

US EPA ARCHIVE DOCUMENT

DATE OUT: 27/AUG/08

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [X]; EUP [x]

BARCODE NO.: 355348

REG./FILE SYMBOL NO.: 11195-1

PRODUCT NAME: The Fruit Doctor

MRID NO.: 474665-01

COMPANY NAME: Snowden Enterprises, Inc.

ACTION CODE: 674

FROM: Maria Rivera Piansay, Chemist [sign. M. Piansay, 8/27/08]
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 Inorganic Sulfites, which include the chemicals sulfur dioxide (SO₂) and sodium metabisulfite (Na₂S₂O₅). According to the RED, the generic data base supporting the reregistration of the Inorganic Sulfites have been reviewed and found to be substantially complete.

In the 8-month response to the Inorganic Sulfites RED, the registrant provided a basic formulation Confidential Statement of Formula (CSF) dated 6/25/08; draft label, EPA received 7/3/08; and product chemistry data in MRID number 474665-01, to support the reregistration of EPA Reg. No. 11195-1.

FINDINGS:

1. EPA Reg. No. 11195-5 is a manufacturing use/end-use product produced through an integrated process and contains 100% Sulfur Dioxide.
2. The CSF for the basic formulation, dated 6/25/08, was filled out correctly and completely and in compliance with PR Notice 91-2 and 40 CFR 158.175(b)(2) and (c). The CSF is acceptable for reregistration of this product.
3. The product chemistry data presented in MRID number 474665-01 satisfy the requirements as specified in 40 CFR §158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. The data also satisfy the requirements under 40 CFR §158.190 which pertain to the Physical and Chemical Properties of the product.
 - 4a. The Ingredient statement on the label is acceptable as per PR Notice 91-2 and 40 CFR 156.10(g).
 - 4b. The Physical and Chemical Hazards statements currently on the label are deemed acceptable as per guidance in the Label Review Manual.
 - 4c. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10(i)(2)(ix) and PR Notice 83-3. We recommend placing the Storage and Disposal section in a box of solid lines for increased prominence. The recommendation should be addressed during label review.

CONCLUSIONS:

The registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. 11195-1.

Product Chemistry Data**Group A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)****Product Identity, Composition, and Analysis**

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
830.1550 Product Identity and Composition	158.320	474665-01	Y
830.1600 Description of Materials Used to Produce the Product	158.325	474665-01	Y
830.1620 Description of Production Process	158.330	474665-01	Y
830.1650 Description of Formulation Process	158.335		NA
830.1650 Discussion of Formation of Impurities	158.340	474665-01	Y
830.1700 Preliminary Analysis	158.345	474665-01	Y
830.1750 Certified Limits	158.350	474665-01, CSF	Y
*830.1800 Enforcement Analytical Method	158.355	474665-01	Y

Subgroup B: Series 830.6302 - 7950 (40 CFR §158.310)**Physical and Chemical Properties**

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION	MRID number	Data Fulfilled
.6302 Color	Colorless	474665-01	Y
.6303 Physical State	Gas at standard conditions	474665-01	Y
.6304 Odor	"Rotten eggs" (strong)	474665-01	Y

.6314 Stability to Normal and Elevated Temperatures, Metals and Metal Ions	The product is stable. Moist gas corrodes most metals. Reacts with water. Reacts violently with strong alkalis (e.g. sodium hydroxide, fluorine), bromine pentafluorine, chlorine trifluoride, chlorates, powdered metals (e.g. chromium, manganese, aluminum), metal oxides, metal acetylides, sodium hydride, cesium azide, silver azide, and diethyl zinc.	(taken from MSDS)	
.6314 Oxidation/Reduction: Chemical Incompatibility	Strong reducing agent	(based on MSDS and other available data)	Y
.6315 Flammability/Flame Extension	Non-flammable	(MSDS and CSF)	Y
.6316 Explodability	Not applicable as the product has no impact explosive characteristics.		NA
.6317 Storage Stability	Sulfur dioxide is stable. Temperatures above 2000°C are required to bring about detectable decomposition. The pure, anhydrous SO ₂ will not decompose under normal conditions of storage.	474665-01	Y
.6319 Miscibility			NA

