Petition for Glycolic Acid Inclusion in National Organic Program

Item A - Section Petitioned for Inclusion:

- Synthetic substances allowed for use in organic livestock production, § 205.603.

Item B— Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned:

1. The substance's chemical or material common name.

Glycolic acid or hydroxyacetic acid; IUPAC Name 2-hydroxyethanoic acid

2. The manufacturer's or producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.

Manufacturer:
The Chemours Company
1007 Market Street
PO BOX 2047
Wilmington, DE 19899
302-773-1000

Contact:
Jeff Horsager Global Product Manager
The Chemours Company
5325 Wooddale Ave
Edina, MN 55424
952-922-6626
Jeff.horsager@chemours.com

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).

Glycolic acid is chemically synthesized, but is also a naturally-occurring compound present in the human body, a natural constituent of milk, and in a variety of food substances. It is also widely used in cosmetic applications, such as chemical skin peels and skin care products at concentrations up to about 30 percent to improve human skin conditioning due to its excellent capability to penetrate skin. Once applied, glycolic acid reacts with the upper layer of the epidermis, weakening the binding properties of the lipids that hold the dead skin cells together. This allows the stratum corneum to be exfoliated, which in turn increases the production of live skin cells and other elastin skin compounds.

The current use of Glycolic Acid in livestock production is as a pre and post milking sanitizing teat dip that aids in reducing the spread of mastitis-causing organisms. It is an alternative active ingredient in teat dips to iodine. Its microbial effects are similar to iodine, a NOP accepted synthetic ingredient for livestock production. Glycolic acid has the added benefit of penetrating into the skin and exfoliating the outer layer of skin. This promotes healing of compromised skin (such as cracks and wrinkles) thereby improving teat condition. Glycolic acid, as an active ingredient in teat dips, and working together with an emollient, improves the animal's skin condition equating to the betterment and safety of the animal. Glycolic acid teat dips have excellent disinfection properties to provide fast reduction of contamination that can lead to contagious mastitis and continue to disinfect the teat and teat canal between milkings.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.

Glycolic acid, an excellent germicide, will be used as the active ingredient in teat dips for pre-post and barrier dipping year round. The rate is 3% glycolic acid in a solution that contains emollients and other excipients. The method of application includes dipping, spraying, or in automatic milking machines. It is recommended to use a non-return dipping cup, providing fresh dipping solution for each use. A clean cup should be started or if the solution becomes visibly dirty or sediment is introduced.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.

The majority of the world's supply of glycolic acid is made in a catalyzed reaction of formaldehyde with synthesis gas (carbonylation of formaldehyde), as this is a particularly economical preparative route. Other methods, not apparently in use, include hydrogenation of oxalic acid with nascent hydrogen and the hydrolysis of the cyanohydrin derived from formaldehyde. The carbonylation of formaldehyde route of manufacture has no impurities of toxicological concern. Glycolic acid can be isolated from natural sources, such as sugarcane, sugar beets, pineapple, cantaloupe, and unripe grapes. But none of these natural sources have a high enough concentration to economically isolate and concentrate from nature. Glycolic acid can also be prepared using an enzymatic biochemical process which requires less energy in production.

Although glycolic acid is found in nature and is the smallest of the “fruit acids”, no natural source of glycolic acid has a concentration high enough that would allow for economical extraction/concentration. In fact extraction of glycolic from natural sources would be energy intensive and generate a lot of waste material. As a result, all glycolic acid commercially available today is made by one of three processes:

1. High temperature/High pressure continuous flow route practiced by The Chemours Company (formerly DuPont). This is the dominant form of glycolic acid production globally. Formaldehyde and carbon monoxide are the raw materials.
2. Neutralization and reacidification of monochloroacetic acid (MCA). This is small, batch conversions of MCA to glycolic acid with chlorinated organic and salt impurities. MCA is made from chlorine gas and acetic acid. Sodium hydroxide neutralizes the MCA and HCl reacidifies the product to glycolic acid.
3. Enzymatic conversion of glycolonitrile to glycolic acid. Glycolonitrile is made from hydrogen cyanide and formaldehyde and has a similar impurity profile as the high temperature and pressure route of manufacture.

All of these processes would be considered synthetic routes of manufacture. No “natural” source of glycolic acid is viable.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.

No previous organic certification applications are known. For non-agricultural certification of cleaning formulations, formulations inclusive of glycolic acid have been accepted by the Underwriter Laboratories' EcoLogo program.

Glycolic acid is approved by ECHA (European Chemical authority) for use in veterinary hygiene disinfectants and food and feed area disinfectants.

Full Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) registration in Europe.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

Glycolic acid is an EPA registered manufacture use product for hard surface disinfecting cleaning formulations. End use product labels included in Attachment 1 are Chemours formulation EPA label # 71654-5 (pages 7-12) and Clorox' Pine Sol product, 5813-101 (pages 13-21).

Glycolic acid is the active ingredient in DeLaval's teat dips currently drug listed with the FDA, NDC 55756 – 065 (OceanBlu™ Barrier) and 55756-062 (OceanBlu™ PrePost). See Attachment 1 for the aforementioned example labels on pages 22 and 23.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.

CAS #: 79-14-1

9. The substance's physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

a) Glycolic acid is an organic acid and will react with bases to form a neutralized solution. Ending pH is dependent upon the relative amount of glycolic acid and base. It is compatible with most commonly used formulating compounds. As with any acid, it should not be used with or mixed with bleach containing products as chlorine gas can form.
b) Glycolic acid has low toxicity and is non-persistent in the environment. It is considered readily biodegradable being 90% degraded in 7 days. See Attachment 2 for the Glycolic Acid Toxicity Summary.
c) No environmental impacts are expected from the use and/or manufacture of glycolic acid. Available data has shown that glycolic acid is readily biodegraded and is non-toxic to fish, aquatic animals, aquatic plants and mammals.
d) No impacts on human health are expected from the proposed use of glycolic acid. First, most glycolic acid is metabolized by animals and incorporated into proteins, fats and carbohydrates. Secondly, as noted above, glycolic acid does not result in any adverse health effects in humans upon ingestion.
e) No known effects on soil organism or livestock.

Link to ECHA (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances)

Link to NICNAS (http://www.nicnas.gov.au/chemical-information/information-sheets/existing-chemical-info-sheets/glycolic-acid-safety-factsheet)

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

See Attachment 3 for the Safety Data Sheet.

There does not appear to be a substance report from NIEHS. However, the National Toxicology Program (a division of the NIEHS) did review glycolic acid for dermal photocarcinogenicity (http://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr524.pdf). A solution of 10% glycolic acid (the maximum concentration tested) did not induce carcinogenicity in this assay.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

Petition for **Inclusion** on National List:
No known reviews or bibliographies as to why glycolic acid should not be included on the National List is known. Glycolic acid is a naturally occurring compound found in a wide variety of foods. It is one of the smallest of the "fruit acid" molecules. One governmental agency (Australian) estimates that human consumption of glycolic acid in typical diets is 1mg/kg/day. Although found in nature, commercial sources of naturally derived glycolic acid are not available anywhere in the world. The carbonylation of formaldehyde route of manufacture is considered the most efficient and least environmentally impactful route of manufacture.

Glycolic acid is a well-known human cosmetics and personal care active ingredient. (See embedded pdf file for research bibliography on human applications.) It has a unique mode of action in that it penetrates the outer layers of skin to enhance exfoliation of dead skin cells. In addition it stimulates cellular activity to produce new skin cells increasing the thickness of the epidermis, moisturizing the outer layer of skin and increasing the production of elastin compounds in the skin. The ultimate benefit is firmer, moisturized, and more uniform skin layers. This benefit in livestock translates to animals that are healthier; more comfortable; and provide better production.

Glycolic acid based teat dips give excellent teat skin conditioning when combined with an emollient and reduce mastitis infections. See Attachment 4 for the Glycolic Acid Skin Care Literature Review.

12. A "Petition Justification Statement" which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

Explain why the synthetic substance is necessary for the production or handling of an organic product.

Glycolic acid based teat dips provide a combination of effectiveness in microbial protection similar to iodine based products improving the health of a dairy herd. In addition, Glycolic acid containing teat dips provide skin conditioning benefits that is unique to any other teat dip active ingredient. Glycolic acid is naturally present in milk. When used according to the label, a glycolic acid teat dip presents no milk residue risk.

Additionally, glycolic acid based teat dips are an economical alternative to iodine based teat dips during iodine shortages, thus allowing disinfection at the same rate as before the iodine shortage. Glycolic acid dips are a safe alternative to other more harmful chemicals that may be used by some farmers during times of iodine shortages, which may occur due to unexpected environmental factors occurring that affect the production and supply of iodine. For example, the 2011 earthquake in Japan eliminated that country's supply, adversely affecting the availability of iodine worldwide. Chilean producers have been dealing with a water shortage, which has also decreased the production of iodine since the process relies heavily on the availability of water. Both of these countries account for 90% of the world's supply of iodine, so when adversity strikes these countries it is difficult to fulfill the existing demand for iodine. In addition, whenever the supply is decreased the suppliers often react to the existing demand like a carte by increasing the prices by 200% to 300%. See Attachment 5 for information regarding the iodine shortages and effects.

Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

Chlorhexidine, Iodine, Hydrogen Peroxide, Chlorine Dioxide. However, none of these compounds have the combination of microbial protection and skin conditioning benefit. Currently there is no commercially available non synthetic glycolic acid for purchase.

Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

The use of glycolic acid in teat dip formulations provides active microbial protection and beneficial skin conditioning effects for the betterment of the livestock. Glycolic acid is readily biodegradable with its degradation products ultimately being carbon dioxide and water. Waste treatment is not a significant issue given its relatively low BOD and rapid biodegradation.

