



09/28/2012

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

September 28, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Cristina Griffin
Agent for KIK Pool Additives, Inc.
Delta Analytical Corporation
12510 Prosperity Drive Suite 160
Silver Spring, Maryland 20904

Subject: Shock Power 67
EPA Registration No.: 7616-78
Application Date: 09/12/2012
Receipt Date: 09/14/2012

Dear Ms. Griffin:

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Alternate brand names:
 - Kem-Tek Pool & Spa Care Super Shock Quick 20
- Additional label claim, "salt system compatible"
- Symbols and graphics

General Comments

Based on a review of the submitted materials, your notification for the alternate brand name above, the additional label claim, symbols and graphics is acceptable. It is in compliance with PR notice 91-2 and in agreement with the label. This has been made a part of your file.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-0410 or by e-mail at harris.monisha@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
NOTIF

Application for Pesticide - Section I

1. Company/Product Number 7616-78	2. EPA Product Manager Monisha Harris	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) KIK Pool Additives Inc. / Shock Power 67	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) KIK Pool Additives Inc. c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 <i>Check if this is a new address</i>		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

Amendment - Explain below
 Resubmission in response to Agency letter dated _____
 Notification - Explain below.

Final printed labels in response to Agency letter dated _____
 "Me Too" Application.
 Other - explain below.

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

Label Notification (PR-Notice 98-10) to add minor label claims, graphics and an alternate brand name: "Kem-Tek Pool & Spa Care Super Shock Quick 20".

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 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material this Product will be Packaged in:

Child-Resistant Packaging <input type="checkbox"/> Yes* For retail <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	2. Type of 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," Unit Package wgt. No. per container	

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Direction <input type="checkbox"/> On Label or: <input type="checkbox"/> On Labeling accompanying product
6. Manner In Which Label Is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other: _____		

Section - IV

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

Name Cristina Griffin	Title Agent for KIK Pool Additives Inc.	Telephone No. (Include Area Code) 301-680-7971
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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 kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for KIK Pool Additives Inc.	6. Date Application Received (Stamped)
4. Typed Name Cristina Griffin	5. Date September 12, 2012	

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September 12, 2012

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

Attn: Monisha Harris, PM 32

RE: Notification per PR Notice 98-10 to make minor label changes

Product: Shock Power 67
EPA Reg. No.: 7616-78
Company: KIK Pool Additives Inc.

Dear Ms. Harris:

On behalf of KIK Pool Additives Inc., I am submitting a notification per PR Notice 98-10 to add minor label claims, graphics and an alternate brand name, "Kem-Tek Pool & Spa Care Super Shock Quick 20", for Shock Power 67, EPA Reg. No. 7616-78. The minor label claims include "salt system compatible" which EPA approved on another similar KIK Pool label. Under the label claims (page 4), symbols and their corresponding text have been grouped for ease of use. The double asterisk (**) symbol was added to link "weekly use" under directions for use to the number of gallons claim. The symbol (†) and corresponding text was added to clarify the timing claim, and is the same as the changes made per EPA's request for the product EPA Reg. No. 7616-73. (All other non-highlighted claims on this label were approved by EPA in the 04/19/12 stamped label). The graphics are consistent with label claims that have been approved by EPA.

The following documents are enclosed in support of this notification:

- EPA form 8570-1
- One copy of the revised label (changes are highlighted)

If you have questions, please contact me at 301-680-7971 or cgriffin@delta-ac.com.

Sincerely,

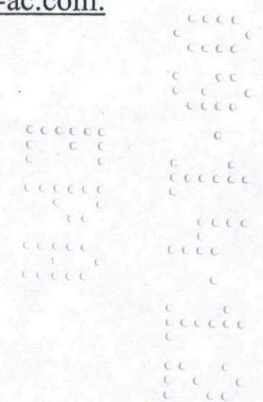

Cristina Griffin

Agent for KIK Pool Additives Inc.

Enclosures

cc: Elvia Angulo, KIK Pool Additives Inc.
Justin Lowe, KIK International

12510 Prosperity Drive Suite 160 Silver Spring, Maryland 20904
(301) 680-7971 fax (301) 680-7975 www.delta-ac.com



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Shock Power 67

[Adding the following new Alternate Brand Name:]

Kem-Tek Pool & Spa Care Super Shock Quick 20

[Previously approved Alternate Brand Names to be used with kit containing EPA Reg.# 7616-57 and -78:]

Aqua Guard Swimming Pool Winterizing Kit

Kem Tek Swimming Pool Winterizing Kit

[Previously approved Alternate Brand Names:]

Aqua Guard Super Shock Quick

Great Value Super Shock Quick

Kem Tek Shock & Swim

Kem Tek Super Shock Quick

Leslie's Swimming Pool Supplies Genesis Shock

Leslie's Swimming Pool Supplies Genesis Shock Fast Dissolving Trichlor Shock

Leslie's Swimming Pool Supplies Genesis Shock Fast Dissolving Tri-Chlor Shock for Swimming Pools

Paddock Super Shock Power

Pro Side Super Shock Quick

Pro Side Winterizing Kit

Swimming Pool Winterizing Kit

NOTIFICATION
Date Reviewed: 9-28-12
Reviewed By: J. CARL

Active Ingredient:

Trichloro-s-triazinetriene.....67.0%

Other Ingredients33.0%

Total.....100.0%

[60.3% available chlorine or Available Chlorine – 60.3%]

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE BACK PANEL FOR FIRST AID STATEMENT AND OTHER PRECAUTIONS

[or SEE FIRST AID STATEMENT AND ADDITIONAL PRECAUTIONS ON BACK PANEL]

[the "See back panel..." may be omitted if all labeling is on the same panel, e.g., the kit box]

Net [Wt.]: _____

[The following may appear in any appropriate place on the label:]

Manufactured by [for]:
KIK Pool Additives Inc.
5160 E. Airport Dr.
Ontario, Calif. 91761

[Optional: Following may be included in addition to "Manufactured by [for]" address above: Distributed by [or Sold by] [or Marketed by] Insert additional company name and address]

EPA Reg. No. 7616-78
EPA Est. Nos.: 7616-CA-01

[Free Pool Care Advice 1-800-SOS-POOL • www.kem-tek.com]

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Danger: CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. May be fatal if inhaled. Do not breathe dust or spray mist. Irritating to nose and throat. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID: Call a poison control center [(1-800-222-1222)] or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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. **If on Skin or Clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **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. **If swallowed:** Have 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 give anything by mouth to an unconscious person. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

[First Aid may be in table form]

[For containers smaller than 50 pounds use the following:]

Environmental Hazards

This product is toxic to fish and aquatic organisms.

[In accordance with PR notice 95-1, use the following complete Environmental Hazards statement for containers 50 pounds and larger]

Environmental Hazards

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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.

Physical or Chemical Hazard

STRONG OXIDIZING AGENT. WILL BURN WITH THE EVOLUTION OF CHLORINE AND EQUALLY TOXIC GASES. CONTACT WITH WATER SLOWLY LIBERATES IRRITATING AND HAZARDOUS CHLORINE CONTAINING GASES. DECOMPOSES AT 460° F TO 480° F WITH THE LIBERATION OF HARMFUL GASES.

Mix only with water. Use clean, dry utensils. Do not add this product to any dispensing device containing remnants of any other product. Such use may cause a violent reaction leading to fire or explosion. Contamination with moisture, organic matter or other chemicals may start a chemical reaction with the generation of heat, liberation of hazardous gases and possible generation of fire or explosion.

IN CASE OF FIRE, if possible, isolate container in open air or well-ventilated area. Flood with a large volume of water. [IN CASE OF] CONTAMINATION [OR DECOMPOSITION:] do not reseal container.

[Optional Label Claims/location optional:] [Claims may be in upper or lower case]

[Insert #] Pack

[Insert #] Step Pool Care System

ABC Smart[er] [Pool Care] [System]

Add Directly to [Skimmer] [or] [Pool]

Add [Dry Product] Through Skimmer or Directly To Pool

Buffered Sanitizer Shock Treatment For Crystal Clear Water

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

Built In Clarifier

C

Can Be Used In Salt Pools

Clarifies Water

Clears Cloudy Water

Compatible With Salt Pools

Contains 5 *[or other number]* [x 13.5 oz. *[or other size]*] [Convenient Pre-Measured] Pouches

Contains A Filter Enhancer

Contains No Calcium *[or Calcium Free]* *[info for customer who needs a calcium free product for pool]*

Controls Algae *[[&] [And]]* Bacteria*

Controls Algae Sanitizes Pool Water

Convenient Skimmer Application

Destroys [Organic] [Swimmer] [Contaminants] [Wastes]

Dissolves [Completely] [Instantly] [Quickly]

Do Not Mix This Product With Any Other Product

Do Not Pre-Dissolve

[Each Pouch] Treats XX,XXX Gallons Of Water ***[size] [[&] [And]]*

Easy Skimmer Application

Enhances Filtration

Fast [Acting] [Dissolving] [Dissolving Shock] [Sanitizer]

Fast Dissolving Tri-Chlor Shock For Swimming Pools

For All Pool[s] [Surfaces] [Including Vinyl, Plaster *[[&] [And]]* Fiberglass]

For [Daily] [Everyday] Chlorination *[[&] [And] [or]]* Shock

For Heavy Bather Loads *or* After Heavy Rains

For Pool Startup *[[&] [And]]* Weekly Shock Treatment

For Shocking *[[&] [And]]* Everyday *[Or Daily]* Chlorination

For Superchlorination *[or Super-Chlorination]*

For Use As A Shock

For Use With All Pool Surfaces

Good For All Pool Surfaces

Ideal for Use After Heavy Rains

Ideal For Vinyl Pools

Improves Filter Performance

Keeps Water [Clean] [Crystal Clear]

Kills [Algae] *[[&] [And] [or]]* [Bacteria] [Rapidly]

No Need To Pre-Dissolve

One Bag Treats 15,000 Gallons *[change # gallons according to size of package]*

Oxidizer

Part C

Part Of The Kem Tek Pool Care System

Part Of The Simply Smart^{er} [Pool] [Care] [System]

Patented [Chlorine] [Formula] [Technology]

pH Balanced

Pools, Patios *[[&] [And]]* Spas

Quality *[[&] [And]]* Satisfaction Guaranteed *Or Your Money Back*

Quick [Dissolving] [Formula] [Shock Treatment]

Quick Chlorine Boost

Quick Sanitizer

Reduces Chemical Needs

Reduces Chlorine Odor

Removes Organic [Contaminants] [Waste *[[&] [And]]*] *[Produces Sparkling Swimming Pool Water]*

Restores A Crystal Clarity To Pool Water

Routine Maintenance Chlorinator

Salt System Compatible

Shock

Shock Treatment *[[&][And]]* Super Chlorinator For Swimming Pools *[[&] [And]]* Spas Patented Technology

Shocks Water Clear

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets]] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

[Simply C] [Smart(er) C] [Step C]
 Simply Smart(er) [Pool Care] [System]
 Stabilized
 Step [Insert #]
 Suitable For [Closing Pools] [Opening Pools] [Pool Closing] [Pool Winterization][Use In All Pools]
 Swim [After Use] [In 15 Minutes†] [In Just 15 Minutes After Use†]
 Swimming Pool Water Disinfectant
 Use For [Closing Pool] [Opening Pool]
 Use Once [A] [Per] Week
 UV Protected
 Works Immediately

[location optional:]

*During Super-Chlorination

**[reader's note: this double asterisk links to Weekly Use in the Directions for Use]

†Pool may be used in 15 minutes after adding this product only when chlorine level is at or below 3 ppm.

[Optional Claims and marketing language continued (previously approved):]

SHOCK TREATMENT

Shocking / Super Chlorinating Your Pool Water

Shock the pool when:

- An increased number of swimmers are using the pool.
- Chloramines are present in the water and the chlorine is not effectively working.
- The water is cloudy even though a proper chlorine level is maintained.

Shocking must be done periodically to remove waste materials like suntan oils, perspiration, body oils and other organic waste.

SHOCK SCHEDULE

Summer – Once per week

Fall – Twice per month

Spring – Twice per month

Winter – Once per month

SHOCK POWER 67 Features & Benefits:

Patented Formula / Dissolves Quickly / Controls Algae and Bacteria*

The best time to shock is early evenings with the pool circulating system in operation. This way the sun will not reduce the effectiveness of the treatment.

The SHOCK POWER 67 Advantages:

[This patented blend of ingredients] [or SHOCK POWER 67] [or This product] works fast allowing swimmers back into the pool in just 15 minutes. This is a premium grade shock product, so it takes only [10 oz.] [or 12.5 oz.] [or 13.5 oz.] [or 1 lb.] of SHOCK POWER 67 to treat 12,000 [to 15,000] [or to 18,750] [or to 20,000] [or to 24,000] gallons of pool water.

SHOCK POWER 67 can be added directly into the water without pre-dissolving and it is ideal for all types of swimming pools. It destroys swimmer wastes and other impurities that cause cloudy water. SHOCK POWER 67 dissolves faster than ordinary shock products without leaving residue. It does not increase the pH of the pool water or contain calcium that causes scale build-up.

DO NOT PRE-DISSOLVE [IN CONTAINER (ie. bucket)] BEFORE APPLYING.

[READ ALL PRECAUTIONARY STATEMENTS BEFORE USE]

Step #1	Step #2	Step #3	Step #4	Step #5
Balance	Chlorinate	Shock	Algae Care	Clarify

[The following wording can be used depending on size of package:]

For 10 oz package:TREATS 15,000 GALLONS!

For 12.5 oz package:TREATS 18,750 GALLONS!

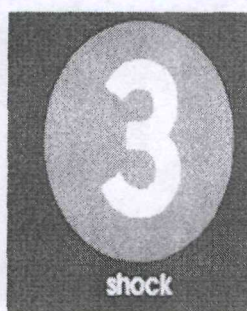
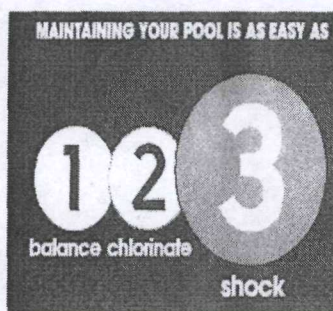
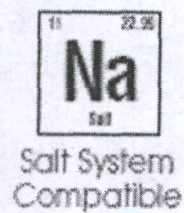
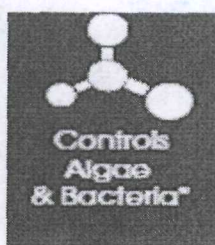
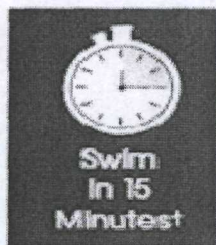
For 13.5 oz package [pouch]: TREATS 20,000 GALLONS!

For 1 lb package: TREATS 24,000 GALLONS!

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

[GRAPHICS]



DIRECTIONS FOR USE

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

DAILY USE: [After steps 1 and 2 [or insert letter or other number]], regularly check chlorine residual with a test kit and chlorinate daily or as needed to maintain 1.0 to 1.5 ppm residual chlorine. NOTE: 2¼ ounces of this compound per 10,000 gallons of pool water will increase an existing chlorine level by 1.0 ppm (¼ rounded measuring cup = 1 oz.)

[]WEEKLY USE [or ROUTINE USE]:**

1. Check the pH of the pool water daily, adding sodium bisulfate [(may insert product name)] or soda ash [(may insert product name)] or equivalent products as necessary to maintain pH in the 7.2-7.6 range.
2. SHOCK POWER 67 is made up of fine particles that dissolve almost instantly when applied to water. Use the entire bag for each application [(if applicable)]. For best results, pour a steady stream of SHOCK POWER 67 into the deep end of the pool or pour [it] into the skimmer with the pump operating. Pour near the water surface (particularly if the wind is present while applying) to ensure the entire dose enters the water.
3. Operate the pump system 4-8 hours (minimum) after applying SHOCK POWER 67. [4.] Use 10 oz. of SHOCK POWER 67 to treat 12,000 -15,000 gallons of pool water every week for best results.

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

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SUPER CHLORINATION: Whenever the pool water loses its sparkle, turns green, or the chlorine residual falls rapidly after regular chlorination, super chlorinate the pool. During the summer months, super chlorinate the pool with 1 lb. per 10,000 gallons of pool water every 10 to 14 days. Do not use the pool until the chlorine residual has dropped to 3 ppm.

[The following directions may be used without other directions on labeling:]

TO CLOSE POOL FOR WINTER: adjust pH, if necessary, to 7.2 – 7.6. Next, use one (1) pound per 10,000 gallons to shock (superchlorinate) to a chlorine level of 5ppm. For best results, pour a steady stream of SHOCK POWER 67 into the deep end of the pool or pour into the skimmer with the pump operating. Pour near the water surface (particularly if the wind is present while applying) to ensure the entire dose enters the water. Operate the pump system 4-8 hours (minimum) after application. Do not add algaecide or apply pool cover until chlorine level drops below 5 ppm.

[Reader's Note: Other appropriate ounces product and corresponding gallons of water treated may be substituted]

STORAGE AND DISPOSAL

STORAGE: Keep product in tightly closed container when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container in open area if possible, and flood with large amounts of water. **CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. **IF EMPTY:** Place in trash [collection] or offer for recycling if available. **IF PARTLY FILLED:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

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[Optional: Kit Label front panel]

[Brand name AQUA GUARD™ or Kem Tek™ may be used]

[optional]: 5-Step Pool Care System

SWIMMING POOL WINTERIZING KIT

For Closing Pool for the Winter
Algaecide – Shock – Metal Out

FREE POOL CARE ADVICE
1-800-SOS-POOL

[this information may be on another panel]

Net Contents:

- ___ Qts [or Gal]

[insert ABN for 7616-57]

- ___ Lbs.

[insert ABN for 7616-78]

- ___ Gal. **Aqua Guard Metal Out**

[Non-EPA registered product; may substitute name for same product]

KEEP OUT OF REACH OF
CHILDREN

NO SE DEJE AL ALCANCE DE LOS
NIÑOS

DANGER

See back and side panels and individual
containers for first aid statements
and other precautions

[Note: Kit is to include EPA Reg. No. 7616-57 and 7616-78 labels fully visible on outside kit box as well as on the corresponding container inside the box.]

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]

[[Information in brackets[] is optional or instructional; italics in brackets indicate instructions not part of labeling.]

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[Optional: Kit Label]

[The following may placed on front, side, or back panel of box and/or as an insert]

STEPS FOR USING WINTERIZING KIT:

- (1) Clean pool by skimming, brushing and vacuuming thoroughly.
- (2) Add Aqua Guard Metal Out [or similar brand name for non registered product] per dosage in directions for use.
- (3) Balance pool water. Adjust pH to 7.2- 7.6. Adjust Alkalinity to 80-120ppm.
- (4) Shock (superchlorinate) pool. Follow [insert ABN for EPA Reg. No. 7616-78] dosage in directions for use.
- (5) Allow the chlorine level to drop below 5.0 ppm before adding algaecide and using pool cover.
- (6) When chlorine level reaches 3 ppm, add [insert ABN for EPA Reg. No. 7616-57] per dosage in directions for use.
- (7) Lower pool water level 12" - 18" below the skimmer for mesh covers and 3" - 6" below the tile for solid, floating covers.
- (8) Winterize the pool plumbing and equipment properly according to region weather and manufacturer's instructions.

[The following information may be used on the insert or panel containing this information, location optional]

**SWIMMING POOL
WINTERIZING KIT**
For Closing Pool for the Winter
Algaecide – Shock – Metal Out
FREE POOL CARE ADVICE 1-800-SOS-POOL

[The following may appear in any appropriate place on the box label or on the insert:]

Manufactured by [for]:
KIK Pool Additives Inc.
5160 E. Airport Dr.
Ontario, Calif. 91761

[Optional: Following may be included in addition to "Manufactured by [for]" address above: Distributed by [or Sold by] [or Marketed by] Insert additional company name and address]

[In the text "this product" or alternate brand name may be substituted for Shock Power 67 name]
[[Information in brackets] is optional or instructional; italics in brackets indicate instructions not part of labeling.]