

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE [] OR AN END-USE PRODUCT [✓]
DP Barcode 205997 Reg. No. or File Symbol No. 5813-LN

TO: (PM Team Reviewer)
PM Team No. 32 (Ruth Douglas)

FROM: (Chemist/Date) Anna Skapars 8-17-94
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head 24 8/17/94.
Registration Support Branch/RD (WH705W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Registrant is proposing to register high strength pH controlled Sodium hypochlorite

- A. Confidential Statements of Formulas dated 4-29-94 one basic and four alternate, alternate A1, A2, A3 and A4 are in compliance with PR Notice 91-2, agree with the label claim the nominal concentration and are acceptable.

Registrant is proposing wider range in certified limits which are supported by storage and stability data therefore there should be no objection from product chemistry.

- B. Product chemistry data in MRID No. 432329-1 includes Guidelines Ref. No. Series 61, 62 and 63 and it is in compliance with 40 CFR part 158.155 through 158.190 and it satisfies product chemistry data requirement.

This product is substantially similar with the product EPA Reg. No. 5813-LE

These two products EPA Reg. No. 5813-LE and 5813-LN are similar with product EPA Reg. No. 5813-LR they are not substantially similar from product chemistry's point of view.

H7505W:RD:RSB:PCRS:CS-1:Rmxxx:Reviewer:Typist Initials:xx/xx/94:703-308-xxxx:Code No. (Reg or Rereg No.).

Note to PM:

Is hand sanitizing regulated by EPA or FDA?
There is hand sanitizing claim in the label.

Anna Skapars
8-17-94

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT ☒ MANUFACTURING-USE PRODUCT ☐
EPA Reg. No. (or File Symbol No.) 5813-LN

Registration ☒

Reregistration ☐
Case No.: _____

DP Barcode/Chemist: D 205995 Anna Skapars

1)

3)

2)

4)

1. Product Name: Ultra Clorox Brand Regular Bleach

2. Company: The Clorox Company

3. Type of Submission: New ☒ Resubmission ☐ Amendment ☐
"ME-TOO" ☐ Alternate Formulation ☐ REPACK ☐
Expt Use Permit ☐ Other (Specify) _____

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system ☒
 - Are all TGAIs used registered • yes ☒ • no ☐
- Integrated formulation system ☐
- If "ME-TOO", specify EPA Reg. No. of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40CFR§180.1001:

- yes ☐ • no ☐. If yes: • c ☐ • d ☐ • e ☐
- Cleared for non-food use: • yes ☒ • no ☐

4c. Physical state of product: Liquid

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes ☒ • no ☐

- 4e. Density (or bulk density for solids): ^{lb/gal} 9.18 at 25 °C.
- 4f. pH (if dissolved or dispersed in water): 11.4 ± 0.40
- 4g. Flash point and/or flame extension: N/A
- 4h. NCs and CLs are acceptable: • ☒ • not acceptable ☐
- 4i. Active ingredient(s) NC LCL UCL
- | | | | |
|------------------------|-----|-----|-----|
| A. Sodium hypochlorite | 6.0 | 4.8 | 7.2 |
| B. | | | |
| C. | | | |
| D. | | | |
- 4j. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL: • yes ☐ • no ☐ • not applicable ☐
 - All impurities $\geq 0.1\%$ in the product have been identified: • yes ☐ • no ☐ • not applicable ☐

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes ☒ • no ☐
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: • yes ☐ • no ☒
 - 1% 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 ☒
- 5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this? • yes ☐ • no ☐ • not applicable ☒
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label: • yes ☒ • no ☐ • not applicable ☐

6a. <u>Chemical IDs/Manufacture/Analytical Information</u>	<u>Accept of Information</u>	<u>MRID No.</u>
61-1 Chemical ID (see Appendix) ¹	Accepted	432329-1
61-2a Manufacturing Process ²	Accepted	432329-1
61-2b Formulation Method ³	Accepted	432329-1
61-3 Discussion of Impurities ⁴	Accepted	432329-1
62-1 Analysis ⁵	Accepted	432329-1
62-2 Certified Limits ⁶	Accepted	432329-1
62-3 Analytical Method for AIs ⁷	Accepted	432329-1

6b. <u>Physical/Chemical Properties</u>	<u>Accept of Data</u>	<u>Value or qualitat descrip⁸</u>	<u>MRID No.</u>
63-3 Physical State	Accepted	Liquid	432329-1
63-7 Density/Bulk Density (g/cc)	Accepted	1.18 g/cc	432329-1
63-12 pH of product ⁹	A	11.4 ± 0.4	432329-1
63-14 Oxid/Red Action	A	oxidizer	432329-1
67-15a Flash Point(°C) ¹⁰	N/A		
63-15b Flame Extension	N/A		
63-16 Explodability	N/A		
63-17 Storage Stability (% degradation of AIs at 20-30°C for ≥ 1 year)	Accepted	4 weeks at 37°C + 21°C	432329-1
63-18 Viscosity	Accepted		432329-1
63-19 Miscibility (with hydrocarbon solvents) ¹¹	N/A		
63-20 Corrosivity (specify metals/conditions)		Corrosive	432329-1
63-21 Dielectric Breakdown Voltage ¹²	N/A		

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

Footnotes: ¹ See Confidential appendix A for additional information; ² For MP/EP products produced by an integrated formulation system; ³ For products produced from a TGAI or MP; ⁴ May be waived unless actual/possible impurities are of tox 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. ⁸ 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; ⁹ If product is a water solution or dispersion; ¹⁰ Not required for aerosols; ¹¹ Emulsifiable liquids only; ¹² For end-use products used near electrical equipment.

Attachment: Confidential Appendix A (page 5).

cc: Reviewer's Name and Central File (Reg. No. or Rereg Case No.)

H7505W:RD:RSB:PCRS:CS-

1:Rxxxx:Reviewer's Name:Typist Initials:xx/xx/94:703-308-xxxx:Code (Reg or Rereg No).

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