Also as a well-known and widely used component in personal care and cosmetic products, glycolic acid effects on human health is well documented and well known.

A search of the current toxicological literature revealed concerns that glycolic acid causes skin and eye irritation associated with cosmetic applications at high concentrations and low pH.

ATTACHMENT 1:

EXAMPLE LABELS FOR GLYCOLIC ACID PRODUCTS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 2, 2015

Mr. Thomas C. McEntee
Registration Manager
The Chemours Company FC, LLC
1007 Market Street
Wilmington, DE 19898

Subject: Label Amendment – Change Product Name Following Company Transfer From DuPont™ Kleanit To Glyclean® Hard Surface Cleaner
Product Name: **DuPont Kleanit**
EPA Registration Number: **71654-5**
Application Date: November 25, 2014
Decision Number: 498784

Dear Mr. McEntee:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Killian Swift by phone at 703-308-6346, or via email at Swift.Killian@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

NOTE TO REVIEWER: <denotes optional text>, e. g. <optional>

GLYCLEAN® HARD SURFACE CLEANER

ACTIVE INGREDIENT: Glycolic acid 5.0%
OTHER INGREDIENTS: 95.0%
TOTAL: 100.0%

Keep Out of Reach of Children

WARNING

FIRST AID STATEMENTS
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.
Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice.
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.

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 poison control center or doctor for further treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-441-3637 for emergency medical treatment information.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling poison control center or doctor or going for treatment.

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS
WARNING
Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (such as goggles). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed or inhaled. Avoid breathing spray mist. Do not use with chlorine bleach or any other chemical product.

EPA Registration No. 71654-5
EPA Establishment No. XXXXX-YY-ZZ

The Chemours Company FC, LLC
1007 Market Street
Wilmington, DE 19898

January 28, 2015

LIMITED WARRANTY AND DISCLAIMER
The manufacturer warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. The manufacturer makes no other express or implied warranties either of merchantability or fitness for a particular use. Handling, storage, and use of the product by buyer or user are beyond the control of the manufacturer and seller. Risks such as ineffectiveness, or other unintended consequences, resulting from failure to follow directions will be assumed by the buyer or user. To the extent permitted by law, the manufacturer or seller will not be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product.

GLYCLEAN® HARD SURFACE CLEANER:
CLEANS AND DISINFECTS MOST HARD NON-POROUS SURFACES IN 1-STEP
KILLS VIRUSES* AND BACTERIA.
A 10-minute contact time is necessary for disinfection
* Herpes Simplex Virus Type 1, Rhinovirus Type 37, and Influenza Virus Type A2

KILLS HOUSEHOLD GERMS:
Staphylococcus aureus <ATCC 6538>
Salmonella enterica <ATCC 10708> <(Salmonella)>
Pseudomonas aeruginosa <ATCC 15442> <(Pseudomonas)>
<Escherichia coli> <ATCC 11229>
<Escherichia coli O157:H7> <ATCC 43888>
< Herpes Simplex Virus Type 1>
<Rhinovirus Type 37>
<Influenza Virus Type A2>

<CLEANS & DEODORIZES>
<ANTIBACTERIAL>
<DISINFECTANT>
<DISINFECTS THE SURFACE AS IT CLEANS>
<CLEANS DISINFECTS AND DEODORIZES>
<NON-STAINING FORMULA>
<ELIMINATES OFFENSIVE ODORS>
<DISINFECTS WITHOUT CHLORINE ODORS.
<[PRODUCT NAME]….<TUB>, <TILE>, , <SINK>, < TOILET†>
<FOAMING ACTION ….SEE IT CLEAN!>
<HEAVY DUTY CLEANING>
<SAFE FOR WHITE OR COLORED HARD NON-POROUS SURFACES>
<DEODORIZES – LEAVES A FRESH CLEAN SCENT>
<THICK LIQUID>
<REMOVES STUBBORN RUST & HARD WATER STAINS>
<CONTAINS NO <PHOSPHATES>
<CONTAINS BIODEGRADABLE CLEANING AGENTS>
<CLEANS AND DESTROYS LIMESCALE>
<DISINFECTS WITHOUT HARSH CHEMICALS>
<WILL NOT HARM PLUMBING OR SEPTIC SYSTEMS>
<QUICKLY ELIMINATES HARD WATER STAINS, MINERAL DEPOSITS AND RUST STAINS>

January 28, 2015

<THE FOAMING ACTION QUICKLY AND EFFECTIVELY CLEANS ALL YOUR BATHROOM SURFACES>
<FOAMING ACTION…….SEE IT WORK! … CLEANS AND DEODORIZES>
<CUTS THROUGH SOAP SCUM, GREASE AND GRIME>

DIRECTIONS FOR USE
IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

FOR USE AS HOUSEHOLD <INSTITUTIONAL> DEODORIZER, CLEANER, AND DISINFECTANT ON HARD NON-POROUS SURFACES
If used on food preparation surfaces, all food must be removed prior to application and the application must be followed by a potable water rinse

TO CLEAN, DISINFECT AND DEODORIZE: Pre-clean heavily soiled surfaces. Spray 6 to 10 inches from surface for 3 to 4 seconds until thoroughly wet. Allow surface to remain wet for 10 minutes then wipe clean with a wet sponge or cloth, or rinse with water. Never use with chlorine bleach or any other chemical product.

<TO DISINFECT AND DEODORIZE: Pre-clean heavily soiled surfaces. Use a mop or brush to apply this product for pre-cleaned surfaces such as floors, maintaining a thoroughly wet surface for 10 minutes. Then wipe clean with a wet sponge or cloth, or rinse with water. No rinsing necessary except on rubber, asphalt tile, no wax floors, and on food contact surfaces. Use full strength for cutting grease, crayon, old wax or other heavy-duty cleaning jobs; rinse immediately. Never use with chlorine bleach or any other chemical product.>

<TO CLEAN: Remove gross dirt. Use one cup per gallon of water. Use a mop or brush to apply for pre-cleaned surfaces such as floors, maintaining a thoroughly wet surface for 10 minutes. Then wipe clean with a wet sponge or cloth, or rinse with water. No rinsing necessary except on rubber, asphalt tile, no wax floors, and on food contact surfaces. Use full strength for cutting grease, crayon, old wax or other heavy-duty cleaning jobs; rinse immediately. Never use with chlorine bleach or any other chemical product.>

† Use only on exterior toilet surfaces.

[Note to Reviewer: For Institutional Use]

STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry area. Always store pesticides in the original container. Store out of reach of children.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill.

[Note to Reviewer: For Household/Residential Use]

STORAGE AND DISPOSAL
Store out of reach of children. Store in a cool, dry area away from food and pet food. Nonrefillable container. Do not reuse or refill this container. Wrap (container) and put in trash or offer for recycling if available.

Net Contents:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 6, 2016

Ms. Elisa Estremera
Federal Registration Specialist
The Clorox Company
C/o PS&RC; Post Office Box 493
Pleasanton, CA 94566-0803

Subject: Notification per PRN 98-10 – Add non-Mandatory Marketing Claim and one Symbol
Product Name: Tuck 3
EPA Registration Number: 5813-101
Application Date: March 11, 2016
Decision Number: 515421

Dear Ms. Estremera:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Killian Swift at 703-308-6346 or via email at Swift.Killian@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Tuck 3

Active Ingredient:
Glycolic Acid 1.75%
Other Ingredients: 98.25%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN.

CAUTION:

SEE BACK -or- SIDE LABEL FOR ADDITIONAL PRECAUTIONS.

[NET] [CONTENTS] _____

NOTIFICATION

5813-101

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/06/2016

General/Cleaning/Deodorizing/Non-pesticidal Claims:

~~[~~Now~~]~~ ~~[~~ -and/or- New~~]~~[!] -and/ ~~-or-~~ [&/or- Improved~~]~~[!] ***to be used as a claim~~s~~ descriptor only for the first 6 months of product on shelf.***

