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Sunhancer™ ECO SPF Booster

Toxicology Studies

Toxicity studies were conducted on two raw materials: Copernicia Cerifera (Carnauba) Wax (95%) and Oryza Sativa (Rice) Bran Wax (5%). It is believed that the following results for the test material represent the toxicity potential for Sunhancer ECO SPF Booster.

Acute Oral Toxicity

The acute oral toxicity of the Oryza Sativa (Rice) Bran Wax was evaluated according to OECD Guidelines for Testing of Chemicals No. 423. A group of female rats was given a single oral dose of undiluted test material at a dose level of 2000 mg/kg bodyweight. The animals were observed for fourteen days. The acute oral median lethal dose (LD_{50}) of the test material was found to be greater than 2000 mg/kg bodyweight. Thus, it was determined that the test material had no acute oral toxicity.

The test material, Copernicia Cerifera (Carnauba) Wax, did not meet classification criteria based on available data.

Eye Irritation

The irritation potential of Oryza Sativa (Rice) Bran Wax was conducted on bovine cornea according to OECD Guidelines for Testing of Chemicals No. 437. The tissue was exposed to a standard amount of the substance for 4 hours. It was concluded that no serious eye damage or eye irritation occurred.

The test material, Copernicia Cerifera (Carnauba) Wax, did not meet classification criteria based on available data.

Skin Irritation

The skin irritation potential of Oryza Sativa (Rice) Bran Wax was evaluated in reconstructed human epidermis (RhE) in accordance with OECD Guidelines for Testing of Chemicals No. 439. Intact RhE tissue was exposed for a period of 15 minutes. It was determined that no skin irritation resulted from the test material

The test material, Copernicia Cerifera (Carnauba) Wax, did not meet classification criteria based on available data.

Skin Sensitization

The skin sensitization potential of Oryza Sativa (Rice) Bran Wax was evaluated using a mouse local lymph node assay in accordance with OECD Guidelines for Testing of Chemicals No. 429. No sensitization was observed with the test material, which was classified as not a sensitizer.

The test material, Copernicia Cerifera (Carnauba) Wax, did not meet classification criteria based on available data.

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Mutagenicity

The Reverse Mutation Assay "Ames Test" using *Salmonella typhimurium* of Oryza Sativa (Rice) Bran Wax was conducted in accordance with OECD Guidelines for Testing of Chemicals No. 471. The study was conducted with and without metabolic activations. No significant increases in the frequency of revertant colonies were recorded at any dose level with or without metabolic activation. The test material was considered non-mutagenic under the conditions of this test.

The test material, Copernicia Cerifera (Carnauba) Wax, did not meet classification criteria based on available data.

Acute Aquatic Toxicity

The acute aquatic toxicity of Oryza Sativa (Rice) Bran Wax was evaluated using *Daphnia Magna* in accordance with OECD Guidelines for Testing of Chemicals No. 202. The 48-hour EC_{50} of the test material in the fresh water invertebrate *Daphnia Magna* based on nominal concentrations was determined to be greater than 100 mg/l, using the end point immobilization under static conditions. It was determined that the details of the toxic effect relate to the nominal concentration

The acute aquatic toxicity to algae and aquatic plants was evaluated using *Pseudokirchneriella subcapitata* in accordance with OECD Guidelines for Testing of Chemicals No. 201. The 72-hour NOEC of the test material was 31.6 mg/l and the 72-hour EC_{50} was >100 mg/l using the growth rate as the endpoint.

Assessment of Ready Biodegradability

The biodegradability of Oryza Sativa (Rice) Bran Wax was evaluated using the CO_2 Evolution Test in an aerobic aqueous media in accordance with OECD Guidelines for Testing of Chemicals No. 301B. The test material was exposed to activated sludge micro-organisms at a concentration of 16 mg/l in a sealed vessel for 28 days. The degradation of the test material was assessed by the determination of carbon dioxide produced, as compared to a control solution. The test material attained 25% degradation after 28 days.

A second biodegradability test on Oryza Sativa (Rice) Bran Wax was conducted by through the CO_2 Evolution Test in accordance with ISO 17556. The test material was exposed to soil for 390 days. The degradation of the test material was assessed by the determination of carbon dioxide produced, as compared to a control solution. The test material attained 90.5% degradation after 390 days.

According to test data on Copernicia Cerifera (Carnauba) Wax, it was found that this test material is biodegradable.

Cosmetic Ingredient Review

Oryza Sativa (Rice) Bran Wax has been reviewed by the Cosmetic Ingredient Review and found to be safe for cosmetic use. Reference: IJT 25(S2):91-120, 2006

Copernicia Cerifera (Carnauba) Wax has been reviewed by the Cosmetic Ingredient Review and found to be safe for cosmetic use. Reference:
IJT 24(Suppl. 1):1-102, 2005; JACT 3(3):1-41, 1984