

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



Office of Pesticide Programs

Antimicrobials Division (AD)

June 9, 2010

DP BARCODE: 375686

MRID : 480175-01

SUBJECT: Puma
(Name of Product)

REG. NO.: 5813-RNN

DOCUMENT TYPE: Product Chemistry Review

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

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
014703	7681-52-9	Sodium hypochlorite

TEST LAB: (submitter's facility))

SUBMITTER: The Clorox Co.

GUIDELINE: Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVER: Karen P. Hicks

APPROVED DATE: June 9, 2010

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

June 9, 2010

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 5813-RNN

Product Name: Puma

DP Barcode: 375689

CODE: (A540) New Product Registration

DATE DUE: June 4, 2010

FROM: Earl Goad, Biologist
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: Wanda Henson (acting PM#32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: The Clorox Co,

PRODUCT FORMULATION FROM LABEL:

<u>PC Codes</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
014703	Sodium Hypochlorite	8.25
	<u>Other Ingredient(s):</u>	<u>91.75</u>
	Total:	100.00

BACKGROUND:

The Clorox Company has submitted an application for registration of a new end-use product, Puma. This product is for use as a disinfectant (bactericide, fungicide, virucide), sanitizing rinse, sanitizer, and deodorizer on hard, non-porous surfaces in household, commercial, institutional, food processing, animal care, and hospital or medical environments. This product also is for use as a laundry sanitizer. The data package included a Confidential Statement of Formula (CSF) for the basic formulation (dated March 3, 2010) and CSFs for three alternative formulations (each dated March 3, 2010). The product is produced by a non-integrated system. The source of the active ingredient is the registered product, [REDACTED]

FINDINGS:

1. Confidential Statements of Formula (CSFs): The basic and three alternate (A01, A02, A03) formulations dated March 3, 2010 are found to be acceptable.
2. Product Label: The label dated March 5, 2010 is acceptable from the Product Chemistry standpoint.
3. Product Chemistry Group A and B.
 - a. Product Chemistry Group A: Product Identity data requirements have been satisfied with the following exceptions: See Table A for complete listing of Group A responses to data provided.
 - i. An upgrade has been requested for the previously submitted OPPTS: 830.1800 Enforcement Analytical Method cited as MRID# 479539-01. The method was found lacking with respect to method validation data. The method must include discussion of the suitability of the method for measurement of the specific analyte in the product given by limit of detection, method linearity and precision characteristics. An upgrade has been discussed with the registrant. The registrant was in agreement has supplied a revised method (MRID #: 481141-01) which was found acceptable..
 - ii. The registrant has provided justifications for the request to use even wider certified limits than would typically be allowable in standard "bleach" formulations. The explanations appear sound.- however final approval of the use of these wider limits may depend the adequacy of support provided for the products efficacy claims (at the low end) and acute toxicity support provided at the higher end of the usage range.

b. Product Chemistry Group B:

- i. The “waivers” requested relative to data requirements which may not apply or not required for this product are found to be acceptable. See Table B: Physical and Chemical Properties.
- ii. All other 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). Results for a minimum of 1 year (or a period of time which has been agreed upon) from a GLP-compliant storage stability and corrosion characteristics study must be provided. Testing of the product is currently underway. The concentration of the active ingredient in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year. Storage and disposal information on the product label must be revised if product composition (or packaging) deteriorates over time.

CONCLUSION:

The data provided to support the registration of this product is found to be generally acceptable. The CSFs for the basic and three alternate formulations (dated 3/3/2010) and the product label (dated 3/5/2010) are acceptable. The upgraded enforcement method (MRID # 481141-01) as received and found acceptable

The request for broader certified limits for the active ingredient is found acceptable from the viewpoint of the product chemistry. The determination of the stability/expiration of the product depends upon the one year product storage stability and corrosion characteristic studies which are currently in progress.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

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

Note: A tolerance exemption has been approved suitable for the active ingredient in this product found in 40 CFR §§180.940 – not to exceed 200 ppm total available chlorine for food contact surface sanitization.

