) if you have any questions.

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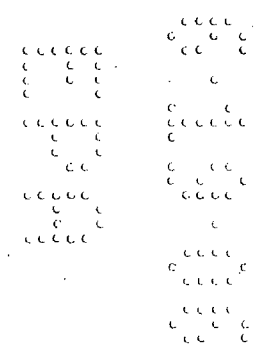
Sincerely,



Ana Rodriguez-Koster  
for,  
Microban Systems, Inc.

Enclosures

cc: Cliff Zlotnik, Microban Systems, Inc.  
Bill Todd, Preventec International, LLC





United States  
 Environmental Protection Agency  
 Washington, DC 20460

Registration  
 Amendment  
 Other: Notification

OPP Identifier Number  
 265394

**Application for Pesticide - Section I**

1. Company/Product Number 70263-3		2. EPA Product Manager Velma Noble		3. Proposed Classification	
4. Company/Product (Name) <b>Microban X-580 Institutional Spray Plus</b>		PM# Team 31		<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted.	
5. Name and Address of Applicant (Include ZIP Code) Microban Systems, Inc. 4660 Elizabeth Street Coraopolis, PA 15108 <b>PLEASE DIRECT ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</b> <input type="checkbox"/> Check if this is a new address			6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		

**Section - II**

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_  
 Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application  
 Notification - Explain below.  Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**NOTIFICATION OF MINOR LABEL CHANGES PER PR-NOTICE 98-10**

**Notification of MINOR LABELCHANGES in Accordance With PR Notice 98-10**

*This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.*

Signature: *Ana Rodriguez-Koster* Date: *6/15/06*

**Section - III**

**1. Material This Product Will Be Packaged In:**

<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes* <input type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt.      No. per container	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt.      No. per container	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input type="checkbox"/> Plastic: <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
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**\*Certification must  
be submitted**

<b>3. Location of Net Contents Information</b> <input type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b>	<b>5. Location of Label Directions</b> <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
<b>6. Manner in Which Label is Affixed to Product</b> <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)**

Name: <b>Ana Rodriguez-Koster, Lewis and Harrison, LLC</b> 122 C St., NW Suite 740 Washington, DC 20001	Title: <b>Agent for Microban Systems, Inc.</b>	Telephone No. (Include Area Code): <b>(202) 383-3903 ext. 17</b>
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**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

<b>2. Signature</b> <i>Ana Rodriguez-Koster</i>	<b>3. Title: Agent for Microban Systems, Inc.</b>	<b>6. Date Application Received (Stamped)</b>     
<b>4. Typed Name</b> Ana Rodriguez-Koster, Lewis & Harrison LLC	<b>5. Date</b> 6/15/2006	

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United States  
**Environmental Protection Agency**  
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number  
**265394**

**Application for Pesticide - Section I**

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**NOTIFICATIONS**

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt.    No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

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# MICROBAN

## X-580 INSTITUTIONAL SPRAY PLUS

**[MOLD &] MILDEWCIDE [MILDEWSTAT] • BACTERICIDE [BACTERIOSTAT]**  
**• FUNGICIDE [FUNGISTAT]**  
**DISINFECTANT • ANTI-MICROBIAL**  
**INSECTICIDE AND DEODORANT**

FOR INSTITUTIONAL, HOUSEHOLD, FARM PREMISE USES AND ANIMAL QUARTERS

[Microban Formula X-580 Institutional Spray Plus is a Broad Spectrum Disinfectant Against most Bacteria and is also effective in controlling insects, fungus and bacterial or organic odors.]  
[Commercial Insecticide & Multi-Purpose Antimicrobial Cleaner]  
[Kills and Controls Insects, Mold, Mildew, Fungus and Bacteria\*]  
[Cleaner]  
[Apply Every 28 Days as an Insecticide]

### ACTIVE INGREDIENTS

o-Phenylphenol .....0.22%  
Diisobutylphenoxyethoxy ethyl dimethyl  
benzyl ammonium chloride monohydrate .....0.70%  
N-octyl bicycloheptene dicarboximide .....0.33%  
Piperonyl butoxide technical .....0.20%  
Pyrethrins .....0.10%

INERT INGREDIENTS .....98.45%

TOTAL .....100.00%

[ equivalent to (butylcarbityl) (6-propyl piperonyl) ether: 0.16% and related compounds: 0.04% ]

