

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 505
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

February 20, 2015

David Lach
Sanosil International
91 Lukens Drive
New Castle, DE 19720

re: Sanosil S010, EPA Reg. No. 84526-1
Sanosil HaloSpray, EPA Reg. No. 84526-1
Sanosil HaloMist, EPA Reg. No. 84526-6
Acute Toxicity Categories

Dear Mr. Lach:

You asked me to provide an assessment of the applicable acute toxicity categories for the above products. By way of background, the acute toxicity categories were established by EPA for categorizing acute hazards associated with pesticide products. The categories range from I (acutely toxic) to IV (innocuous). As you are aware, the acute toxicology suite of studies were conducted, in 2007, with Sanosil S010. All of the studies were performed in accordance with EPA's Good Laboratory Practice (GLP) requirements for laboratory studies. The studies have been evaluated by EPA and all were determined to be satisfactory. Since Sanosil HaloMist is identical in composition (same active ingredients and inerts at the same concentration) to Sanosil S010, the study results with Sanosil S010 also apply to Sanosil HaloMist. In addition, the study results also apply to Sanosil HaloSpray, which is another brand name for Sanosil S010 and is identical in composition.

The chart below summarizes the results of the studies and the appropriate EPA toxicity categories.

Study Title	Guideline Number	MRID No.	Study Results	Toxicity Category
Acute Oral Toxicity Up and Down Procedure	870.1100	47186203	The acute Oral LD ₅₀ is greater than 5,000 mg/kg since no mortality was observed in the study. In addition, no signs of gross toxicity, adverse pharmacological effects or abnormal behavior were observed.	IV
Acute Dermal Toxicity Study in Rats –Limit Test	870.1200	47186204	The acute Dermal LD ₅₀ is greater than 5,000 mg/kg since no mortality was observed in the study. In addition, there were no signs of gross toxicity or adverse pharmacological effects.	IV

Study Title	Guideline Number	MRID No.	Study Results	Toxicity Category
Acute Inhalation Study in Rats- Limit Test	870.1300	47261601	The acute inhalation LC ₅₀ is greater than 2 mg/L since no mortality was observed in the study. In addition, all test animals appeared active and healthy throughout the study	IV
Primary eye irritation in rabbits	870.2400	47186206	Moderately irritating to the eye.	III
Primary skin irritation in rabbits		47186207	Slightly irritating to the skin. All animals were free of dermal irritation by 72 hours.	IV
Dermal sensitization study in Guinea pigs (Buehler Method)	870.2600	47205501	Not dermal sensitization reactions were observed after the test animals were induced and challenged.	Not a sensitizer

The test results show that Sanosil S010 does not lead to any systemic acute effects when ingested, inhaled or applied to the skin. Therefore, the acute oral, dermal and inhalation toxicity category for Sanosil S010, Sanosil HaloSpray and Sanosil HaloMist is Category IV. Sanosil S010 exhibits slight skin irritation and moderate eye irritation so the appropriate toxicity category for skin and eye irritation are Category IV and III, respectively, for all three products. Finally, none of the products can be considered a dermal sensitizer.

If you have any questions about this issue, please contact me at 202-393-3903, ext. 14 or by e-mail at eharrison@lewisharrison.com.

Sincerely,



Eliot Harrison