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 [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

Note: Non-standard certified limits were proposed for the active ingredient, inert ingredients, and by-products. Explanations of the basis for the non-standard limits were provided. The explanations appear sound.

f. Active ingredient(s)

	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
Sodium hypochlorite	8.25	5.9	10.5

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 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 [X] 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 [X] 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	480175-01 and CSFs
830.1600 Description of Materials	A	480175-01 and CSFs
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	480175-01 and CSFs
830.1670 Formation of Impurities ⁴	A	480175-01
830.1700 Preliminary Analysis ⁵	A – Results from the analysis of five batches of the product were provided (i.e., 09PUMA01, 09PUMA02, 09PUMA03, 09PUMA05, and 09PUMA11).	480175-01
830.1750 Certified Limits ⁶	A – Non-standard certified limits were proposed for the active ingredient, inert ingredients, and by-products. Explanations of the basis for the non-standard limits were provided. The explanations appear sound. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	480175-01
830.1800 Enforcement Analytical Method ⁷	A – A study previously submitted to the Agency was cited. An upgrade for this method is requested to include method validation parameters (limit of detection, linear range, precision, and discussion of the suitability as it applies to analysis of the ingredient in this product) Upgraded method provided as MRID 481141-01.	Data Matrix cites 479539-01 Revised EAM 481141-01
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

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	The color of the product is clear, light yellow.	480175-01
830.6303 Physical State	A	The product is a liquid.	480175-01
830.6304 Odor	A	The product has a sodium hypochlorite bleach odor.	480175-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	[Not required for end-use products.]	
830.6314 Oxidation/ Reduction: Chemical Incompatibility	---	The standard potential of hypochlorite is +0.90 volts.	480175-01
	A	The label includes a "Physical or Chemical Hazards" section, which states the following: "Product contains a strong oxidizer. Always flush drains before and after use. Do not use or mix with other household chemicals, such as toilet bowl cleaners, rust removers, acids or products containing ammonia. To do so will release hazardous irritating gases."	Label
830.6315 Flammability/ Flame Extension	NA	The product does not contain combustible liquids. [Waiver requested.]	480175-01
830.6316 Explodability	A	The product is not potentially explosive. [Waiver requested.]	480175-01
830.6317 Storage Stability	G	A storage stability study is currently underway.	480175-01
830.6319 Miscibility ¹	NA	The product is not an emulsifiable liquid and is not to be diluted with petroleum solvents. [Waiver requested.]	480175-01
830.6320 Corrosion Characteristics	G	A corrosion characteristics study is currently underway.	480175-01
830.6321 Dielectric Breakdown Voltage	NA	The product is not intended for use around electrical equipment. [Waiver requested.]	480175-01
830.7000 pH ²	A	The mean pH of the product was reported to be 12.066. Each of three samples was analyzed in duplicate. Clorox SOP 001-02-03 was referenced.	480175-01
830.7050 UV/Visible Absorption	NA	[Not required for end-use products.]	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7100 Viscosity	A	The viscosity of the product was reported to be 1.52 centipoises at 20°C and 1.02 centipoises at 40°C (using a Wells-Brookfield cone/plate viscometer). Three determinations were made at each temperature.	480175-01
830.7200 Melting Point/Melting Range	NA	<i>[Not required for end-use products.]</i>	
830.7220 Boiling Point/Boiling Range	NA	<i>[Not required for end-use products.]</i>	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.085 g/mL (9.06 lb/gal). Each of three samples was analyzed in duplicate. Clorox SOP 000-032-00 was referenced.	480175-01
830.7370 Dissociation Constants in Water	NA	<i>[Not required for end-use products.]</i>	
830.7550/830.7560/830.7570 Partition Coefficient	NA	<i>[Not required for end-use products.]</i>	
830.7840/830.7860 Water Solubility	NA	<i>[Not required for end-use products.]</i>	
830.7950 Vapor Pressure	NA	<i>[Not required for end-use products.]</i>	

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.

* 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