E.P.A. Reg. 70263-3  
E.P.A. EST. 70263-PA-001

### KEEP OUT OF REACH OF CHILDREN

### WARNING

#### FIRST AID

IF IN EYES:	<ul style="list-style-type: none"> <li>• Hold eye 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED:	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>

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

See other precautions [and First Aid] on side panel

Net Contents 8 OZ. (0.237) Litres 1 PT. (0.473) Litres 1 QT. (0.946) Litres  
1 GAL. (3.785) Litres 5 GAL. (18.925) Litres 55 GAL. (208.175) Litres

[Mfg by:] [Manufactured for:] [Distributed by:] MICROBAN® SYSTEMS, INC., 1135 Braddock Ave., Braddock PA 15104-1706

**SHAKE WELL BEFORE AND DURING USE**

U.S. Patent No. 3,458,629

Microban X-580 Institutional Spray Plus (EPA Reg. No. 70263-3)  
Revised 6/15/2006 via Notification

Language in brackets ( ) denotes alternate marketing language that may or may not be used

## GENERAL METHOD OF APPLICATION

Surfaces and objects must be cleaned of gross filth with suitable detergent before treatment. Spray surfaces and articles until thoroughly wet, use enough so that treated surfaces and objects remain wet for at least 10 minutes. May be applied with a sponge to pre-cleaned, hard non-porous surfaces [(such as impervious covers and surfaces)], allowing to dry for 10 minutes. For fogging and other large volume applications use appropriate spraying equipment, protective clothing, gloves and respirator. Heavily treated spaces should be adequately ventilated and not re-entered for at least one hour after treatment.

**AS A MILDEWICIDE, FUNGICIDE AND BROAD SPECTRUM DISINFECTANT:** (Kills most gram negative and gram positive bacteria and influenza virus). In hospitals, operating rooms, emergency rooms, lobbies, hallways, patient rooms, wards, washrooms, scrub stations, mop rooms, morgues, pathology labs, nurse's stations, laboratories, veterinary clinics and other health care facilities; in schools, hotels, motels, restaurants, offices, homes and industrial buildings. For use on pre-cleaned hard non-porous surfaces such as glazed tiled porcelain, waste receptacles, compactors, on, in and around rest room fixtures, toilet seats, locker rooms, telephones, door knobs, hospital apparatus and equipment, furniture and empty containerized storage units. For athletes foot fungus on floors, shower stalls and rest rooms. Follow method of application specified above. [Do not use on medical devices.]

### **AS A BACTERIOSTAT, FUNGISTAT AND DEODORIZING AGENT**

Apply Microban® Formula X-580 Institutional Spray Plus as directed to floors, walls, ceilings that have been damaged by smoke, fire, floods and sewage backups. For cleanup operations in areas such as attics, wall voids, basements, areas above suspended ceilings and similar inaccessible spaces in buildings. Spray avian, rodent and other animal and human wastes and carcasses as directed above, prior to removal and disposal. Treat spaces and surfaces as specified in method of application. For use as a bacteriostat, fungistat and deodorizing agent on carpeting found in schools, hotels, motels, homes, shelters, commercial, industrial and public buildings. After flood or water damage, vacuum or extract as much water as possible before application. Apply full strength with sprayer until moist to carpet nap and rake or brush in. To treat the backing and padding a fogger is recommended. Allow to remain dry. For best results, carpets should be cleaned before application.

*(Note for reviewer: 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

*(or)*  
Do not use on medical devices

### **AS A CLEANER**

Apply Microban® Formula X-580 Institutional Spray Plus undiluted to surfaces with a cloth, mop, sponge, or sprayer. Wipe or allow to air dry.

### **TO DISINFECT FARM PREMISES, POULTRY HOUSES, ANIMAL PENS AND VEHICLES**

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers, with soap or detergent and rinse with potable water before reuse. Apply Microban Formula X-580 Institutional Spray Plus full strength as directed in general method of application until thoroughly wet. Allow all surfaces to dry thoroughly, ventilate enclosed spaces adequately. Do not house animals in treated areas until thoroughly dry and free from odors.

### **PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**WARNING:** May be harmful if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Causes eye (and skin) irritation. Do not get in eyes, on skin or on clothing.