<p>.6320 Corrosion Characteristics</p>	<p>“SO₂ is released as a gas in a controlled manner and is not corrosive as a gas, unless it comes into contact with moisture. It frequently comes into contact with moisture in the cold storage chambers in which the gas is released at which point sulfurous acid is formed. In addition, combination with oxygen in the atmosphere leads to the formation of sulfuric acid. These chemicals form as a result of their contact with the condensates that occur, particularly on metallic surfaces associated with the cold storage radiators, typically made of aluminum, and occasionally copper. SO₂ is likely to be corrosive of any metal that would be found in a cold storage room on which condensates would occur.</p> <p>On that basis SO₂ gas used in a cold storage facility would be considered as having corrosive characteristics. And if an accident occurred outside of a cold storage facility and the SO₂ gas came into contact with water moisture, it would corrode most metals.”</p> <p>metals.</p>		Y
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.6321 Dielectric Breakdown Voltage	Not used around electrical equipments.		NA
.7000 pH	"Not applicable as a gas"	474665-01	NA
.7050 UV/Visible Absorption	NA		NA
.7100 Viscosity	NA		NA
.7200 Melting Point	-75.55°C (-104°F)	474665-01	Y
.7220 Boiling Point	-9.99°C (14°F)	474665-01	Y
.7300 Density/Relative Density	Specific gravity: 1.45	474665-01	Y
.7370 Dissociation Constant in Water			NA
.7550 Partition Coefficient (n-octanol/water)	NA		NA
.7840 Water Solubility	11.9% by wt. in water at 15°C (60°F) and 760 mmHg. Also soluble in alcohol, chloroform, and acetic acid.	474665-01	
.7950 Vapor Pressure	NA	474665-01	NA

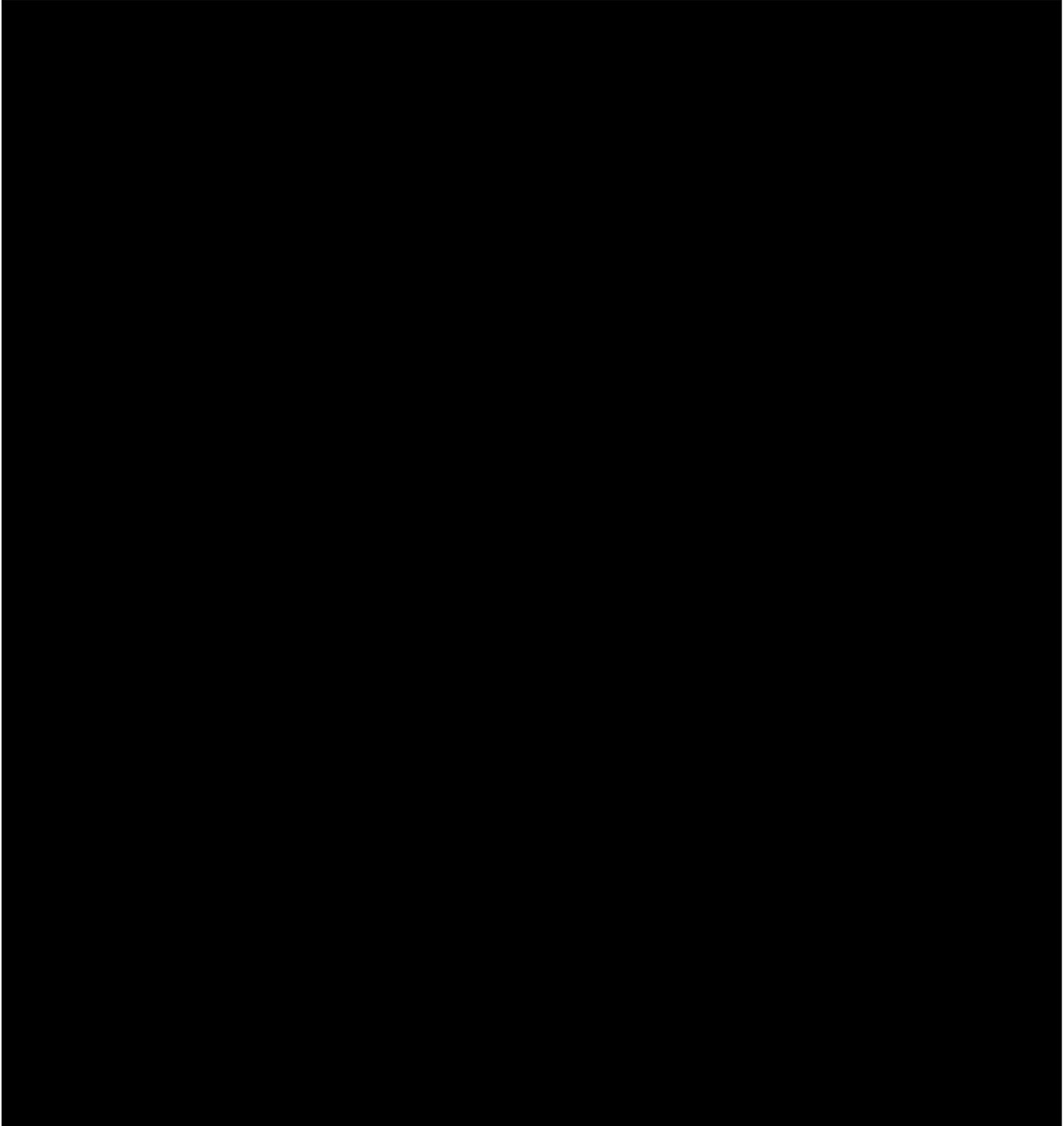
Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