- 1 -or- one [24 oz] [40 oz] [60 oz] bottle of Pine Sol = up to [14] [20] [30] gallons of cleaning power
- ***9 oz. bottle:*** Makes nearly 5 gallons of cleaner -or- cleaning solution -or- over 4 gallons of cleaner -or- cleaning solution.
- Can be used on a variety of hard, nonporous surface materials -or- surfaces
- Can be used on many hard, nonporous surfaces: wood†, glazed tile, linoleum
- Can be used on most hard, nonporous surfaces -or- surface materials
- Clean you can see, smell & feel
- Cleans [&] [and] [Deodorizes]
- Cleans and deodorizes basins, tubs, and glazed tiles
- Cleans and shines kitchen, bathroom, and other [household] hard, nonporous surfaces without [leaving] a [filmy] [sticky] residue
- Cleans and shines [hard, nonporous surfaces] [throughout the house] without [leaving] a [filmy] [sticky] residue
- Cleans -and/or- dissolves -and/or- removes -and/or- cuts through [tough] grease in commercial kitchens** -and/or- food service operations**
- Cleans-and/or- dissolves -and/or- removes [greasy] stains on fabric -and/or- upholstery
- Cleans right the first time
- Cleans so much more than floors
- Cleans the toughest soils
- Contains [real] pine oil
- Cuts [through] -and/or- cleans [tough] grease -and/or- grime [fast]
- Cuts -or- cleans greasy -and/or- grimy dirt -and/or- [household] grime -and/or- soils [fast] [on contact]
- Cuts through soap scum - [even faster]
- Deodorizes and has a [clean] [fresh] [pine] scent
- Deodorizes [washable] hard, nonporous surfaces
- Deodorizes [with a clean -and/or- fresh -and/or- pine scent]
- Dirt and odors have met their match
- Easily cleans the toughest dirt and grime inside and outside [the home]
- Easy[-]pour formula -or- Easy to pour
- Easy to use
- Fights grease and/or grime -and/&/or- soapscum
- Fill the room with scent
- [For] use on Wood †[Floors] -and/or- Carpet -and/or- fabric -and/or- upholstery
- Get the Cleaning Power of Pine-Sol
- Good for [nearly] [every] -or- [many] rooms -and/&/or- hard, nonporous surfaces
- Great for use [on many hard, nonporous surfaces in the bathroom] -or- [on many hard, nonporous bathroom surfaces]: floors, walls, showers, glazed tile, countertops, tubs, sinks, toilets
- Great for use [on many hard, nonporous surfaces] in the kitchen, bathroom, counters, and on floors
- Hard working [cleaner] [since 1929]
- [Hard[er] on -or- tough[er] on grime -and/&/or- soapscum -and/&/or- rust -and/&/or- hard water
- [Harder working] [cleaning] formula -or- power [on bathroom soils]
- It's about the clean!
- It's not just about the smell.
- Lasting scent technology
- Leaves a fresh, clean scent
- Less mess with [control-pour] flip-cap
- Long-lasting scent
- Longer-lasting scent [versus existing formula]
- More cleaning power [versus previous formula]
- More than just a floor cleaner
- Multi-faceted clean
- Multi-purpose Cleaner
- Multiple -or- many uses, multiple -or- many rooms
- Not harmful for most surfaces†
- [Now] [New] Improved [cleaning] [formula -or- power] on [bathroom]soils
- [Now] pine fragrance -or- scent
- Penetrates and breaks down [the toughest] [household] soils
- One cleaner for nearly all your hard, nonporous surfaces
- One -or- 1 bottle cleans the whole -or- entire house
- One -or- 1 bottle does it all
- One -or- 1 bucket -or- bottle of Pine Sol cleans kitchen, bathroom, counters, and floors
- One product, multiple -or- many -or- so many -or- thousands of uses
- Powerful deep clean
- Powerful degreaser
- Powerful Scent [of clean -or-pine]
- Quicker clean [versus previous formula]
- Reliable clean [since 1929]
- Removes -or- cleans dirt, grease -and/or- grime, scuff marks, and mud stains
- Removes -or- Cleans food -and/or- beverage stains
- Save money. Clean it right the first time.
- Shines
- Splash-less bottle -or- formula
- Strong cleaning power
- [Stronger] [Harder] [Hard(er) Working] [Tougher] [More] [Effective] on soapscum [versus previous formula]
- Removes tough dirt -and/&/or- grease -and/&/or- grime
- Removes [tough] grease -and/or- grime -and/or- dirt
- Same great cleaning power
- The [clean] [intense] [powerful] scent of [real] pine
- The Cleaning Power of Pine-Sol. The Smell of Clean!®
- Tough against dirt even when diluted
- Tough Jobs
- Tough, versatile cleaner [since 1929]
- Unapologetically powerful cleaner
- Use in [nearly] every room of your house -or- home
- Variety of uses [around the house -or- home]

†see page 6 paragraph 3

Pesticidal claims:

~~[~~Now~~]~~ ~~[~~ -and/or- New~~]~~[!] -and/ ~~-or-~~ [&/or- Improved~~]~~[!] ***to be used as a claim~~s~~ descriptor only for the first 6 months of product on shelf.***

- An effective cleaner, disinfectant, and deodorant for use in the kitchen, bathroom, [and] bedroom [, and other [household] areas]
- Antibacterial action -or- cleaner
- Bactericide[2] -or- Bactericidal[2] [formula]
- Broad spectrum disinfectant [cleaner]
- Broad Spectrum [Disinfectant -or- formula] -or- Broad Spectrum Disinfectant against Salmonella enterica, Staphylococcus aureus and Influenza A virus
- Disinfectant [formula]
- Disinfects
- Disinfects as it cleans [big jobs]
- Disinfects indoor hard, nonporous surfaces
- [Does not just cover up -and/or- mask odors –] Kills -or- Eliminates -or- Destroys -or- Removes -or- Wipes out odors caused by bacteria -or- germs[1]
- [Does not just cover up -and/or- mask odors –] Disinfects and deodorizes [by killing [99.9% of] germs[1] and the[ir] odors [they cause]]
- [Does not just cover up -and/or- mask odors –] Eliminates -or- removes odors caused by bacteria
- Germicide[1] -or- Germicidal[1] [formula]
- [Home -or- Household] [Cleaner] [and] Disinfectant
- Kills [99.9% of] Germs[1]
- Kills [99.9% of] germs[1] on hard nonporous surfaces
- Kills [99.9% of] [household] germs[1] -or- bacteria[2] while it cleans [tough] [everyday] [kitchen] [bathroom] [household] messes
- Kills [99.9% of] [household] germs[1] on [washable] hard, nonporous surfaces [such as kitchen -and/or- bathroom floors -and/or- toilet exteriors -and/or- diaper pails -and/or- pet areas -and/or- urinals]
- Multi-Purpose -or- Multi-Room -or- Multi-Surface [Cleaner] [and] [Disinfectant]
- [This product] Kills -and/or- Eliminates -and/or- Destroys -and/or- Removes -and/or- Wipes Out gram-negative bacteria [Salmonella enterica [(Salmonella)]]
- [This product] Kills -and/or- Eliminates -and/or- Destroys -and/or- Removes -and/or- Wipes Out [[99.9% of] [Household] Germs[1]:] Staphylococcus aureus [(Staph)][ATCC 6538], Salmonella enterica [ATCC 10708], and Influenza A virus [Hong Kong strain] [ATCC VR-544]
- [This product] Kills -and/or- Eliminates -and/or- Destroys -and/or- Removes -and/or- Wipes Out [99.9% of] bacteria[2]
- [This product] cleans -and/or- kills germs[1] on the following [hard, nonporous] surfaces: ***See "Surfaces for Disinfecting, Deodorizing and Cleaning" on page 5***
- You'll discover that it cleans, deodorizes and disinfects wherever you clean in your home
- Wipes Out -or- Kills [99.9% of] [household] [odor-causing] germs[1] -or- bacteria[2]

[1][Kills] Salmonella enterica [(Salmonella)] [ATCC 10708], Staphylococcus aureus [(Staph)] [ATCC 6538], and Influenza A virus [(Hong Kong strain)] [ATCC VR-544]

[2][Kills] Salmonella enterica [(Salmonella)] [ATCC 10708] -and/or-Staphylococcus aureus [(Staph)] [ATCC 6538]

Pandemic 2009 H1N1 Influenza A virus*

Claims:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (***Product Name***) is a broad-spectrum hard surface disinfectant that has been shown to be effective against influenza A2 virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A2 virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against influenza A2 virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

****** per Agency guidance dated October 22, 2009 "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (formerly called Swine Flu)" www.epa.gov/oppad001/h1n1-guide.html***

Organisms:

Bacteria:
Staphylococcus aureus [(Staph)] [ATCC 6538]
Salmonella enterica [ATCC 10708]

Virus Eveloped:
Influenza A virus [Hong Kong strain] [ATCC VR-544]

Packaging Related Statements and Icons:

~~[~~Now~~]~~ ~~[~~ -and/or- New~~]~~[!] -and/ ~~-or-~~ [&/or- Improved~~]~~[!] ***to be used as a claim~~s~~ descriptor only for the first 6 months of product on shelf.***

- ____% free
- ____ oz at the ____ oz price
- Bonus __% More ! __ oz for the price of __ oz.
- Bonus 20% More ! 48 oz for the price of 40 oz.
- Cap that gives you more control
- Control-pour cap
- Easy[-]pour cap
- Easy to control flip-cap
- Economy size
- Flip-top [-and/or-][,] Easy-pour cap
- [Flip-top] cap -or- Flip top
- Free sample
- Get ____ oz free
- Institutional size
- One-handed use of flip-cap
- Trial size
- Twin pack
- Value -or- Twin pack
- Value size -or- Twin

Use Sites/Surfaces for Disinfecting, Deodorizing and Cleaning:

[WHERE TO USE]

Use this product on the following [washable] hard, nonporous surfaces:

- Baby furniture (cribs**, changing tables)
- Basement[s] [areas]
- [BATHROOM -] Floors, showers, glazed tile, countertops, tubs
- Bathroom -or- restroom surfaces
- Cabinets
- Cat -and/or- Pet [litter] boxes -or- pans
- Glazed [Ceramic] Tile[s]
- Chairs
- Chrome
- [CLEANING/DISINFECTION -] [Washable] walls, sinks, counters
- Commercial kitchens** -and/or- food service operations**
- Countertops -or- Counters
- Diaper pails
- Doorknobs
- Baked Enamel
- Sealed Fiberglass surfaces
- Finished -or- painted wood† surfaces
- For the bathroom: Use on floors, [washable] walls, showers, glazed tile, countertops, tubs, sinks, toilet exteriors
- For the [commercial] kitchen -and/or- food service operations: Use on floors, walls, sinks, range hoods, stove exteriors, counters, cabinets, refrigerator exteriors, microwave exteriors.
- For the kitchen: Use on floors, walls, sinks, range hoods, stoves, counters, cabinets, refrigerator exteriors, microwave exteriors.
- Glazed bathroom -or- restroom tiles
- Glazed ceramic [tile]
- Glazed porcelain [tiling]
- Garage[s] [floors -and/or- doors]
- Garbage cans
- [Hard] Plastic
- Hard vinyl
- Highchairs (non-food contact areas)
- [Kitchen] Appliance[s] exteriors
- [KITCHEN -] Floors, walls, sinks, range hoods, stove exteriors, counters, cabinets, refrigerator exteriors -or- exterior surfaces of refrigerators, microwave exteriors -or- exterior surfaces of microwaves
- Light fixtures
- Litter boxes -or- pans
- Metal -and/or- plastic patio furniture
- Metal [blinds]
- Microwave oven exteriors
- [No-wax] Floors
- Oven doors
- Pet areas
- Plastic laundry hampers -or- baskets
- Plastic dog houses
- Playroom[s]
- Range hoods
- Recycling bins
- Refrigerator[s] [exteriors]
- Shower[s] [doors]
- Sinks
- Stainless steel or metal surfaces in bathrooms -or- restrooms -and/or- kitchens
- Stove[s] [tops]
- Tables
- Telephones
- Toilet exterior[s] -or- exterior surfaces of toilets
- Tools
- Tubs
- Urinal[s] [exteriors]
- [Washable] Kitchen surfaces
- [Washable] Cupboards
- [Washable] Doors
- [Washable] Railings
- [Washable] Trim
- [Washable] Walls
- Window[s] [sills]

