

1677-158

2-10-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 10 2003

Brian Brosdahl
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390


**Subject: KX-6049
EPA Reg. No. 1677-158
Your Re-Submission Dated 11/12/02 (Original Amendment Dated 3/14/2002;
Prior Re-Submissions Dated 3/14/02 and 6/14/02)**

The latest re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which responds to the label changes required in the EPA letter dated 9/10/02, and which adds a new section for sanitizing the outside surfaces of food containing packages, replaces the bottled water and water filter sterile-rinse statement with an FDA rinse statement listed in 21 CFR 129.80(d)(5), replaces the accidentally deleted use directions for antimicrobial treatment of returnable containers, adds specific organisms to the conveyor section, adds a non-pathogenic bacteriophage control section, deletes the "asphalt" use from disinfection, changes the single disinfection use rate of 0.2% to a range of 0.2-1.0% with an acceptable justification, changes the official primary brand name to "Vortexx", and makes other label changes, is acceptable with the following label change.

On page 3 in the foam sanitizing section, change "Contact your Ecolab representative for information on Liquid K and a recommended foamer", to the following, "Contact your Ecolab representative for information on the Liquid K or EcoCare 600 FA foaming agents, and a recommended foam generation device." You have certified to the Agency that EcoCare 600 FA is an alternate name for Liquid K, and does not represent a formula change in Liquid K.

A copy of the label stamped "Accepted With Comments" is attached. Submit three copies of a final printed label which makes the change listed above. Submit a copy of this letter with your response. If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	SURNAME	DATE						

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VORTEXX

ACID LIQUID SANITIZER FOR FOOD PROCESSING EQUIPMENT
in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

DISINFECTANT

Hospitals, Nursing Homes, Health Care Facilities, Schools, Colleges, Veterinary Clinics, Animal Life Science Laboratories, Industrial Facilities, Dietary Areas, Office Buildings, Recreational Facilities, Retail and Wholesale Establishments, Animal Care Facilities, Veterinary Facilities, Farms, Livestock Quarters, Poultry Premises, and Poultry Hatcheries

STERILANT FOR ASEPTIC MANUFACTURING AND PACKAGING EQUIPMENT

DISINFECTANT FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

Active Ingredients:

Hydrogen Peroxide.....	6.9%
Peroxyacetic Acid.....	4.4%
Octanoic Acid.....	3.3%

Inert Ingredients:..... 85.4%

Total: 100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

1677-158

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. When spraying or fogging, wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

FIRST AID

IF IN EYES: 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 eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

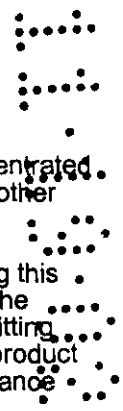
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not anything by mouth to an unconscious person.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS: (containers 5 gal. or greater) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



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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.

SANITIZATION

VORTEXX is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

NOTE: FOR MECHANICAL OPERATIONS prepared use solutions may not be reused for sanitizing but may be reused for other purposes such as cleaning.
FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

SANITIZING FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1 to 2 ounces **VORTEXX** per 6 gallons of water (0.13 - 0.26% v/v concentration). At this dilution **VORTEXX** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa*, and *Vibrio cholerae* as well as beverage spoilage organism *Lactobacillus malefermentans*. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly. Do not rinse.

SANITIZING EATING, DRINKING, AND FOOD PREP UTENSILS

1. Remove gross food particles by a prescrape, preflush and, when necessary, a presoak treatment.
2. Wash with detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1 to 2 ounces **VORTEXX** per 6 gallons of water (0.13 - 0.26% v/v concentration). Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Drain and air dry.

ELEVATED TEMPERATURE SANITIZING

At a temperature of 120 F. **VORTEXX** can be used as a food contact sanitizer at 1 oz. per 14 gallons water (0.055% v/v concentration). At this concentration **VORTEXX** is effective against *Staphylococcus aureus* and *Escherichia coli*. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute, unless otherwise specified by governing sanitary code. Drain thoroughly. Do not rinse.

SANITIZING TABLEWARE

For sanitizing tableware in low-temperature (minimum 120 F) warewashing machines, inject **VORTEXX** into the final rinse water at a concentration of 0.055% v/v (1 oz. per 14 gallons of water) at 120 deg F. Allow 1 minute contact. Air dry.

To insure that the **VORTEXX** concentration does not fall below 0.055%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your local Ecolab Specialist for technical assistance and further information on sanitizing tableware in warewashing machines.