830.1800 Enforcement Analytical Method

Assay of the liquid SO₂ includes Determination of Moisture (Karl Fischer method), Determination of Total Residue (SOP 300/002), and Determination of Acidity (SOP 300/003). The method for determining moisture involves dispensing the sample directly into the titration cell containing a dry solution of HPLC grade methanol and allowing the Karl Fischer titrator to titrate the sample. Total residue is determined by evaporating samples and calculating total residue by difference in weights of crucible and sample before and after evaporation. Acidity is determined by drying the sample in an enclosed flask equipped with a drying tube and titrating the residue with standardized sodium hydroxide.

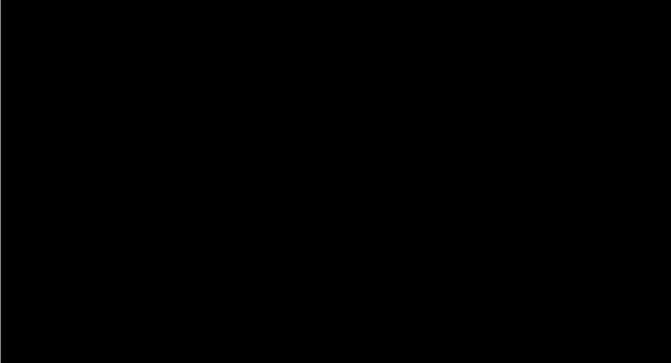
*Methods for testing the SO₂ gas are available in open literature which includes the Dreager Safety, Inc., Industrial Scientific Corporation, and RAE System. The AOAC wet chemistry method can also be used (Standard Method for Sulfurous Acid Determination by Monier-Williams (AOAC, 47.3.39, P29, 17th edition).

