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

MAY 2 3 2006

Confidential Business Information

Memorandum

Subject: Application for registration of Vital-SIGN, EPA File Symbol 42519-EO. Active Ingredient: 54.5% Mono- and Dipotassium Salts of Phosphorous Acid (Chemical Code 076416, CASRNs 13977-65-6 and 13492-26-7 respectively). Decision # 364992. S: 791135. MRIDs 467634-01, 467634-02, 467634-03, 467857-01 and 467751-01. Draft CSF dated 02/13/2006.

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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Action requested

SciReg Inc. submitted on behalf of Luxembourg-Pamol Inc. application for registration of Vital-SIGN, EPA File Symbol 42519-EO. It contains as active ingredients Potassium Dihydrogen Phosphite (CASRN 13977-65-6) and Dipotassium Hydrogen Phosphite (CASRN 13492-26-7). The product is formulated as emulsifiable concentrate by addition of [redacted] to the registered product Vital, EPA Reg. No. 42519-24. Vital contains only the active ingredients in water solution. Vital-SIGN is systemic fungicide for use on turf grass. The product has history of earlier submissions, withdrawal and resubmission. In support of the request the applicant submitted the studies MRIDs 437634-01, 467634-02, 467634-03, 467751-01, 467634-05 and 467857-01, draft label and draft CSF dated 02/13/2006.

Conclusions and recommendations

1. The submission meets the data requirements for registration of new product from registered source of active ingredients and the recommendations made at the pre-registration meeting on 06/23/2005.
2. All the inert ingredients in the formulation are known to the Agency and are cleared for use in pesticide products. They are identified by MSDSs from the producer/supplier.

Inert ingredient information may be entitled to confidential treatment

3. The request to bridge data about Acute Dermal and Acute Inhalation toxicities, Skin Irritation and Dermal Sensitization to the test results for ProPhyt is acceptable, because one and the same toxicity category is determined for ProPhyt and Vital-SIGN for Acute Oral Toxicity and Primary Eye Irritation.
4. The discussion of formation of impurities during the formulation process through oxidation/reduction reactions which involve the active ingredients KH_2PO_3 and K_2HPO_3 is addressed speculatively. Some of the considerations are not correct, but the discussion is acceptable. The storage stability studies conducted by validated analytical method show that the concentration of the active ingredients remains practically unchanged for at least 1 year and the possibly formed impurities are not of toxic concern.
5. It is recommended to state which of the physical/chemical properties of Vital-SIGN differ from those determined for ProPhyt.
6. The application for registration of Vital-SIGN, EPA File Symbol 42519-EO, is acceptable after resolution of the following deficiencies:

- There is inconsistency in the information about the source of the active ingredients in MRID 467634-01 and in the CSF. According to the description of the formulation process Vital-SIGN is prepared by adding [redacted] inert ingredients in total amount of 2.2 % to Vital, EPA Reg. No. 42519-24 (p. 47) or to ProPhyt (formerly Stamina) EPA Reg. No. 42519-24 (p. 50). These two practically identical products are not identified in the CSF by name (Column 2), EPA Reg. No. (Column12) and total amount in the formulation within certified limits (Columns 13a and 13b, 14a and 14b). The inconsistency needs resolution. (Refer to the attached handwritten recommended CSF);

- It is necessary to add to the table on p. 47 the amounts of all the ingredients, used to produce a typical batch of Vital-SIGN and to provide brief description of the equipment and conditions of the formulation process as required by OPPTS Guideline 830.1650.

- The statement that Vital-SIGN is less irritating to the eye than ProPhyt, (p. 4, MRID 467634-03) is not supported by the test results. The irritation, caused by Vital-SIGN is cleared in 96 hours (4 days), while the irritation caused by ProPhyt is cleared in 72 hours. Vital-SIGN is slightly more irritating to the eye (the symptoms disappear more slowly) than ProPhyt, but the both products fall in Toxicity Category III for Primary Eye Irritation.

Studies Summaries

MRID 467634-01. Vital-SIGN: Product Identity and Composition, Description of Beginning Materials, Description of Formulation Process, Discussion of Formation of Impurities and Certified Limits. The study contains Statement for the Certified Limits. In Confidential Attachment it contains the proposed CSF from 02/13/2006, MSDSs for the source of the active ingredient Vital and for all the inert ingredients in the formulation. The table on p.47 contains the trade names, the chemical names and the CASRNs of the

ingredients and brief description of the preparation of Vital-SIGN. Measuring the content of the active ingredient by titration and determination of the density and pH are proposed to assure the quality of the end-use product. The possibility of formation of impurities during the formulation is addressed. Classification: acceptable after resolution of deficiencies.

MRID 467751-01. Acute Oral Toxicity Up and Down Procedure in Rats. The potential of Vital-SIGN to cause adverse health effects by administration of a single dose is tested on 3 rats by the Up and Down procedure for Acute Oral Toxicity at rates of 5,000 mg/b. w. The results show that LD_{50} for Vital-SIGN is greater that 5,000 mg/b.w. Toxicity Category IV is assigned to Vital-SIGN. The performing laboratory is Product Safety. The study is acceptable.

MRID 467634-05. Primary Eye Irritation Study in Rabbits. The potential of Vital-SIGN to cause eye irritation by instillation of a single dose was tested on 3 rabbits. The test was conducted according to OPPTS 870.2400. The results show that the Maximum Mean Total Score for Vital-SIGN is 22.0. On this basis Vital-SIGN is classified as mildly irritating to the eye, Tox Category III. The test substance is identified by Certificate of Analysis. The performing laboratory is Product Safety. The study is acceptable.

MRID 467857-01. Efficacy against *Pythium* on Ryegrass. The efficacy of Vital-SIGN to protect the turf grass from fungal diseases is tested at high disease pressure (LABServices, Hamburg, PA) and low disease pressure (Ohio State University) on Ryegrass, inoculated with *Phytium.* The results demonstrate the ability of Vital-SIGN to mitigate the spread of *Phytium* on Ryegrass, but can not distinguish between the products Vital and Vital-SIGN. The results are not treated statistically. The study is supplemental.

MRID 467634-02. Storage Stability and Corrosion Characteristics – 12 Months Interim Report. The stability of Vital-SIGN when stored in HDPE containers at 13° C- 26° C temperature range is tested by scheduled determination (after 3, 6, 9 and 12 months) of the percentage of the active ingredient (expressed as percentage Phosphorous Acid) by reliable validated analytical procedure. The results show that Vital-SIGN is stable during the storage conditions for at least 12 months. The planned duration of the Storage Stability testing is 2 years. The performing laboratory is Product Safety. The study is acceptable.

MRID 467634-03. Acute Toxicity Bridging Request. On the base of equal results for Acute Oral Toxicity (LD_{50} > 5000mg/kg, Toxicity Category IV) and Primary Eye Irritation (irritation, cleared in less than 7 days, Toxicity Category III) about the products ProPhyt, EPA Reg. No. 42519-22 and Vital-SIGN, EPA File Symbol 42519-EO, waivers for Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Skin Irritation and Skin Sensitization are requested. The composition of ProPhyt and Vital-SIGN are compared in a table on p.3 of the Confidential Attachment. The request for bridging data is acceptable.

cc: N. Simeonova to R. Wilkins, BPPD Subject File.
N. Simeonova, PY1, (703)308-0291, 05/22/2006.