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

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

September 23, 2011

DP BARCODE: 390539

MRID: 484937-01 and 484937-02

SUBJECT: Pure Bright Germicidal 160 Bleach

REG. NO.: 70271-20

DOCUMENT TYPE: Amendment; Non-Fast Track

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
014703	7681-52-9	Sodium hypochlorite (6%)

TEST LAB: NA

SUBMITTER: KIK International Inc.

GUIDELINE: 830 Groups A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: September 23, 2011

COMMENT:

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September 23, 2011

MEMORANDUM

SUBJECT:	Product Chemistry Review for EPA Reg. 70271-20 Product Name: Pure Bright Germicidal 160 Bleach DP Barcode: 390539
CODE:	(570) Amendment; Non-Fast Track
DATE DUE:	October 17, 2011
FROM:	Lynette T. Umez-Eronini, Chemist Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	Monisha Harris PM#32/David Liem Regulatory Management Branch I Antimicrobials Division (7510P)
Applicant:	KIK International Inc.

PRODUCT FORMULATION FROM LABEL:

Active Ingredient:	% by wt.
Sodium hypochlorite (6%)	6.0
Other Ingredient(s):	94.0
Total:	100.0

BACKGROUND:

On behalf of the Registrant, KIK International Inc., the Consultant, Delta Analytical Corporation has submitted an amendment to add an alternate formulation on the Confidential Statement of Formula (CSF). The registrant has submitted an end-use product, Pure Bright Germicidal 160 Bleach. This product is a fungicide, bactericide, virucide, and sanitizer that is used on hard non-porous surfaces. The product is produced by a non-integrated end-use system.

The original data package included:

1. A letter from the applicant's representative to EPA, dated May 26, 2011.
2. EPA Form 8570-1 (Amendment), dated May 26, 2011.
3. A CSF for alternate #1 formulation, dated May 16, 2011.
4. EPA Form 8570-27 (Formulator's Exemption Statement), dated May 26, 2011.
5. EPA Form 8570-34 (Certification with Respect to Citation of Data), dated May 26, 2011.
6. EPA Form 8570-35 (Data Matrix) 4 pages, dated May 26, 2011.
7. A draft label, pin-punched May 27, 2011.
8. Product Chemistry Studies volumes. (MRID 484937-01 and 481937-02), dated May 23, 2011.
   Volume 1 of 8: Pure Bright Germicidal 160 Bleach Alternate Formula: Product Identity and Manufacturing Process
   Volume 2 of 8: Pure Bright Germicidal 160 Bleach Alternate Formula: Physical and Chemical Properties

FINDINGS:

1. Confidential Statement of Formula
   a. A comparison is made between the CSF of the proposed alternate #1 formulation, dated May 16, 2011 and the basic formulation, dated January 6, 2011.
      - The basic CSF, dated January 6, 2011 would be used as a reference.
      - The reviewer used "Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient", as a reference, which would be referred as RED, 1986.
      - The nominal concentration of the active ingredient on both CSFs is consistent with the draft label, pin-punched May 27, 2011.
      - The certified limits of the active ingredient are the same on both CSFs.
      - The lower certified limit of the active ingredient on both CSFs fails to be in compliance with the guidelines as specified in the RED, 1986.

b. Alternate #1 CSF, dated May 16, 2011
   - Alternate #1 formulation consists of ingredients that differ from the originally registered product (see basic CSF, dated January 11, 2011).
   - All EPA registered numbers for the active ingredient sources are found acceptable.
   - The lower certified limit of the active ingredient not only fails to comply with RED, 1986 standard but also with EPA standard certified limits.
   - Inert ingredients were approved for non-food use.

2. Product Label
   a. The active ingredient on the label, pin-punched May 27, 2011 is consistent with those on the alternate #1 CSF.

3. Product Chemistry:
   a. Group A Product Chemistry is met (see Table A below for details).
   b. Group B Product Chemistry is met, except 830.6317 Storage Stability and 830.6320 Corrosion Characteristics, which is on-going (see Table B below).

      Note: A product storage stability study was not provided. The registrant addressed product storage stability by citing "1992 Sodium Hypochlorite RED, bibliographic citation 00007226 and stating the inerts added for the alternate formulation are minimal and are not expected to affect stability of the sodium hypochlorite. However, the best available copy of this document is illegible, is specific to a product (EST No. 193-PA-1) and is unrelated to the current alternate #1 formulation.
      The registrant has addressed corrosion characteristics with a statement that these studies are ongoing.

CONCLUSION:

Alternate #1 CSF, Label, and Product Chemistry Group A and Group B have been reviewed. The proposed amendment is unacceptable. Group A Product Chemistry and Group B Product Chemistry are met, with some exceptions. However, the profile of alternate #1 differs from the basic formulation.

RECOMMENDATIONS:

The alternate #1 formulation should be submitted as a new product (See Tables below). The basic formulation must be revised so the lower certified limit must be the same as the nominal concentration, as based on the RED, 1986. The alternate formulation #1 does not qualify to use the RED 1986, therefore, the registrant needs to use EPA standard certified limits or provide a justification letter to have wider certified limits range.

PRODUCT CHEMISTRY REVIEW FOR ALTERNATE #1 FORMULATION

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [X] No [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]

Note: Product is not intended for food use

Note: All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on March 28, 2010 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

Note: The pH of the product falls below the pH range as cited on the CSF.

e. The NCs and CLs are acceptable. Yes [ ] No [X]

f. Active ingredient(s)	NC%	LCL%	UCL%
Sodium hypochlorite	6.00	5.70	7.50

Note: The LCL fails to comply with the 1986 RED and EPA standard certified limits.

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Corrosion characteristics of product to container studies are ongoing and have not been completed.

Note: Storage stability study has not been provided.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	484937-01
830.1600 Description of Materials	A	484937-01
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	484937-01
830.1670 Formation of Impurities[4]	NA	484937-01
830.1700 Preliminary Analysis[5]	*[Not required for products produced by a non-integrated system.]*	
830.1750 Certified Limits[6]	U Certified Limits are consistent with the basic formulation. Lower certified limits of active require correction.	484937-01
830.1800 Enforcement Analytical Method[7]	A	484937-01 Cites 481008-01
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		484937-02
830.6303 Physical State	A	Liquid	484937-02
830.6304 Odor	NA	*[Not required for end-use products.]*	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	No signs of reaction with water, powdered iron, or oxidizing agent; monoammonium phosphate: foam produced, gas given off, 30°C temperature rise	484937-02
830.6315 Flammability/ Flame Extension	NA		484937-02
830.6316 Explodability	NA	This product is not potentially explosive	484937-02
830.6317 Storage Stability	N	See 1992 Sodium Hypochlorite RED, bibliographic citation 00007226. The inerts added for the alternate formulation are minimal and are not expected to affect stability of the sodium hypochlorite.	484937-02
830.6319 Miscibility[1]	NA	The product is ready to use.	484937-02
830.6320 Corrosion Characteristics	G	Testing on going.	484937-02
830.6321 Dielectric Breakdown Voltage	A	The product is not to be used around electrical equipment.	484937-02
830.7000 pH[2]	A	11.21 pH at 25°C	484937-02
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	A	1.314 mm^2/s(cSt)	484937-02
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	1.1030 Relative density at 21°C	484937-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water