

US EPA ARCHIVE DOCUMENT

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

December 1, 2010

DP BARCODE: D381844

MRID: 481955-00, 481955-01

SUBJECT: Ygiene™ 206

REG. NO. OR FILE SYMBOL: 81242-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use OR End-use Product

INGREDIENTS (PC Codes) Hydrogen peroxide (000595); Peracetic acid (063201)

CAS Number: 7722-84-1, 79-21-0

TEST LAB: Eurofins Product Safety Laboratory

SUBMITTER: BioNeutral Group, Inc.

GUIDELINE: 830 Group A & B

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 12/02/10

COMMENT:

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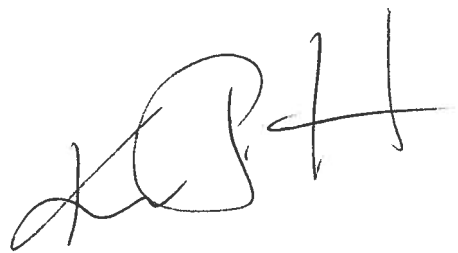
December 1, 2010

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 81242-R.
Product name: Ygiene™ 206
DP # 381844

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)



To: Marshall Swindell / Abigail Downs
PM Team 33

APPLICANT: BioNeutral Group, Inc.

Action code: A540

Due date: 01/06/11

Product Formulation from label

Active Ingredient(s)

% by wt.

Hydrogen peroxide 6.14

Peracetic acid 0.60

BACKGROUND:

On behalf of the registrant, BioNeutral Group, Inc., the consultant, to Xcel Toxicology & Regulatory Affairs, has submitted a new non-integrated end-use product, Ygiene™ 206. This product is for use as a hard non-porous surface disinfectant, fungicide, and sporicide cleaner used in commercial, hospital and medical environments. Product Chemistry Reviewer has received the following documents:

- A letter, dated 08/13/2010. MRID # 481955-00.
- A label, dated 08/13/2010 by the registrant.
- Confidential Statements of Formula (CSFs) dated 08/13/2010, & 12/01/10, for the pre & post-equilibration for the basic formulation.
- Transmittal document, dated 08/13/10.
- Study titled “Ygiene 206 Product Chemistry” (MRID 481955-01)

FINDINGS:

1. Group A product chemistry data requirements applicable to end-use products have been met. See Table A of this report.
2. All Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). See Table B of this report.
3. The CSF, dated 08/13/10, for the basic formulation is obsolete. The CSF shows a pre & post-equilibration and both equilibration are identical. The CSF and the label did not have the same nominal.
4. The CSF, dated 12/01/10, for the basic formulation is revised. The registrant updated the CSF by removing the pre & post-equilibrium.
5. The CSF and the label have the same nominal.
6. The product is produced in a non-integrated system. However, the registrant conducted a preliminary analysis. The laboratory that performs the assays targeted the hydrogen peroxide to be 5.5% and peracetic acid to be 0.3%. The laboratory conducted an assay for 5 lots and the results are as follows:

| Hydrogen Peroxide | Peracetic acid |
|-------------------|----------------------------------|
| % | % |
| 5.458 | 0.343 |
| 5.732 | 0.355 |
| 5.812 | 0.329 |
| 5.516 | 0.308 |
| 5.529 | 0.292 |
| (5.609) | 0.325) Average of 5 lots. |

7. The certificate of analysis for the 5 lots are as follows:

| Hydrogen Peroxide % | Peracetic acid % |
|------------------------|---------------------|
| 5.5 | 0.3 |
| 5.7 | 0.4 |
| 5.5 | 0.3 |
| 5.5 | 0.3 |
| 5.8 | 0.3 |

8. The registrant submitted a justification for wider certified limits for both active ingredients. The wider certified limits are based on preliminary analysis results.

CONCLUSION

The CSF, dated 12/01/10, for the basic formulation is acceptable. The product chemistry package is acceptable with the exception of the OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). These guidelines are currently in progress and will be made available to the Agency upon their completion.