FINAL SANITIZING BOTTLE RINSE

VORTEXX may be used as a final sanitizing rinse for returnable and non-returnable bottles (e.g. glass or PET) at a 0.13% dilution (1 oz to 6 gallons). At this dilution **VORTEXX** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Vibrio cholerae*, and *Lactobacillus malefermentans*. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Drain thoroughly. No rinse necessary.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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CONTINUOUS TREATMENT OF CONVEYORS

Wash, rinse and sanitize conveyor equipment. During processing, apply Vortexx at no more than 0.13% - 0.26% v/v (1 to 2 oz. per 6 gallons of water) concentration to conveyor with Mikro Master or other suitable feeding equipment. At this dilution **VORTEXX** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa*, and *Vibrio cholerae*. Controlled volumes of Vortexx are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of Vortexx from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray the processing equipment with Vortexx solution at not more than 0.26% v/v concentration. Conveyor equipment must be free of product when applying coarse spray. Conveyor surface should be exposed to the sanitizing solution for a period of not less than 60 seconds.

SANITIZING NON-FOOD CONTACT SURFACES

Preclean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, drip pans with 1 oz **VORTEXX** per 8 gal water (0.1% v/v concentration). At this concentration the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* in 500 ppm hard water. The product is also effective against beverage spoilage organisms: *Aspergillus niger*, *Saccharomyces cerevisiae*, *Pediococcus damnosus* and *Lactobacillus malefermentans*. All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. No rinse necessary.

SANITIZING HARD, NON-POROUS OUTSIDE SURFACES OF AIRTIGHT, SEALED PACKAGES CONTAINING FOOD OR NON-FOOD PRODUCTS

VORTEXX may be used as a final sanitizing rinse for hard, non-porous outside surfaces of airtight, sealed packages containing food or non-food products at a 0.13% - 0.26% v/v dilution (1 to 2 oz. per 6 gallons water). All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly. No rinse necessary.

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FOAM SANITIZING NON-FOOD CONTACT SURFACES

VORTEXX is an effective foam sanitizer of precleaned non-food contact surfaces, such as boots, floors, walls, and drains, and equipment surfaces. For this application, prepare a solution of 0.13% v/v (1 oz. per 6 gallons water) **VORTEXX** and 0.13% v/v (1 oz. per 6 gallons water) **Liquid K**. For example, in six gallons of water, add 1 ounce of **VORTEXX** and 1 ounce of **Liquid K**. Apply solution as a foam using recommended equipment. Wet surfaces thoroughly. At this concentration, the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, and *Listeria monocytogenes*. Surfaces should be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on Liquid K and a recommended foamer.

DIRECTIONS FOR FOGGING

To sanitize hard surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces: Prior to fogging, food products and packaging materials must be removed from the room or carefully protected. Fog desired areas using one quart of a 0.2% to 1.3 % **VORTEXX** solution (3 oz. to 14 oz. per 8 gallons of water) per 1000 cu. ft. of room volume. Vacate the area of all personnel during fogging and until the hydrogen peroxide air concentration is below 0.5 ppm. Allow surfaces to drain thoroughly before operations are resumed. Solutions above 0.5% may be corrosive and are not to be used on all surfaces. Test solutions on surfaces prior to use. All hard non-porous food contact surfaces treated with the disinfectant and fog must be rinsed thoroughly with a potable water rinse.

SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For sanitization against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* as well as beverage spoilage organisms, *Aspergillus niger*, *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Saccharomyces cerevisiae*, apply 0.1 - 0.5% (1 to 5 oz. per 8 gallons of water) of **VORTEXX** to surfaces at a temperature of 25 to 45 deg. C and allow to remain wet for at least 5 minutes. Allow surfaces to drain thoroughly before operations are resumed. Drainage may be followed by a potable or sterile water rinse.

SANITIZE PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE BOTTLED WATER CONTAINERS

To sanitize precleaned or new returnable or non-returnable containers for bottled water processing, apply **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 40 to 60 deg. C for at least 7 seconds. At these conditions, **VORTEXX** is effective against *Staphylococcus*

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VORTEXX label

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aureus, Escherichia coli, Salmonella typhi, Pediococcus damnosus, Lactobacillus malefermentans, Saccharomyces cerevisiae and Aspergillus niger. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

ANTIMICROBIAL TREATMENT OF WATER FILTERS

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus, Lactobacillus malefermentans, Saccharomyces cerevisiae and Aspergillus niger,* apply **VORTEXX** as a 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) solution at 25 to 45 deg C for a minimum contact time of 5 minutes. After thorough draining, rinse filters with a disinfected water rinse free of pathogenic bacteria.

ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus, Lactobacillus malefermentans, Saccharomyces cerevisiae and Aspergillus niger,* apply **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 40 to 60 deg C for at least 7 seconds. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS WITH THE ADDITION OF SURFACTANT

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus, Lactobacillus malefermentans, Saccharomyces cerevisiae, and Aspergillus niger,* apply **VORTEXX** as follows. Add 6.7 oz. of surfactant product to 10 gallons of prepared **VORTEXX** solution. Prepare **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) solution. Use one of the following surfactants, KX-7014, KX-7015, KX-7016, or KX-7017. Apply at a temperature of 40 to 60 deg C with a contact time of at least 7 seconds. After thorough draining, rinse interior container surfaces with disinfected water rinse free of pathogenic bacteria.

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BACTERIOPHAGE CONTROL

VORTEXX will reduce the incidence of *Lactococcus lactis* subsp. *Lactis, lactococcus lactis* subsp. *Cremoris,* and *Streptococcus thermophilus* bacteriophage in cheese manufacturing establishments by spraying or immersion of equipment at concentrations of 1-2 oz. per 6 gallons (0.13 - 0.26% concentration) of water. All surfaces should be exposed to the solution for a period of one minute. Drain thoroughly. Do not rinse.

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DISINFECTION

VORTEXX disinfects as it cleans in one operation. **VORTEXX** can be used to disinfect floors, walls and other hard, nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of Use: In Hospitals, use **VORTEXX** for Surgical and Obstetrical Suites; Housekeeping Services; Physical Therapy Departments; Nursing Services; Autopsy Facilities. Also, use **VORTEXX** in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments. Not for use on food contact surfaces, medical devices or medical equipment surfaces.

Combination Disinfection and Cleaning

VORTEXX is effective against *Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa* at 0.2% - 1.0% (1 oz/4 gallons to 5 oz/4 gallons) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue on hard nonporous surfaces. For heavily soiled areas a precleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

Virucidal

At 0.2% (1 oz/4 gl) **VORTEXX** is effective against Influenza B, Influenza A(H3N2), Influenza A (H1N1), Influenza A (H10N7) and Reovirus on hard inanimate surfaces when used at 20 deg C with a 10 minute contact time in the presence of 500 ppm hard water and organic soil. Apply as directed under disinfection.

Fungicidal

VORTEXX can be used on hard nonporous inanimate surfaces such as shower room floors, locker room benches, shower stalls and bath mats. At 0.2% (1oz/4gl) the product is effective against *Trichophyton mentagrophytes* (Athletes Foot Fungi) and *Candida albicans* (pathogenic yeast) in the presence of

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VORTEXX label

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protein (5% blood serum) and soap scum in 500 ppm hard water with a 10 minute contact time. Apply as directed under disinfection.

STERILIZATION OF MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT IN ASEPTIC PROCESSES

Prior to use of this product, remove gross soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a 5% sterilizing solution of VORTEXX. Circulate, coarse spray, or flood the sterilizing solution as appropriate to the equipment. All surfaces should be exposed to the sterilizing solution for 30 minutes. This product is effective against *Clostridium sporogenes* and *Bacillus subtilis* at 5% (25 oz/4 gl) in 100 ppm hard water and 5% organic load at 20 deg C. Thoroughly rinse food contact surfaces with either a sterile water or potable water rinse. This product is not for use as a sterilant on medical devices.

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

VORTEXX is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities.

VORTEXX is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* at 0.2% (1 oz/4 gl) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue. For heavily soiled areas a precleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product should be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT

ACCEPTED
with COMMENTS
in EPA Letter Dated:
FEB 10 2003

EPA Reg. No. 1677-129
EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2(R),
1677-TX-1(D), 1677-OH-1(H), 1677-IL-1(J), 1677-GA-1(M),
1677-PR-1(B), 1677-CA-1(S), 1677-NJ-1(W), 1677-WV-1(V)
Superscript refers to first letter of date code

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Ecolab Food and Beverage Division
Ecolab Inc., 370 N. Wabasha Street
St. Paul, MN 55102

U.S. Patent No. 5200189 and 5314687
Other Patents Pending

Net Contents:	1 U.S. Gal. (3.78 L)	•••••
	4 U.S. Gals. (15.1 L)	•••••
	2.5 U.S. Gals. (9.45 L)	•
	15 U.S. Gals. (56.8 L)	•••••
	30 U.S. Gals. (113.5 L)	•••••
	50 U.S. Gals. (189 L)	•••••
	300 U.S. Gals. (tote)	•••••