Preliminary Analysis of Product Samples (MRID number 474665-01):



Quality control process information may be entitled to confidential treatment

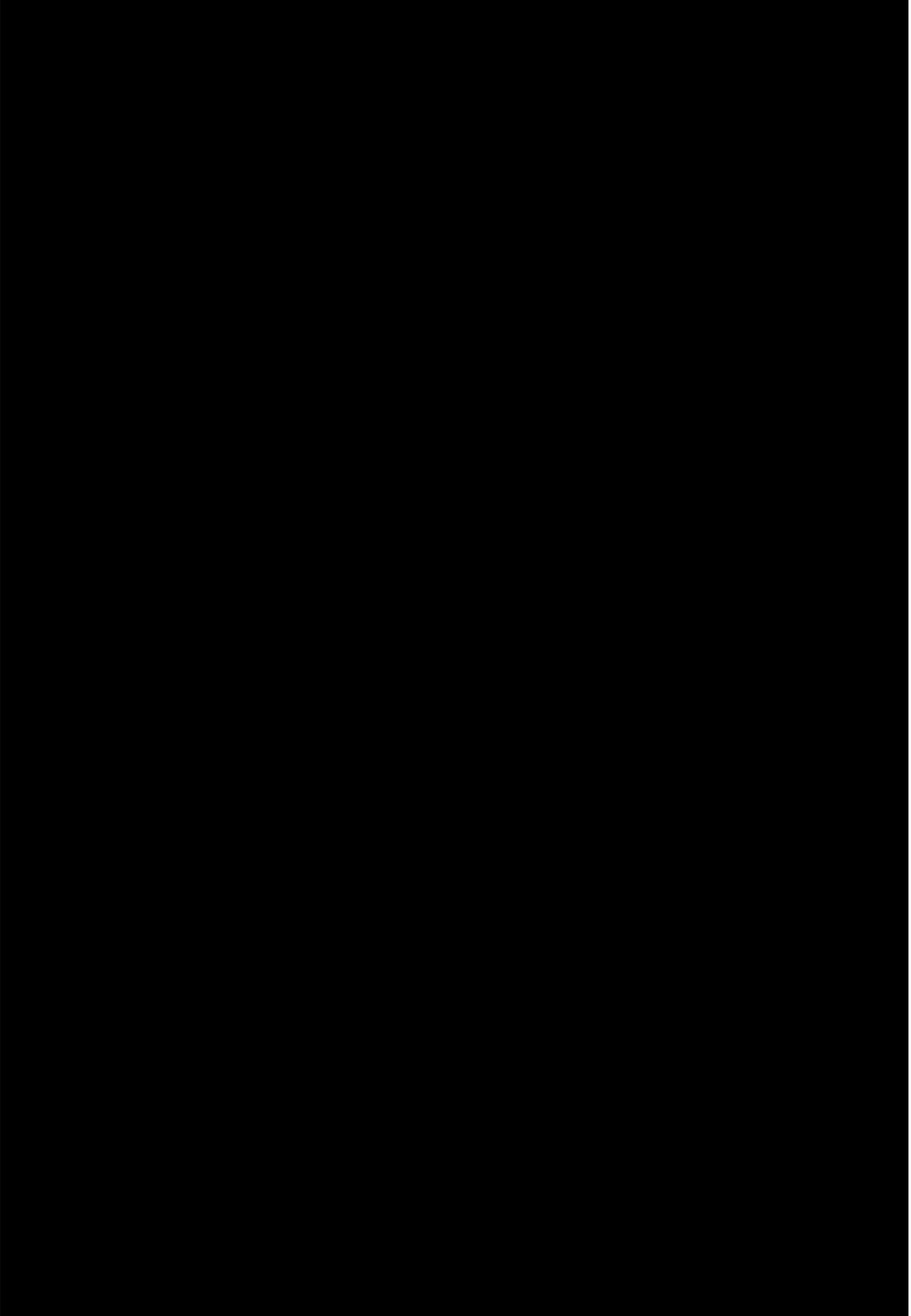
Commercial Grade Sulfur Dioxide (MRID number 474665-01)



830.1620 Description of Production Process

A schematic for SO₂ production follows next page (taken from MRID number 47466501).

Quality control process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment