

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 06 1982

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
4524-24

FOR THE DAIRY FARM Sanitizing with KABON.

IN THE MILKHOUSE—Sanitize milking equipment by immersion or recirculation with KABON solution containing one ounce KABON to 4 gallons of water (200 ppm).

UDDER WASHING WITH KABON—Approximately one minute before applying milking unit, wash and massage teats with a clean paper towel wetted with a solution of KABON at 1 oz. to 4 gallons of water at 110°F. Provides 200 ppm solution. Never reuse towels or dip a used towel back into solution. Always use freshly prepared solutions and non-corrodible utensils.

DILUTION DIRECTIONS: Stir 1 oz. KABON into 4 gallons water (200 ppm. solution).

In all applications an exposure time of at least two minutes should be maintained. The temperature of the solutions should be maintained. The temperature of the solution should be 75°F. or above. The pH of the solution should be 6.0 or higher.

Use dilutions providing not more than 200 ppm. active quaternary (1 oz. KABON in 4 gallons water) do not require a final potable water rinse in accordance with Federal Food Additive Regulation 178-1010.

FOR THE FOOD PLANT Sanitizing with KABON.

KABON sanitizing solutions are stable at temperatures up to boiling.

SANITIZING PREVIOUSLY CLEANED SURFACES WITH KABON. For fittings pipelines, pumps, freezers, vats, etc., use 1 ounce KABON per 4 gallons water (200 ppm).

KABON is a concentrated sanitizing agent and should be diluted before using.

KABON solutions should not be used with soaps or anionic detergents as such mixtures will impair the anti-bacterial effectiveness of KABON.

Authorized by USDA for use in federally inspected meat and poultry plants.

H.B. Fuller*

SUPER KABON®

10% Solution
QUATERNARY GERMICIDE
REG. U.S. PATENT OFFICE

ACTIVE INGREDIENTS: N-Alkyl (50% C₁₂, 40% C₁₄, 10% C₁₆)

dimethyl benzyl ammonium chloride..... 10.0%

Ethanol..... 2.5%

INERT INGREDIENTS: Water..... 87.5%

E.P.A. Registration No. 4524-24 E.P.A. Est. No. 4524-MN-1 100.0%

DANGER: KEEP OUT OF REACH OF CHILDREN
See side panel for additional precautions

H.B. Fuller Company
Monarch Chemicals Division

3900 Jackson Street Northeast
Minneapolis, Minnesota 55421

NET CONTENTS: 1 U.S. GAL.

(3.785 LITERS)

MONARCH SUPER KABON FOR USE AS A HAND SANITIZING DIP IN FOOD PLANTS

1. Wash hands thoroughly with soap and water.
2. Rinse hands thoroughly.
3. Dip hands in a solution containing Monarch Super Kabon made at the rate of 1 oz. of Monarch Super Kabon to 4 gallons of water.
(This solution contains 200 ppm active quaternary ammonium compound).

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Form 81

ACCEPTED
with COMMENTS
in EPA Letter 1144-2

DEC 06 1982

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4524-24

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REG. U.S. PATENT OFFICE

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H. B. Fuller Company
Monarch Chemicals Division

3900 Jackson Street Northeast
Minneapolis, Minnesota 55421

NET CONTENTS: 1 U.S. GAL.

3.785 LITERS

DANGER:

KEEP OUT OF REACH OF CHILDREN

CORROSIVE, CAUSES SEVERE EYE & SKIN DAMAGE

Do not get in eyes, on skin or clothing. Wear goggles or face shield, rubber gloves when handling.

HARMFUL OR FATAL IF SWALLOWED

AVOID CONTAMINATION OF FOOD

FIRST AID: In case of contact immediately flush eyes or skin promptly with water for at least 15 minutes. For Eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly a large quantity of milk, egg white, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous injection of a short-acting barbiturate drug.

Do not reuse container. Destroy when empty.

Form 810-001

SANITIZING DIP IN FOOD PLANTS
soap and water.

Monarch Super Kabon made at the
Kabon to 4 gallons of water.
(ppm active quaternary ammonium compound).

06 DEC 1982

H. B. Fuller Company
Monarch Chemical Division
P.O. Box 21159
Minneapolis, MN 55421

Attention: Jeanne Brooks Dahl
Microbiologist

Gentlemen:

Subject: Monarch Super Kabon (added use--hand sanitizing)
EPA Registration No. 4524-24

A review has been completed by both EPA and FDA and the following comments apply:

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

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

- a. The product name as declared on your application form "Monarch Super Kabon" must be consistently declared throughout the label text. Abbreviated variations are not acceptable.
- b. Verify your correct company's address. The company's address as declared on your application form must be declared on the label.

Our records indicate that company number 4524 is located at 3900 Jackson Street N.E. If P.O. Box 21159 is your new address, submit an address correction to our office.

- c. We prefer the word Danger (center panel only) to appear directly below the statement "KEEP OUT OF REACH OF CHILDREN."
- d. Revise the statement:
See side panel for additional precautions

to read:

See side panel for additional precautionary statements.

- e. Revise the statement

"FIRST AID"

to read:

Statement of Practical Treatment

- f. Add the following statements:

Precautionary Statements
Hazards to Humans and domestic animals

to appear directly above the statement "DANGER (upper right panel only).

- g. Add the following statements:

Directions for Use

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

to appear at the top of left panel.

- h. Revise the statement

Do not reuse container. Destroy when empty

to read:

STORAGE AND DISPOSAL

PROHIBITIONS

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. OPEN DUMPING IS PROHIBITED.

PESTICIDE DISPOSAL

Pesticide, spray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

Metal Containers:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other approved state and local procedures.

Plastic Containers:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

- i. Revise the entire NOTE to Physician to read:

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

- j. Revise the statement:

178.1010

to read

21 CFR 173.1010

- k. Revise the statement (food plant section): *freezers, cuts, etc.*

to read:

"...freezers, vats, and other hard nonporous surfaces..."

- l. Add the following statements (food plant section):

Remove gross food particles and soil. Pre-clean all surfaces. Rinse with potable water prior to application of sanitizing solution. Apply with mop brush or cloth. Thoroughly wet all surfaces. Treated surfaces must remain wet for one minute, followed by adequate draining. Fresh solution should be prepared daily or when use solution becomes visibly dirty. For mechanized applications, use solution may not be reused for sanitizing applications.

2. Ref: Hand sanitizing claim

Note that the FDA is currently reviewing all OTC drugs including topical antimicrobials to establish conditions whereby they are generally recognized as safe and effective. Proposed regulations covering these preparations were published in the Federal Register September 13, 1974, vol. 39, No. 172, part II and January 6, 1978, vol. 43, No. 4, Part II.

Pending final regulations covering these types of claims, we have no objections to the label claim: Hand sanitizer, as declared on your label.

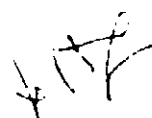
However, future label revisions and/or data requirements may be required once these above regulations are in effect.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

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.

Sincerely yours,

John H. Lee 
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosures

TS-767C:J.LEE:DCR-03522:WANG-0887C:qmm:Raven:479-2013:10/28/82