5-3-94

REG. NO: ______
FILE SYMBOL: 37425-GU

PRODUCT CHEMISTRY REVIEW FOR END USE PRODUCTS

TO: PM 13

PRODUCT NAMES: Dura Sect Livestock Pour-On

FROM: T. Alston

THRU: H. Podall HP 5/31/94.

CHEMICAL: -

MRID NOS. ______

Food Use ______ Non Food Use ______

Inerts cleared: c ( ) d ( ) e ( ) yes ( ) no ( )

Inerts List 1 ( ) Other ( )

Please provide the requested information for the following checked items:

1. [ ] Submit the product specific product chemistry data for your product. ( ) If submitted earlier, provide MRID Number(s). ( ) Your product is not sufficiently similar to the product your referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

   [ ] a) pH of product at a specified water dilution.

   [ ] b) Density of product.

   [ ] c) Flash point of product.

   [ ] d) Flash point of product with propellent as per item #6(q) or item #5(c).

   [ ] e) Flash extension of product including flashbacks if noted.

The material safety data sheets for the identity of the inerts— [redacted] are not acceptable in fulfillment of the requirement for the identity to determine if such product is cleared for use. See page #2 of this form #4. The supplier must provide the components, ~~and~~ percentage composition, and CAS#'s of the [illegible]

INERT INGREDIENT INFORMATION IS NOT INCLUDED

[ ] f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate.

[ ] g) The upper and lower certified limits of the individually added inerts.

[ ] h)

[ ] i)

[ ] j)

3. Based on the current CSF dated_____, your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

4. Provide the chemical identify of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1. [redacted]
2.
3. INERT INGREDIENT INFORMATION IS NOT INCLUDED
4.
5.

The supplier may contact EPA directly referencing the File Symbol of EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provided for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non-food type. The Confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

[ ] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [ ] PR Notice 84-1 for non-aerosol containers for houses and institutional uses of [ ] PR Notice 83-3 for all other uses.

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[ ] b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).

[ ] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as extremely Flammable (because your product contains flammable propellents).

[ ] d) Provide that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.

[ ] e) Add a footnote to the inert ingredients indicating: Contains petroleum distillates, xylene or xylene-range aromatic solvent.

[ ] f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the physical or Chemical Hazards heading;

> Do not use this product in or on electrical equipment due to the possibility of shock hazard.

[ ] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.

[ ] h)

[ ] i)

6. In reference to the product specific data requirements, provide the following information:

[ ] a) Statement of Composition: A complete description of the manufacturing formulation process. Describe equipment used, mixing time, temperature, pressure, etc.

[ ] b) Discussion of Formation of Unintentional Ingredients: A brief description of impurities formed during the manufacturing/formulation process, in packaging or during storage. If you do not expect any impurities during these stages please so state.

[ ] c) Certification of Limits: Upper and lower limits or each active and individually added inert component.

[ ] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s)

[ ] e) Color: In common terms.

[ ] f) Physical State: e.g., solid, liquid, pressurized liquid, etc.

[ ] g) Odor: In common terms

[ ] h) Density: e.g., lbs/gallon for liquids or lbs/cu.ft for solids.

[ ] i) Ph: Provide pH of product or pH of a specified water dilution.

[ ] j) Oxidizing or Reducing Action: Note these characteristics, if any.

[ ] k) Explodability: Note these characteristics, if any.

[ ] l) Viscosity: Can be expressed in centipoise or centistoke.

[ ] m) Miscibility: Note these characteristics if product is an emulsifiable liquid and mixed with oil.

[ ] n) Corrosion Characteristics: This information can be noted during the storage stability study.

[ ] o) Dielectric Breakdown Voltage: For products used near electrical equipment.

[ ] p) Storage Stability: The formulated product must be analyzed for its active ingredients at time zero and during one year of storage. The storage should be at warehouse conditions of temperature and humidity and stored in the product's commercial package. Note: For the storage stability study, you may not reference the data on source product concentrate you are using to formulate your product.

[ ] q) Flammability: Flash point/flame extension. The flash point reported exceeds the one expected for this product. Please check and resubmit. Mixtures marketed under pressure, including those containing hydrocarbons, are subject ~~in their~~ entirety to tests indicated in 40 CFR Section 156.10(h)(2)(iii) of the maxipackage. Note that flash points for pressurized liquid from the container

[ ] If any of the items are not applicable, write N.A. and explain reasons are specified under chemistry data requirements footnotes. See 40 CFR Part 158.

7. [ ] The following is the regulatory status of the inert ingredients under 40 CFR 180.1001 for for the exemption of the requirement of a tolerance.

8. Other

Note to PM: Inter-office use only

SUMMARY ATTACHED

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

CLR #	TITLES	
	Series 61-Product Identity and Composition (40CFR158.155, 160, 162, 165 & 167)	
61-1	Product Identity & Disclosure of Ingredients	
61-2	Description of Starting Materials & Manufacturing Process	
61-3	Discussion of Formation of Impurities	
	Series 62-Analysis and Certification of Product Ingredients (40CFR158.170, 175 & 180)	
62-1	Preliminary Analysis of Product Samples	
62-2	Certification of Ingredient Limits	
62-3	Analytical Methods to Verify Certified Limits	
	Series 63-Physical and Chemical Characteristics (40CFR158.190)	
63-2	Color	
63-3	Physical State	
63-4	Odor	
63-5	Melting Point	
63-6	Boiling Point	
63-7	Density, Bulk Density, or Specific Gravity	
63-8	Solubility	
63-9	Vapor Pressure	
63-10	Dissociation Constant	
63-11	Octanol/Water Partition Coefficient	
63-12	pH	
63-13	Stability	
63-14	Oxidizing or Reducing Action	
63-15	Flammability	
63-16	Explodability	
63-17	Storage stability	
63-18	Viscosity	
63-19	Miscibility	
63-20	Corrosion Characteristics	
63-21	Dielectric Breakdown Voltage	

A - Acceptable
W - Waived
NA - Not Applicable
DG - Data Gap

Reviewer: _____

Section Head _____

Date: _____