**rinse with potable water.

†see page 6 paragraph 3

Use Site/Surface for Cleaning -and/or- deodorizing:

- Cleans -and/or- dissolves -and/or-removes -and/or- cuts through [tough] grease on [quarry] tile -and/or- grout between [quarry] tile(s)
- [For use on Wood†] [Floors -or- Flooring] -and/or- Carpet -and/or- Fabric -and/or- Upholstery
- Toilet[s] [bowls]

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

TO CLEAN [/DEODORIZE -OR- AND DEODORIZE] -or- GENERAL CLEANING [/DEODORIZING -OR- AND DEODORIZING] -or- GENERAL CLEANING [/DEODORIZING -OR- AND DEODORIZING] AND [WOOD†] FLOORS -or- GENERAL CLEANING [/DEODORIZING -OR- AND DEODORIZING], [WOOD†] FLOORS AND SIMILAR SURFACES: ***(Note: Deodorize -or- Deodorizing is to be used in the cleaning header for the state registration label/production label if a deodorizing claim is made.)***

Use 1/4 cup per gallon of water. For tough jobs, use full strength and rinse immediately.

Toilet Bowls -and/or- Urinals: Pour 1/2 cup into bowl and brush thoroughly, including under the rim.

Laundry: Rub in full strength on grease spots, [collar and cuff stains,] -and/or- heavily soiled areas before washing. For extra cleaning [and deodorizing] power, add 1/2 cup to load [along with regular detergent]. Use only on white or colorfast fabrics.

TO DISINFECT -or- GENERAL DISINFECTING: Apply [This product] full strength on hard, nonporous surfaces with a clean sponge or cloth. Wet surface, let stand 10 minutes, then rinse. For heavily soiled surfaces, precleaning is required.

Rinsing is required for surfaces that may come in contact with food [and rubber or asphalt tile]. For painted surfaces, test a small area first. ***Dagger symbol to be used with wood claims*** [†]Do not use on marble, aluminum, copper or wood that is unfinished, unsealed, unpainted, waxed, oiled or worn.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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. **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. Have the product container or label available when calling a poison control center or doctor or when going for treatment. Questions? Call 1-800-227-1860.
PHYSICAL OR CHEMICAL HAZARDS: Do not use or mix with bleach-containing products or other [household] cleaners. **COMBUSTIBLE:** Do not use or store near heat or open flame.

Residential/Household uses (24, 28, 40, 48, 60, 100, 175 fl oz)
STORAGE AND DISPOSAL: Store in a cool dry area. Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or place in trash collection.

Professional/Institutional uses (100, 144, 175 fl oz)
STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal. Store in a cool dry area. **CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. [Triple rinse container (or equivalent) promptly after emptying.] Offer for recycling if available, or place in trash collection.

EPA Reg. No. 5813-101
EPA Est. No. 5813-GA-1 (A4), GA-2 (VG); 9019-OH-1 (KD); 58455-IN-1 (C6); IN-2 (01) 71106-GA-1 (E8); 71681-GA-1 (JQ), IL-1 (~~GU~~03), IL-2 (24)
Beginning of batch code indicates Est. No.

Please visit www.pine-sol.com or call 1-800-227-1860.
-or- QUESTIONS OR COMMENTS? CALL 800-227-1860.
Need MSDS information? Please visit www.cloroxprofessional.com
A list of this product's ingredients is available at www.IngredientsInside.com
-or- A list of [this product's] [***product name***] ingredients is available at [***insert company website***].
Mfd. for & ©2011
The Clorox Company, 1221 Broadway, Oakland, CA 94612
Made in U.S.A.

PROOF OF PURCHASE

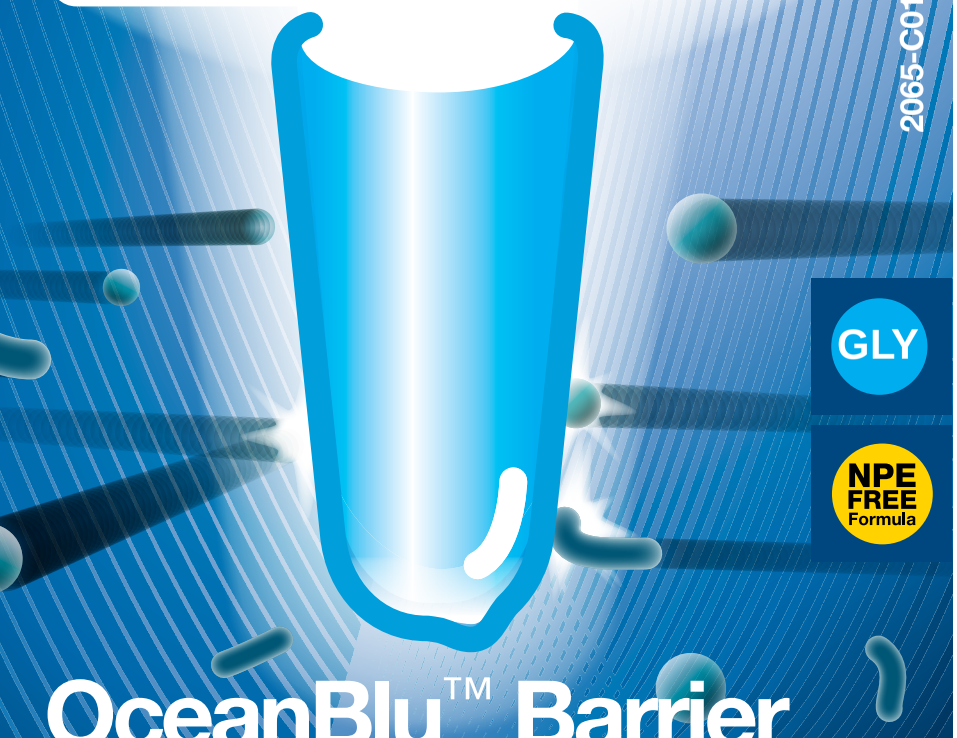
0 12345 67890 5

- [BOTTLE IS MADE FROM PLASTIC THAT CONSUMERS RECYCLE (50% POST-CONSUMER RESIN)]
- [BOTTLE IS MADE WITH POST-CONSUMER PLASTIC]
- [BOTTLE IS MADE WITH 50% MINIMUM POST-CONSUMER PLASTIC]
- CONTAINS NO PHOSPHORUS

[[Use your phone to] go here -and/or- scan [[the] tag -or- [this] code] to learn -or- get -or- see [more] uses -or- information [on how-to-use [This Product]] -or- [how-to] tips -or- [how-to [-use]] videos] [(Data rates may apply)]

DeLaval

2065-C0116



GLY

NPE FREE Formula

OceanBlu™ Barrier

Sanitizing Post dip Barrier with 10% emollients

Aids in reducing the spread of mastitis-causing organisms

Desinfectante post ordeño con 10% de glicerina

Ayuda a reducir la transmisión de microorganismos que causan mastitis

ACTIVE INGREDIENTS:

Glycolic Acid..... 3.0%

INACTIVE INGREDIENTS:

Emollient*..... 10.0%

* From Glycerin and Sorbitol

GlyTec™

US Patent: Pending

KEEP OUT OF REACH OF CHILDREN

⚠ CAUTION

MANTENER FUERA DEL ALCANCE DE LOS NIÑOS

⚠ CUIDADO

2065

NDC NUMBER: 55756-065

SI USTED NO PUEDE LEER ESTA ETIQUETA, POR FAVOR PIDA A ALGUIEN MAS QUE SE LA LEA ANTES DE USAR ESTE PRODUCTO

READ AND UNDERSTAND ALL INSTRUCTIONS BEFORE USING THIS PRODUCT

FIRST AID

Contact with product can cause irritation to eyes. Avoid contact with eyes.
If in Eyes: Flush with water. Remove contact lenses, if present, after first 5 minutes. Then continue rinsing.
If Swallowed: Do not induce vomiting. Get immediate medical attention.

STORAGE AND DISPOSAL

THOROUGHLY RINSE ALL MEASURING DEVICES AND STORE OUT OF REACH OF CHILDREN. Avoid contact with food or feed. Avoid storing near heat or open flame. Keep from freezing. If product is frozen, thaw in warm room and mix well before using. Keep from exposing product to direct sunlight. Keep container tightly closed when not in use. Do not reuse empty container. Rinse empty container before disposing in a safe manner. Keep away from chlorine or chlorinated products.