### **PHYSICAL AND CHEMICAL HAZARDS**

Flammable. Keep away from heat and open flame.

*(Note to Reviewer: the following language will be used on containers larger than 1 gallon in size.)*

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.  
PESTICIDE STORAGE: Keep from freezing. Store in ventilated areas.  
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.  
CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

*(Note to Reviewer: the following language will be used on household/residential containers.)*

#### **STORAGE AND DISPOSAL**

If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Microban X-580 Institutional Spray Plus (EPA Reg. No. 70263-3)

Revised 6/15/2006 via Notification

Language in brackets ( ) denotes alternate marketing language that may or may not be used



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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.

Microban® Formula X-580 Institutional Spray Plus should be applied with hand or power operated sprayers, foggers, automated metering systems or gravity drip dispensers as an insecticide, bactericide, mold and mildewicide, fungicide and deodorizing agent, to previously cleaned surfaces. Spray areas until thoroughly moist, giving special attention to cracks and crevices. Allow ten to twenty minutes for drying. It is not necessary to wipe the sprayed surface.

Microban® Formula X-580 Institutional Spray Plus should not stain those materials not stained by water.

Direct and repeat spraying of **Ants, Roaches, Bedbugs, Silverfish and other harmful insects** and in the cracks, crevices and hidden surfaces where they hide are necessary for control. Apply every 28 days or as often as needed.

**To Kill Fleas and Ticks:** Remove and destroy old animal bedding. Spray sleeping quarters of animals, floor areas, around baseboards, window and door frames, cracks, crevices and wherever the presence of these insects are suspected. Repeat as necessary. Thoroughly vacuum rugs and carpets prior to application. Do not spray animals. Put fresh bedding in animal quarters after spray has dried. Treat animals with a registered flea and tick control product before allowing them to enter treated area.

**To Kill Sowbugs, Centipedes, Firebrats and Mites:** Contact as many insects as possible with the spray. Also thoroughly spray all parts of the room suspected of harboring these pests. Special attention should be paid to cracks, crevices, hidden surfaces under sinks, basement and utility rooms, floors, doorjams, behind and under stoves and refrigerators.

**To Kill Flies, Mosquitoes, Gnats and Wasps:** Close all doors and windows and spray upward into center of room with a slow sweeping motion. Spray 5-10 seconds for average room. Keep room closed for 15 minutes after spraying. Ventilate room thoroughly before re-entry. Sweep up and destroy fallen insects. Before spraying cover exposed food and utensils.

**To Kill Carpet Beetles, Lice and Moths:** Clean all articles prior to application. Thoroughly spray top and undersides of rugs and carpets. Thoroughly spray the interiors of lockers, trunks, closets, cupboards and other storage areas. Spray directly on restroom fixtures. When treating upholstered furniture and mattresses thoroughly spray exterior, paying particular attention to seams and folds. Interior should be treated to eliminate hidden infestations.

Microban® Formula X-580 Institutional Spray Plus when used as directed is effective in decontaminating the treated exposed surfaces of bedding, mattresses, textiles, drapes, upholstered furniture, rugs, carpets and in storage areas to control mold, mildew, fungus, insects and odors wherever they are a problem.

SHAKE WELL BEFORE AND DURING USE  
TEST FABRIC OR SURFACE IN AN INCONSPICUOUS  
AREA FOR COLOR FASTNESS OR ADVERSE REACTION

- Pest Control Service
- Odor Control Service
- Carpet Cleaning Service
- Water Damage Service
- Restoration Service
- Disinfection Service
- Waste-Removal Service
- Cleaning Services
- Offices
- Health Care Facilities
- Restrooms
- Furniture
- Trash Chutes and Garbage Rooms
- Waste Compactors
- Storage areas and Basements
- Condensation collection and Drainage areas
- Refuse trucks
- Second hand furniture stores
- Shoes & boots
- Commercial, Industrial, Institutional, and Public Buildings
- Hotels and Motels
- Hospitals
- Shower Stalls
- Floors
- Movie booths
- Bowling alleys
- Exercise rooms
- Veterinaries [Veterinary Clinics]
- Laundry receiving stations
- Antique shops
- Upholsters shops
- Schools
- Restaurants
- Laboratories
- Toilet Seats
- Waste Receptacles