RECOMMENDATIONS:

To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. Testing of the product is currently underway.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system []
- 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]

c. Physical state of product:

Liquid

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredients

| | <u>NC</u> | <u>LCL</u> | <u>UCL</u> |
|-------------------------|-----------|------------|------------|
| | (%) | (%) | (%) |
| Hydrogen peroxide | 6.14 | 5.04 | 6.45 |
| Peracetic acid | 0.60 | 0.66 | 0.27 |

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 $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes No

b. The formula contains one of the following:

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

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

d. Appropriate warning statements regarding flammability or explosive characteristics of the product are listed on the label.

Yes No Not applicable

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: Storage stability studies are ongoing and have not been completed.

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

| Data Requirements | Acceptance of Information | MRID No. |
|---|--|-----------------|
| 830.1550 Product Identity ¹ | A | 481955-01 |
| 830.1600 Description of Materials | A See CSF & MSDS | |
| 830.1620 Production Process ² | NR | |
| 830.1650 Formulation Process ³ | A | 481955-01 |
| 830.1670 Formation of Impurities ⁴ | A | 481955-01 |
| 830.1700 Preliminary Analysis ⁵ | A | 481955-01 |
| 830.1750 Certified Limits ⁶ | A – Standard certified limits were proposed. | 481955-01 |
| 830.1800 Enforcement Analytical Method ⁷ | A | 481955-01 |
| 830.1900 Submittal of Samples | <i>Available upon request</i> | 481955-01 |

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.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate 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 | A | Colorless | 481955-01 |
| 830.6303 Physical State | A | Clear liquid | 481955-01 |
| 830.6304 Odor | A | Vinegar like | 481955-01 |
| 830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions | NR | <i>[Not required for end-use products.]</i> | |
| 830.6314 Oxidation/Reduction; Chemical Incompatibility | A | Compatible with water, iron, kerosene, 10% ADP, incompatible with 10% KMnO ₄ | 481955-01 |
| 830.6315 Flammability/Flame Extension | A | Flash point 74.2°C | 481955-01 |
| 830.6316 Explodability | A | The product is largely aqueous and contains no functional groups, such as nitro groups, that would confer explosive potential. | 481955-01 |
| 830.6317 Storage Stability | U | A storage stability study is currently underway. Results will be provided to EPA once the study is complete. Note: Interim results show that, after storage of the product for 6 weeks at 40°C, the concentrations of the active ingredients in the product had not changed from those measured initially. | 481955-01 |
| 830.6319 Miscibility ¹ | A | The formulation is not an emulsifiable liquid and will not be diluted with petroleum solvents. | 481955-01 |
| 830.6320 Corrosion Characteristics | U | A corrosion characteristics study is currently underway. Results will be provided to EPA once the study is complete. Note: Interim results show that, after storage of the product for 6 weeks at 40°C, the packaging material remained unaffected. | 481955-01 |
| 830.6321 Dielectric Breakdown Voltage | A | The product will not be used around electrical equipment. | 481955-01 |
| 830.7000 pH ² | A | 3.81 (1% w/w solution). | 481955-01 |
| 830.7050 UV/Visible | NR | <i>[Not required for end-use products.]</i> | |

| Physical/Chemical Properties* | Acceptance of Data | Value or Qualitative Description | MRID No. |
|--|--------------------|--------------------------------------|-----------|
| Absorption | | | |
| 830.7100 Viscosity | A | 2.228 cSt @ 20°C, 1.377 cSt @ 40°C | 481955-01 |
| 830.7200 Melting Point/Melting Range | NR | [Not required for end-use products.] | |
| 830.7220 Boiling Point/Boiling Range | NR | [Not required for end-use products.] | |
| 830.7300 Density/Relative Density/Bulk Density | A | 1.012 g/ml | 481955-01 |
| 830.7370 Dissociation Constants in Water | NR | [Not required for end-use products.] | |
| 830.7550/830.7560/830.7570 Partition Coefficient | NR | [Not required for end-use products.] | |
| 830.7840/830.7860 Water Solubility | NR | [Not required for end-use products.] | |
| 830.7950 Vapor Pressure | NR | [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.

¹If product is an emulsifiable liquid

²If product is dispersible with water