CHEM-TREC EMERGENCY NUMBER 1-800-424-9300

Not For Human Use

Additional Information on Safety Data Sheet

GENERAL INSTRUCTIONS

- **OceanBlu™ Barrier** is a highly visible, persistent barrier post-dip with extended disinfection while hydrating and softening teats.
- Use **OceanBlu™ Barrier** at full strength. Do not dilute.
- Consult your veterinarian before using a teat dip on a cow with sore or chapped teats.
- Thoroughly clean and sanitize teat dip cup before milking.
- Use fresh teat dip for each milking. Dip solution should be changed if it becomes visibly dirty, or if sediment is introduced. Do not pour used teat dip back into original container.
- Do not use for cleaning or sanitizing equipment.
- Discard any teat dip that becomes contaminated for any reason.

PRE-DIPPING

- For optimal removal of organic debris and to remove any residual **OceanBlu™ Barrier** film, use a DeLaval approved pre-dip following label instructions.

POST-DIPPING

- Immediately after removing inflations, dip cow's teats with **OceanBlu™ Barrier**.
- Do not wipe.
- If outside temperature is below freezing, allow dip to air-dry on cow's teats before cow is released outside. Failure to follow these directions may result in frozen teats and injured animals.

Manufactured for:
DeLaval, Inc.
by WestAgro, Inc.,
11100 N. Congress Avenue
Kansas City, MO 64153
Phone: 816-891-7700

NET CONTENTS: 5 US GAL. (18.9 L)

LOT NO.:

EXP. DATE:

7 320461 280852 >

DeLaval

2062-C0116

GLY

NPE FREE Formula

OceanBlu™ Pre-Post

Sanitizing Pre and Post dip with 5% glycerin
Aids in reducing the spread of mastitis-causing organisms

Desinfectante pre y post ordeño con 5% de glicerina
Ayuda a reducir la transmisión de microorganismos que causan mastitis

ACTIVE INGREDIENTS:
Glycolic Acid..... 3.0%
INACTIVE INGREDIENTS:
Emollient*..... 5.0%
* From Glycerin

GlyTec™

US Patent: Pending

KEEP OUT OF REACH OF CHILDREN

⚠ CAUTION

MANTENER FUERA DEL ALCANCE DE LOS NIÑOS

⚠ CUIDADO

2062

NDC NUMBER: 55756-062

SI USTED NO PUEDE LEER ESTA ETIQUETA, POR FAVOR PIDA A ALGUIEN MAS QUE SE LA LEA ANTES DE USAR ESTE PRODUCTO

READ AND UNDERSTAND ALL INSTRUCTIONS BEFORE USING THIS PRODUCT

FIRST AID

Contact with product can cause irritation to eyes. Avoid contact with eyes.
If in Eyes: Flush with water. Remove contact lenses, if present, after first 5 minutes. Then continue rinsing.
If Swallowed: Do not induce vomiting. Get immediate medical attention.

STORAGE AND DISPOSAL

THOROUGHLY RINSE ALL MEASURING DEVICES AND STORE OUT OF REACH OF CHILDREN. Avoid contact with food or feed. Avoid storing near heat or open flame. Keep from freezing. If product is frozen, thaw in warm room and mix well before using. Keep from exposing product to direct sunlight. Keep container tightly closed when not in use. Do not reuse empty container. Rinse empty container before disposing in a safe manner. Keep away from chlorine or chlorinated products.

CHEM-TREC EMERGENCY NUMBER 1-800-424-9300

Not For Human Use

Additional Information on Safety Data Sheet

GENERAL INSTRUCTIONS

- DeLaval **OceanBlu™ Pre-Post** is a pre and post milking sanitizing teat dip that aids in reducing the spread of mastitis-causing organisms.
- Use DeLaval **OceanBlu™ Pre-Post** teat sanitizer at full strength. **Do not dilute.**
- Consult veterinarian before starting or continuing to use teat dip if cow's teats are sore or chapped.
- Thoroughly clean and sanitize teat dip cup before each milking.
- Use fresh teat dip for each milking. Dip solution should be changed if it becomes visibly dirty or if sediment is introduced. Do not pour used teat dip back into original container.
- Discard any teat sanitizing solution that becomes dirty or contaminated for any reason.
- Good dairy practices suggest the thorough cleaning and sanitizing of teats before milking to avoid contamination and assist in the control of mastitis.

PRE-DIPPING

- Remove excess organic debris and forestrip. (If water is used, use a minimal amount and dry thoroughly with clean, single-service paper towel before forestripping.)
- Dip, spray, or foam cow's teats with DeLaval **OceanBlu™ Pre-Post .**
- Allow a 15 - 30 second contact time.
- Dry teats thoroughly with a clean, single-service paper towel or clean, dry towel.
- Attach milker unit.

POST-DIPPING

- Immediately after removing milking unit, dip or spray teats with DeLaval **OceanBlu™ Pre-Post.** Do not wipe.
- If outside temperature is below freezing, allow DeLaval **OceanBlu™ Pre-Post** to air-dry on cow's teats before cow is released outside; or allow teat dip to remain on teats for one minute, then dry teats with a single-service paper towel. Failure to follow these directions may result in frozen teats and injured animals.

Manufactured for:
DeLaval, Inc.
by WestAgro, Inc.,
11100 N. Congress Avenue
Kansas City, MO 64153
Phone: 816-891-7700

NET CONTENTS: 5 US GAL. (18.9 L)

LOT NO.:

EXP. DATE:

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ATTACHMENT 2:

GLYCOLIC ACID TOXICITY SUMMARY

DuPont Haskell Global Centers
for Health and Environmental Sciences
P.O. Box 50
Newark, DE 19714-0050

November 1, 2012

Summary of Glycolic Acid Toxicity Data

NOTE: This document summaries DuPont data as well as data available in the open literature.

Glycolic acid is slightly toxic to rats by the oral route having an LD_{50} of 2040 mg/kg for the 70% technical grade product. It is moderately toxic by the inhalation route in male rats with a 4-hour LC_{50} of 3.6 and >5.2 mg/L in male and female rats, respectively. Toxic effects in animals from a single exposure by inhalation include body weight losses and ocular and nasal discharges. Administration of a single, high oral dose produced severe gastrointestinal tract irritation, liver damage, increased kidney weights, and the formation of calcium oxalate crystals in the kidneys. Undiluted glycolic acid is a skin and eye corrosive, but it is not a skin sensitizer in animals. Repeated inhalation exposures produced liver changes, spleen, liver, and thymus changes, and gastrointestinal tract alterations. Repeated dosing in cats produced weight and appetite loss, depression, vomiting, coma, convulsions, kidney failure due to calcium oxalate deposition, and death. However, dogs given similar and higher doses showed no toxic effects. Long-term dosing in rats resulted in higher mortality in male rats and kidney toxicity due to calcium oxalate deposition. Females showed no such toxic effects. No immunotoxicity or neurobehavioral changes were observed. Maternal and developmental toxicity of crystalline, 99.6% pure glycolic acid was seen in the rat at 300 and 600 mg/kg/day; the maternal and developmental NOEL was 150 mg/kg/day. In another study, glycolic acid, 70% technical grade was administered to rats in solution of deionized water buffered to pH 3.2. The NOAEL for maternal toxicity was the high dose, 900 mg/kg bw/day, and the NOAEL for developmental toxicity was 300 mg/kg bw/day, since fetal changes, reduced weight and increased incidence of malformations and variations were evident in the high dose group. For evaluation of potential human developmental toxicity, it has been shown that the rabbit is a largely unresponsive model for glycolic acid, while the rat and mouse have specific physiological differences in terms of the embryo-fetal environment that render these species more sensitive to fetal effects. Glycolic acid mediated fetal effects may produce developmental toxicity in rats via intra-amniotic ion-trapping mediated by a pH gradient leading to higher intra-amniotic ion concentrations. The physiologic differences in pH between the rat maternal and fetal compartments drive the gradient such that direct embryo fetal exposures are potentiated. In contrast, the physiologic differences in the human maternal and fetal

DuPont Haskell Global Centers
for Health and Environmental Sciences
P.O. Box 50
Newark, DE 19714-0050

environments are reversed such that direct embryo fetal exposure to glycolic acid may be substantially reduced. Therefore, the rat may not be a relevant animal model for assessing potential developmental toxicity of glycolic acid to humans. The conclusion that the developmental toxicity seen in experimental animals is not relevant to humans is supported by the observation that blood levels of glycolic acid in humans needed to reach levels equivalent to those demonstrating effects in experimental animals are deemed unattainable. The weight of evidence indicates no classification of glycolic acid as a developmental toxicant is warranted. No adverse effects on reproductive performance were observed in a one-generation study in rats, and the reproductive NOEL was 600 mg/kg. Glycolic acid was not mutagenic in *Salmonella* and *E. coli* with or without activation, was not clastogenic in Chinese hamster ovary cells, and was negative in an *in vivo* mouse micronucleus study. Topical application of a cosmetic formulation containing 4% or 10% glycolic acid (pH 3.5) for 40-weeks did not alter the photocarcinogenesis of simulated solar light in hairless mice. Glycolic acid is slightly toxic to aquatic organisms having a 24-48 hour LC_{50} in bluegill sunfish of 93 ppm, 96-hour LC_{50} in fathead minnows of 164 ppm, and 48-hour EC_{50} in *Daphnia* of 141 mg/L.

Shawn Gannon
Research Toxicologist
DuPont Haskell Global Centers for Health and Environmental Sciences
P.O. Box 50
Newark, DE 19714
302-366-5757
shawn.a.gannon@usa.dupont.com

ATTACHMENT 3:

GLYCOLIC ACID SAFETY DATA SHEET

Glycolic Acid - 70% Technical Solution

Version 5.0

Revision Date 12/09/2015 Ref. 130000005166

This SDS adheres to the standards and regulatory requirements of the United States and may not meet the regulatory requirements in other countries.

