DATE OUT: 09/DEC/08

SUBJECT: PRODUCT CHEMISTR REVIEW OF: TGAI [ ]; MUP [ ]; EUP [x]
BARCODE NO.: 357851
REG./FILE SYMBOL NO./PRODUCT NAME: 71407-1/Proem Dual Release Grape Guard
71407-3/Proem Slow Release Grape Guard
MRID NOS.: 408236-01, 410078-01, 437823-01, 438557-01, 475428-01, 475626-01, -02, 475552-01, -02, -03
COMPANY NAME: Embalajes Proem Ltda. **ACTION CODE:** 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508P)

TO: Karen Jones, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 4056 was issued in May, 2007 for the Technical Grade Active Ingredient (TGAI), Inorganic Sulfites (Sulfur dioxide or Sodium metabisulfite). According to the RED, the generic data base supporting the reregistration of Inorganic Sulfites have been reviewed and found to be substantially complete.

In the 8-month response to the Inorganic Sulfites RED, the registrant submitted Confidential Statements of Formula (CSF) for each product (basic formulation, both dated 9/15/08); draft labels (pin-punched 9/17/08); and product chemistry data in MRID numbers 408236-01, 410078-01, 437823-01, 438557-01, 475428-01, 475626-01, -02, 475552-01, -02, -03. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. Nos. **71407-1** and **71407-3**.

FINDINGS:

1. EPA Reg. Nos. 71407-1 and 71407-3 are end-use products containing 97.5% Anhydrous Sodium bisulfite. The product is produced through a non-integrated formulation process.

2. The CSF for each product (basic formulation, dated 9/15/08) are not acceptable due to the following:

   a. The nominal concentration of the active ingredient does not match the label claim (97.5% *vs.* 98.0%).
   b. The total weight (active ingredient plus the trace impurities) does not equal 7 grams as claimed.
   c. The total weight "7 grams" found under columns 14a and 14b is in the wrong column and must be moved to Box 17.

3. The data presented in MRID numbers 408201-01, 410079-01, 438557-01, 475427-02, 475550-01, 475552-01, -02, and -03 the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation/Production Process, Discussion of Formation of Impurities,

Preliminary Analysis, Certified Limits, and Enforcement Analytical Method (Group A). The data also satisfy the requirements under 40 CFR §158.190 (new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product (Group B).

4a. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 156.10(g). There are no data present that trigger the Physical or Chemical Hazards statements on the label.

4b. The Storage and Disposal statements must be revised in accordance with 40 CFR 156.10(i)(2)(ix) and PR Notice 83-3:

- The heading "STORAGE" must be changed to "STORAGE AND DISPOSAL".
- The heading "DISPOSAL" should be deleted and the statements currently under it "Do not contaminate water, food, or feed by storage or disposal" must be moved under the heading "STORAGE AND DISPOSAL".
- The heading "Pesticide Storage" must be added before the statements "Keep this product dry in a tightly closed container, when not in use. Store in a cool, dry, well-ventilated area away from heat and flame."
- The heading "Pesticide Disposal" and the statement "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility." must be added to the label.
- The heading "Container Disposal" must be added before the statements "In case of decomposition isolate container…but place in trash collection."
- The statement (currently under "DISPOSAL") "Collect pads for disposal in …and place in regular trash receptacle." must be placed under the Container Disposal subheading.

The revisions should be addressed during label review.

CONCLUSIONS:

Except for Finding 2, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. Nos. **71407-1** and **71407-3**.

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	408236-01	Y
.1600 Description of Materials Used to Produce the Product	410078-01, 437823-01, 438557-01	Y
.1620 Description of Production Process	410079-01	Y
.1650 Discussion of Formation of Impurities	408201-01, 438557-01	Y
.1700 Preliminary Analysis	408236-01, 475428-01	Y
.1750 Certified Limits	475428-01, CSF	Y
.1800 Enforcement Analytical Method	475428-01	Y

Subgroup B: Series 830.6302 -7950 (40 CFR 158.190)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION	MRID Number	Data Fulfilled
.6302 Color	White	408236-01	Y
.6303 Physical State	"Free-flowing crystalline"	408236-01	Y
.6304 Odor	Dry environment: odorless Moist environment: slight sulfur odor	408236-01	Y

.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Stable at room temperature for 14 days; decomposes at a rate of 6.5% at 54°C. Stable to copper and aluminum at room temperature after storage for 14 days. Somewhat unstable to steel and ions of copper acetate, aluminum acetate, and ferric acetate at RT for 14 days. There was a significant decrease in active ingredient when in contact with copper, aluminum, steel, copper acetate, and aluminum acetate for 14 days at 54°C. Decomposed when exposed to ferric acetate for 14 days at 54°C.	475626-01	Y
.6314 Oxidation/Reduction: Chemical Incompatibility	Acts as a weak acid and as a reducing agent.	408236-01	Y
.6315 Flammability/Flame Extension	Product does not contain combustible liquids.		NA
.6316 Explodability	Product does not have explosive characteristics.		NA
.6317 Storage Stability	The study was conducted for 24 months at room temperature in cardboard containers. Chemical and physical stability of the product was demonstrated. Product is expected to have a shelf-life of two years.	475626-02	Y
.6319 Miscibility	N/A. (product is not an emulsifiable liquid to be diluted with petroleum solvents)		N/A
.6320 Corrosion Characteristics	Physical integrity of the packaging was conducted by visual inspection during the 24-month storage stability study. There were no signs or evidence of damage to packaging occurred. No gas dissipation or corrosion around the storage was noted.	475626-02	Y
.6321 Dielectric Breakdown Voltage	Not applicable; product is not labeled to be used around electrical equipments.		N/A

.7000 pH	4.5 (1% by weight solution at 20°C)	408236-01	Y
.7050 UV/Visible Absorption	log ε: neutral sample = 3.2 acid sample = 3.36-2.86 basic sample = 3.15	475552-02	Y
.7100 Viscosity	NA		NA
.7200 Melting Point	"No melting point; decomposition occurs above temperatures 150°C	408236-01	Y
.7300 Density/Relative Density/Bulk Density	82 lbs/cu. ft. (packed)	408236-01	Y
.7370 Dissociation Constant in Water	$K_H = 6.49 \times 10^{-13}$ Base titration: pKb = 6.40 ± 0.12 Acid titration: pKa = 2.21 ± 0.16$K_H = 6.5 \times 10^{-13}$	408236-01 475552-03	Y
Octanol/Water Partition Coefficient .7550 .7560 .7570	Sodium bisulfite anhydrous: 0/100	408236-01	Y
.7840 Solubility	In water: 39.2% @ 20°C Hexane: insoluble Chloroform: 0.1 g/100 mL Methanol: 0.94 g/100 mL	408236-01 475552-01	Y
.7950 Vapor Pressure	Sodium bisulfite anhydrous: 0	408236-01	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Enforcement Analytical Method (GRN 830.1800)

The active ingredient in this product is analyzed using Iodometric Titration Method ("Calabrian Corporation Assay of Sodium Metabilsulfite", MRID number 475428-01). Samples are added with standard iodine solution and titrated against standard sodium thiosulfate solution.

Preliminary Analysis (GRN 830.1700)

Lot #	% Sodium Metabisulfite
044A5	98.70%
45A5	98.60%
46A5	99.10%
177B5	98.40%
075B7	99.40%
50C7	99.50%
17C8	99.20%
27C8	99.10
Average	99.00%