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Glycolic Acid - 70% Technical Solution
Product Use	:	various, For industrial use only.
Restrictions on use	:	Personal care
Manufacturer/Supplier	:	The Chemours Company FC, LLC 1007 Market Street Wilmington, DE 19899 United States of America
Product Information	:	1-844-773-CHEM (outside the U.S. 1-302-773-1000)
Medical Emergency	:	1-866-595-1473 (outside the U.S. 1-302-773-2000)
Transport Emergency	:	CHEMTREC: +1-800-424-9300 (outside the U.S. +1-703-527-3887)

SECTION 2. HAZARDS IDENTIFICATION

Product hazard category

Acute toxicity (Inhalation)	Category 4
Skin corrosion	Category 1
Serious eye damage/eye irritation	Category 1

Glycolic Acid - 70% Technical Solution

Version 5.0

Revision Date 12/09/2015 Ref. 130000005166

Label content

Pictogram :

Signal word : Danger

Hazardous warnings : Causes severe skin burns and eye damage.
Causes serious eye damage.
Harmful if inhaled.

Hazardous prevention measures : Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
Wash skin thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear protective gloves/ protective clothing/ eye protection/ face protection.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Immediately call a POISON CENTER or doctor/ physician.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
Wash contaminated clothing before reuse.
Store locked up.
Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Glycolic Acid - 70% Technical Solution

Version 5.0

Revision Date 12/09/2015 Ref. 130000005166

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 68.426 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No.	Concentration
Glycolic acid	79-14-1	68 - 72 %
Formic acid	64-18-6	0.1 - 1 %

SECTION 4. FIRST AID MEASURES

General advice	:	When symptoms persist or in all cases of doubt seek medical advice.
Inhalation	:	Move to fresh air. Oxygen or artificial respiration if needed. Consult a physician.
Skin contact	:	Wash off immediately with plenty of water. Take off all contaminated clothing immediately. Consult a physician. Wash contaminated clothing before re-use.
Eye contact	:	Rinse immediately with plenty of water and seek medical advice.
Ingestion	:	Do NOT induce vomiting. Call a physician immediately. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	:	No applicable data available.
Protection of first-aiders	:	If potential for exposure exists refer to Section 8 for specific personal protective equipment.

Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	No applicable data available.
Specific hazards	:	No applicable data available.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus and protective suit.
Further information	:	Will react with most metals, releasing potentially explosive hydrogen gas.

SECTION 6. ACCIDENTAL RELEASE MEASURES

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Safeguards (Personnel)	:	Use personal protective equipment.
Environmental precautions	:	Try to prevent the material from entering drains or water courses.
Spill Cleanup	:	Neutralize spill with lime or soda ash. If this product is spilled and not recovered, or is recovered as a waste for treatment or disposal, the CERCLA Reportable Quantity is 100 lbs. (release of an Unlisted Hazardous Waste with the Characteristic of Corrosivity.)
Accidental Release Measures	:	No applicable data available.

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SECTION 7. HANDLING AND STORAGE

Handling (Personnel)	:	Avoid breathing mist. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Wear personal protective equipment. Provide sufficient air exchange and/or exhaust in work rooms.
Handling (Physical Aspects)	:	No applicable data available.
Dust explosion class	:	Not applicable
Storage	:	Keep in a well-ventilated place. Keep tightly closed. Keep away from heat.
Storage period	:	No applicable data available.
Storage temperature	:	< 50 °C (< 122 °F)

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls	:	Use only with adequate ventilation.
Personal protective equipment		
Respiratory protection	:	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Hand protection	:	Material: Impervious gloves
Hand protection	:	Material: Chloroprene Break through time: > 480 min Glove thickness: 0.6 mm
Eye protection	:	Wear coverall chemical splash goggles.
Skin and body protection	:	Where there is potential for skin contact have available and wear as appropriate: Complete suit protecting against chemicals.

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Exposure Guidelines
Exposure Limit Values

Glycolic acid
No applicable data available.

Formaldehyde

Permissible exposure limit:	(OSHA)	0.75 ppm	TWA
Permissible exposure limit:	(OSHA)	2 ppm	STEL
TLV	(ACGIH)	0.3 ppm	TLV-C

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	:	liquid
Form	:	liquid
Color	:	light yellow
Odor	:	mild, of burnt sugar
Odor threshold	:	No applicable data available.
pH	:	0.1 at 25 °C (77 °F)
Melting point/freezing point	:	Melting point 10 °C (50 °F)
Boiling point/boiling range	:	Boiling point 112 °C (234 °F) at 760 mm Hg
Flash point	:	does not flash

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Evaporation rate	:	No applicable data available.
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit	:	No applicable data available.
Lower explosion limit	:	No applicable data available.
Vapor pressure	:	0.017 hPa at 25 °C (77 °F)
Vapour density	:	No applicable data available.
Density	:	1.27 g/cm3 at 20 °C (68 °F)
Specific gravity (Relative density)	:	No applicable data available.
Water solubility	:	completely miscible
Solubility(ies)	:	No applicable data available.
Partition coefficient: n-octanol/water	:	log Pow: -1.11 at 19 °C (66 °F)
Auto-ignition temperature	:	No applicable data available.
Decomposition temperature	:	No applicable data available.
Viscosity, kinematic	:	No applicable data available.
Viscosity, dynamic 3.49 mPa.s at 43.3 °C (109.9 °F)	:	11.28 mPa.s at 15.6 °C (60.1 °F)
Oxidizing Substance	:	May cause or intensify fire; oxidizer.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Stable under recommended storage conditions.

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Chemical stability	:	Stable
Possibility of hazardous reactions	:	Polymerization will not occur.
Conditions to avoid	:	No applicable data available.
Incompatible materials	:	Oxidizing agents Cyanides, Sulphides, active metals (such as sodium, potassium, magnesium)
Hazardous decomposition products	:	Decomposition will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Glycolic Acid - 70% Technical Solution

Sensitisation	:	animals (unspecified species)Not a skin sensitizer.
Reproductive toxicity	:	No toxicity to reproduction

Glycolic acid

Inhalation 4 h LC50	:	3.6 mg/l , Rat
Oral LD50	:	2,040 mg/kg , Rat
Skin irritation	:	Corrosive after 3 minutes to 1 hour of exposure, Rabbit
Eye irritation	:	Corrosive, Rabbit
Repeated dose toxicity	:	Ingestion Rat - 90 d NOAEL: 150 mg/kg LOAEL: 300 mg/kgMethod: OECD Test Guideline 408 No toxicological effects warranting significant target organ toxicity classification were seen below the recommended guidance values for classification.
Carcinogenicity	:	Not classifiable as a human carcinogen. Animal testing did not show any carcinogenic effects.

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Mutagenicity	:	Animal testing did not show any mutagenic effects. Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
Teratogenicity	:	Animal testing showed effects on embryo-fetal development at levels equal to or above those causing maternal toxicity.

Formic acid

Inhalation 4 h LC50	:	7.4 mg/l , Rat
Oral LD50	:	730 mg/kg , Rat
Skin irritation	:	Causes severe burns., Not tested on animals
Eye irritation	:	Corrosive, Not tested on animals
Carcinogenicity	:	Not classifiable as a human carcinogen. Animal testing did not show any carcinogenic effects. Information given is based on data obtained from similar substances.
Mutagenicity	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects. Did not cause genetic damage in cultured bacterial cells. Genetic damage in cultured mammalian cells was observed in some laboratory tests but not in others. Did not cause genetic damage in insects.
Teratogenicity	:	Animal testing showed no developmental toxicity. Information given is based on data obtained from similar substances.

Carcinogenicity

The carcinogenicity classifications for this product and/or its ingredients have been determined according to HazCom 2012, Appendix A.6. The classifications may differ from those listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or those found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition).

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, or OSHA, as a carcinogen.

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SECTION 12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Glycolic acid

96 h LC50	:	Pimephales promelas (fathead minnow) 164 mg/l
72 h ErC50	:	Pseudokirchneriella subcapitata (green algae) 44 mg/l OECD Test Guideline 201
72 h NOEC	:	Pseudokirchneriella subcapitata (green algae) 20 mg/l OECD Test Guideline 201
48 h EC50	:	Daphnia magna (Water flea) 141 mg/l OECD Test Guideline 202

Formic acid

96 h LC50	:	Leuciscus idus (Golden orfe) > 46 mg/l Information given is based on data obtained from similar substances.
72 h ErC50	:	Algae 26.9 mg/l
48 h EC50	:	Daphnia magna (Water flea) 34.2 mg/l
21 d	:	NOEC Daphnia magna (Water flea) 100 mg/l

Environmental Fate

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Biodegradability : Readily biodegradable, according to appropriate OECD test.

Glycolic acid

Bioaccumulation : Bioaccumulation is unlikely.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste disposal methods - : Treatment, storage, transportation, and disposal must be in accordance with

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Product		applicable federal, state/provincial, and local regulations. May be a RCRA hazardous waste due to the corrosivity characteristic (pH).
Contaminated packaging	:	Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

DOT	UN number	:	3265
	Proper shipping name	:	Corrosive liquid, acidic, organic, n.o.s. (Glycolic acid)
	Class	:	8
	Packing group	:	II
	Labelling No.	:	8
IATA_C	UN number	:	3265
	Proper shipping name	:	Corrosive liquid, acidic, organic, n.o.s. (Glycolic acid)
	Class	:	8
	Packing group	:	II
	Labelling No.	:	8
IMDG	UN number	:	3265
	Proper shipping name	:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Glycolic acid)
	Class	:	8
	Packing group	:	II
	Labelling No.	:	8

SECTION 15. REGULATORY INFORMATION

TSCA	:	On the inventory, or in compliance with the inventory
SARA 313 Regulated Chemical(s)	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established

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by SARA Title III, Section 313.

California Prop. 65 : WARNING! This product contains a chemical or chemicals known to the State of California to cause cancer.Formaldehyde

SECTION 16. OTHER INFORMATION

Restrictions for use : Do not use technical grades in personal care applications due to higher level of impurities.

Revision Date : 12/09/2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Significant change from previous version is denoted with a double bar.

ATTACHMENT 4:

GLYCOLIC ACID SKIN CARE LITERATURE REVIEW

Version of 3/11/13

Glycolic Acid Skin Care Literature Review

R.R. Burch, J.J.Horsager

Alpha-hydroxy acids (AHAs), particularly glycolic acid, are widely used in skin care products and are claimed to reduce wrinkles and the signs of aging and to improve the overall look and feel of skin. Over-the-counter AHA-based products are currently limited to 10% AHA. However, glycolic acid at concentrations up to 25% is in use for chemical peels in the clinical setting of the dermatologist's office. Glycolic acid is also used as an adjuvant to enhance the efficacy of other therapeutic agents in clinical applications. This essay summarizes published findings related to the efficacy of glycolic acid in skin care products.

This summary covers literature extending from 1994 to 2009, emphasizing review articles in the scientific and medical literature. The scope includes investigations of glycolic acid itself, as well as comparison to other AHAs, retinoids, peptides, and botanicals. The investigations cited in this literature summary include clinical studies with human volunteers, histological evaluations, animal studies, *in vitro* mechanistic studies, and use of AHAs as adjuvants for other active ingredients.

Some investigators classify AHAs as examples of "cosmeceuticals", which are cosmetic products claimed to have biologically active ingredients with medicinal or drug-like benefits.[1] Functions of various cosmeceuticals include: Skin-whitening / depigmenting, Moisturizing, Antiwrinkling, and Antiphotoaging. Clinicians warn that certain cosmeceuticals can cause unwanted problems including skin irritation, contact dermatitis, photosensitivity, comedogenicity (acne generating), hair and nail damage, hyper- and hypo-pigmentation, infectivity, carcinogenicity, and even systemic adverse effects. Therefore, proper cosmeceuticals use must weigh the benefits against any possible risks.[1] This consideration illustrates the need for proper scientific validation of the claims of skin care agents. Retinoids, peptides, and botanical extracts likewise fall under the category of cosmeceuticals.

Anti-Aging Effects

Clinicians distinguish between intrinsic (natural) aging and extrinsic aging, which is generally due to sun exposure. Sunlight generates reactive oxygen molecules which degrade connective tissue in the skin, especially collagen and keratin, causing the extrinsic aging effects.[1] Over-the-counter skin care products are aimed at reversing the effects of aging due to sun exposure.

The skin care effects of glycolic acid are manifold, including reducing cell cohesiveness in the stratum corneum layer of the epidermis.[2] The stratum corneum is the outermost layer of the epidermis, consisting of remnants of dead cells that are large and flat, being filled with keratin. The reduction in cohesiveness of cells in the stratum corneum results in exfoliation and cell turnover. Deeper in the epidermis, skin

normalization includes increasing thickness, improving the differentiation of the cell times among the layers of the epidermis, and evening out pigmentation. Glycolic acid brings about an increase in the undulating patterns that occur between the epidermis and the dermis of the skin. It promotes elastic fiber distribution, increased collagen synthesis, and hyaluronic synthesis. All of these effects result in a more youthful appearance.

Several studies establish the histological basis of these anti-aging effects. Direct evidence for modulation of skin keratinization and biosynthesis of dermal components has been derived from data on skin thickening of human subjects.[3] The effect is not due to edema or other undesirable reaction to the AHAs because the effect persists for many weeks to months after the end of therapy. In a statistically designed study of 65 patients treated with 15% glycolic acid for 6 months, the skin thickening increased 27% over control ($p < 0.01$), even greater than the effect induced by 0.01% estradiol applied similarly.[4] Electrical conductivity studies of skin show the moisturization effects of glycolic acid, electrical conductivity tracking the moisture content of the stratum corneum.[5] A double-blind vehicle control study of photoaged skin treated with 50% glycolic acid showed a decrease in rough texture and fine wrinkling, fewer solar keratoses [sunspots on the skin], and a slight lightening of solar lentigenes [age spots].[6] Some histologic specimens revealed an increase in collagen thickness in the dermis.

A clinical study by the NeoStrata group confirms that glycolic acid treatment increases type 1 collagen mRNA and hyaluronic acid content of human skin, after a treatment regimen consisting of 20% glycolic acid lotion applied to the skin of the human forearm twice daily for 3 months in comparison to a vehicle control.[7] These findings are corroborated by other *in vivo* studies supplemented by an *in vitro* study revealing the increase of collagen synthesis in cell culture as induced by glycolic acid.[8] The pH and concentration dependence of glycolic acid induced skin repairing effects of glycolic acid shows that increasing the pH may increase efficacy, while glycolic acid is effective across a broad pH range.[9]

In comparison to physical exfoliation, glycolic acid based exfoliation peel improves the cosmetic appearance of photo-aged skin as revealed in a clinical study.[10] In this study, 28 patients with moderate to severe photodamaged skin on the back of the hands were evaluated. After 10 weeks, 95% of the GA-treated hands showed significant improvement.[10] Another clinical study of glycolic acid peels revealed that 9 of the 10 patients in the trial showed overall significant improvement in photodamaged skin, including pigmentation, fine wrinkling, and roughness.[11] No difference was found between a treatment regimen consisting of monthly serial 70% glycolic acid peel over 4 months versus application of a 10% glycolic acid based moisturizer twice daily. Efficacy was likewise established in a clinical study of glycolic acid in combination with tretinoin or L-ascorbic acid in the treatment of unpigmented stretch marks (Striae Alba).[12]

An animal study shows that the rate of uptake of glycolic acid is influenced by formulation type.[13] This is consistent with the NeoStrata report that un-ionized glycolic acid is more rapidly absorbed than ionized glycolic acid and that oleophilic glycolic acid derivatives are more rapidly absorbed.[14]

Activity against Acne

A relatively large clinical trial of 80 women (mean age 22.7) revealed that glycolic acid chemical peels are an effective treatment for all types of acne, inducing rapid improvement and restoration to normal types of skin.[15]

Skin Lightening Effects

A further cosmetic application of glycolic acid is to promote skin lightening. The studies cited here pertain to the treatment of melasma, which is the hyperpigmentation of the face. Incumbent treatments include Jessner's solution, which is salicylate, lactate, and rescorcinol in ethanol. One clinical study compared efficacy of Jessner's solution to 70% glycolic acid combined with tretinoin (retinoic acid) and hydroquinone used between the glycolic acid peels. This study of human subjects quantified the effects colorimetrically. Large variability in the results is evident in the large standard deviations in the average lightening, which are 3.14 ± 3.1 on the glycolic acid-treated side and 2.96 ± 4.84 on the Jessner's solution-treated side. The authors state that there was an overall decrease in melasma area and severity of 63%.[16]

Another clinical study was focused on melasma treatment specifically for Asian women, including glycolic acid peels in the treatment.[17] While the results show that glycolic acid provides large improvement subjectively, the investigators caution that the improvement does not reach statistical significance due to small samples size ($N = 10$).

Photoprotective Effects

Several studies have evaluated use of glycolic acid in photoprotection and in its relationship to sun sensitivity. One trial with human subjects evaluated glycolic acid's effects in commercial skin creams on thickness of the stratum corneum and on the sensitivity to UVR, concluding that glycolic acid does not compromise skin sensitivity to sunlight.[18] In contrast, another clinical study evaluating topical glycolic acid suggested that some individuals may have enhanced sun sensitivity resulting from the use of glycolic acid, although the investigators also conclude that the effects are reversed within one week. They further indicate that this could be due to "subclinical – that is, nonerythematous – irritation", the implications of this being unclear in this writer's view.[19]

Another clinical study indicates that glycolic acid may have a photoprotective effect equivalent to spf 2.4. This study showed that glycolic acid applied to irradiated skin accelerates resolution of the redness or erythema.[20] While the authors of the study suggested that these observations could be due to a mild antioxidant effect of glycolic

acid, it would not seem to be consistent with the bulk of the literature which indicates that there is little or no antioxidant character of glycolic acid.

Retinoids, Peptides, Botanicals

While few direct comparisons of relative efficacy of glycolic acid to the retinoids, peptides, and botanicals exist, published data reveals the efficacy of certain retinoids, peptides, and botanicals. Like glycolic acid, these materials are also frequently classified as cosmeceuticals.[1] The literature points to advantages in formulating with glycolic acid over natural products such as the botanicals. Specific advantages of glycolic acid over the botanicals result from the complexity of the plant extracts, being complex mixtures, and varying in composition and also varying according to the season. A key review has pointed out these considerations and the fact that this is not reflected in the labeling.[21] Nonetheless, active ingredients in the botanicals often have beneficial effects in skin care.[25]

Many peptides are bioactive in skin care, modulating cell proliferation, cell migration, inflammation, angiogenesis, melanogenesis, and protein synthesis and regulation. These peptides fall into three main categories: signal peptides, neurotransmitter-affecting peptides and carrier peptides.

Our search revealed no references that compare glycolic acid to peptides. However, several articles review the use of peptides in skin care. The simplest of these is hydrolyzed keratin (sometimes from wool) and have high cystine content, which is sometimes S-sulphonated. *In vivo* studies appear to indicate an improvement in the skin's water-holding capacity, hydration, and elasticity for volunteers with dry skin as a result of the keratin peptide treatment.[22] Another study indicates that "A combination of the keratin peptide with the IWL [internal wool lipids] showed beneficial effects, indicating that this combination is suitable for designing new cosmetics products. The effects appear to be hydration and elasticity.[23] Both the keratin hydrolysates and the hair lipids provide moisturizing effects on skin, according to these investigators.

Glycolic acid as an Adjuvant for Other Therapeutic Agents

A key role of glycolic acid as an adjuvant is in pre-treatment of skin prior to application of therapeutic agents, resulting in enhanced activity of the therapeutic agent. For example, photodynamic therapy, which is the use of light for the localized treatment of diseases such as skin cancer, is sometimes limited by hyperkeratosis, or the excessive deposition of keratin. One clinical study demonstrates that pre-treatment with glycolic acid can relieve the effects of hyperkeratosis leading to enhanced efficacy of photodynamic therapy.[24] The authors of this clinical study caution that there are a significant number of pre-treatment adjuvant agents and that current data is insufficient to determine which is the most safe and effective method.

Another study has shown that glycolic acid included in benzoyl peroxide containing acne gels can give improved results.[25] Likewise, glycolic acid can improve the results provided by hydroquinone and kojic acid in the treatment of melasma, those being the dark skin lesions resulting from over exposure to sunlight.[26]

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[14] US5091171

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[21] Z.D. Draelos, Clinics Dermatol., 2001, 19, 474-7.

[22] C. Barba, et al., J. Cosm. Sci., 2007, 58, 99-107.

[23] C. Barba, et al., Skin Res. Tech., 2008, 14, 243-8.

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[25] E. Gans, et al., 2002, 15, 33-6.

[26] A. Garcia and J. Fulton, Am. Soc. Dermatol. Surg., 1996, 22, 443-7.

ATTACHMENT 5:

IODINE SHORTAGE INFORMAITON

Statement from Ecolab

Price Increases

Exceptional and adverse circumstances in the Iodine world market over the last year have caused critical problems for all Iodine related companies. The 2011 earthquake in Japan has led to an elimination of supply from Japan and has put severe pressure on the availability of Iodine worldwide. This also includes Chile, the largest Iodine source for Thatcher Company, the producer of the Povidone Iodine raw material, who has been our supplier since 1995. The demand pressures for Iodine have increased significantly due to the lack of supply from Japan and a continued general increase in world demand. In addition the alternative producers in Chile have had to deal with a critically dry period and an extreme shortage of water (water is critical for Iodine production). This water shortage decreased output dramatically. Following the nuclear tragedy in Japan and declined output, Iodine prices continue to surge. We expect Iodine prices to remain high for the foreseeable future as demand is currently outstripping a declining supply. The contracted supplies have been critically shortened due to the declined output and prices have been dramatically increased, worldwide.

In addition to the Iodine shortage, there is a shortened supply of Povidone as the raw supplier of Thatcher had a flooding in the plant and the production was down for two months.

Given this critical situation we have been able to secure raw material supplies until now. However, the suppliers of Povidone Iodine have now had to declare a Force Majeure due to the shortened supplies of Iodine and Povidone and increased prices.

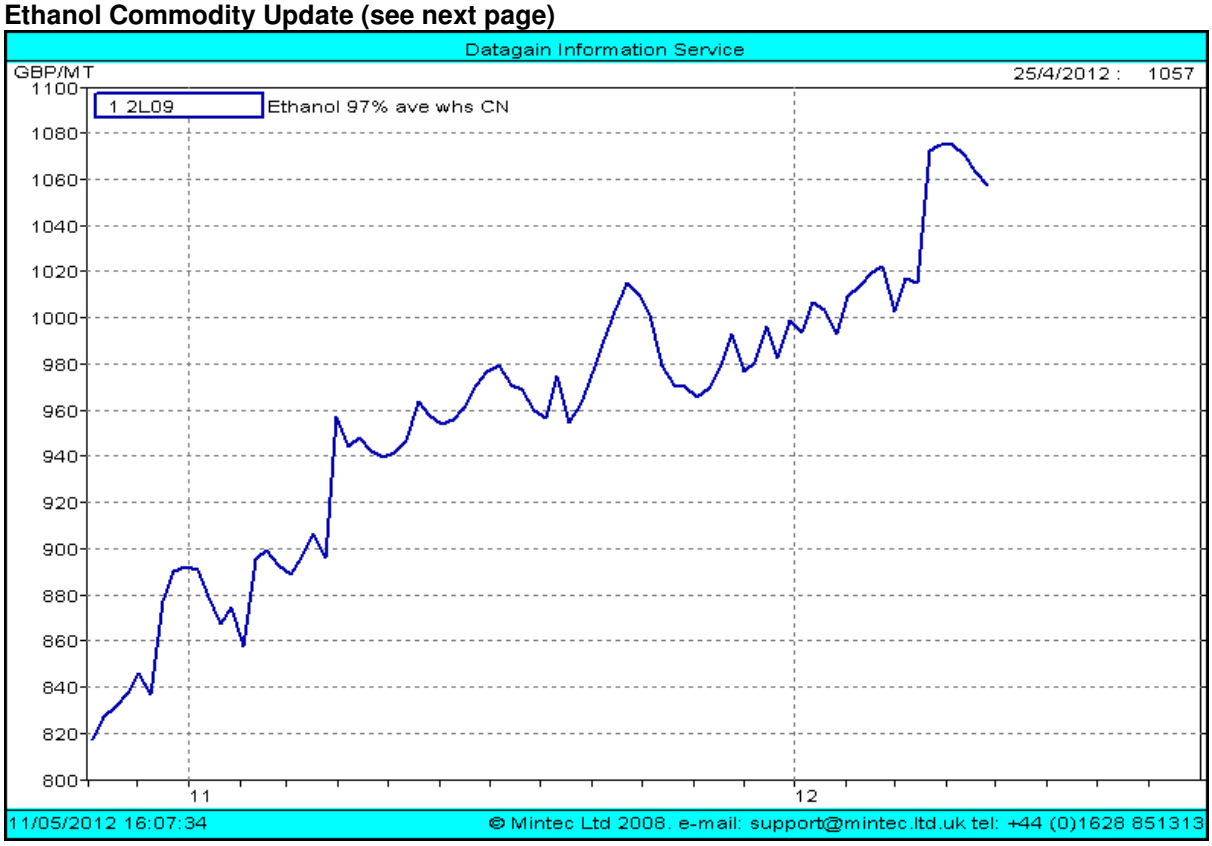
With respect to the change in the Hydrex range of products this has been driven by the continued increases in alcohol based raw materials which are derived from oil. This has consequently affected the alcohol based products within the Hydrex range. Again the price of oil has shown significant increases which have impacted on petrochemical derivatives such as Ethanol and Isopropanol.

In addition there has been increasing emphasis on the need for Ecolab products to meet the exacting standards of the MHRA and to be compliant with the on-going requirements of the Biocide Directive which will come into force under new regulations in September 2013. This requires a substantial body of work and supporting dossier of evidence to be submitted for every product within our current portfolio which is commercially viable.

Historically we have been able to supply the Videne and Hydrex ranges at consistently stable prices which would be reviewed annually and invariably remain unchanged. Due to the aforementioned circumstances we are finding our costs to produce these select ranges increasing on a month by month basis. As a consequence we have had no alternative to apply prices which reflect these cost pressures to support the viability of our continued supply of Videne and Hydrex as specified by Healthcare Professionals over the last 20 years.

We will of course continue to support our customers in the supply, training & education and development of these products as part of our extensive infection prevention package to the Healthcare market. We believe that despite the need to review our pricing in line with raw material and regulatory demands, our range offers excellent value for money solutions that are tried and tested by healthcare practitioners throughout the NHS and associated healthcare organisations.

Ethanol Commodity Update (see next page)



Doe & Ingalls

IODINE MARKET UPDATE

April 19, 2012 by Charlotte Hicks (https://www.doeingalls.com/author/charlotte-hicks/)

Last year, iodine availability and pricing were quite volatile due to the earthquake in Japan and the water shortage in Chile. These two countries alone account for about 90% of iodine's global supply. So when they are impacted, the world feels the effects. Recently I've read some news articles that gave some insight on what to expect for the iodine market in 2012. Here's what I've learned:

1. Demand is projected to remain steady

There was some concern earlier this year that methyl iodine, a controversial fumigant, was to replace the use of methyl bromide for fumigating strawberry fields in California. The concern was that if methyl iodine (sold under the brand name Midas) was accepted by agriculture, specifically in California, the supply of iodine would further tighten. In March, Arysta, the maker of Midas, pulled the material from the U.S.

2. Pricing is expected to remain high, but stable

Recently, Sirocco, one of the major iodine producers reported that iodine pricing is expected to remain high, but stable for 2012[2]. This is a relief from volatile pricing in 2011. In 2011, the average cost was $40/kg, compared to a 2010 average cost of $27/kg. This dramatic price increase, which occurred in a matter of months, impacted electronics manufactures (etchants), LCD manufacturers (optical polarizing films) and those in R&D (Lugol's Reagent, Karl Fischer Reagent, and catalysts).

We will continue to monitor the iodine market and provide updates here. If you have any questions about this product, or about our Management of Risk (MOR) program, please feel free to contact me or your Doe & Ingalls Account Manager.

1. http://www.thegrower.com/news/Arysta-suspends-sales-of-Midas-fumigant-143591066.html (http://www.thegrower.com/news/Arysta-suspends-sales-of-Midas-fumigant-143591066.html)
2. http://www.marketwatch.com/story/sirocco-releases-2011-financials-2012-04-03-83170 (http://www.thegrower.com/news/Arysta-suspends-sales-of-Midas-fumigant-143591066.html)