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Final Report on the Safety Assessment of Pentaerythritol Rosinate[1]

Abstract: Pentaerythritol Rosinate is the ester of rosin acids derived from Rosin with the polyol, pentaerythritol, used as a skin conditioning and viscosity increasing agent in mascaras. Animal data indicate little evidence of subchronic toxicity in feeding studies with Pentaerythritol Rosinate at concentrations up to 5%, or of chronic toxicity in feeding studies with the ingredient at 0.05%. No evidence of carcinogenicity was found in the chronic feeding studies. Historical data indicate that Pentaerythritol Rosinate may be used in cosmetics at concentrations up to 10%. The safety of use of this concentration of Pentaerythritol Rosinate has not been demonstrated. The data needed to evaluate safety include current concentration of use, source and method of manufacture, chemistry (UV spectral analysis, pH, and impurities), ocular irritation, human dermal irritation, sensitization, and photosensitization (only if the ingredient is found to absorb UVA or UVB radiation). It cannot be concluded that this ingredient is safe for use in cosmetic products until the cited data have been obtained and evaluated. **Key Words:** Pentaerythritol Rosinate—Safety—Cosmetic use—Mascara—Rat—Dog—Toxicology—Carcinogenicity.

Pentaerythritol Rosinate is the ester of rosin acids derived from Rosin with the polyol, pentaerythritol. It is used by the cosmetic industry in mascaras. The following report is a review of the safety data on this ingredient.

CHEMISTRY

Chemical and Physical Properties

Pentaerythritol Rosinate is the ester of rosin acids derived from Rosin (q.v.), with the polyol, pentaerythritol. Commercial names for this ingredient are Cellolyn 102 and Pentalyn A (Estrin et al., 1982). The Pentaerythritol Ester of Wood Rosin has an acid number of 6–16, and a drop-softening point of 109–116°C (Rothschild, 1990). The chemical structure for Pentaerythritol Rosinate is not available. However, the chemical structure for the polyol, Pentaerythritol, is given below (Windholz, 1983):

[1] Reviewed by the Cosmetic Ingredient Review Expert Panel.

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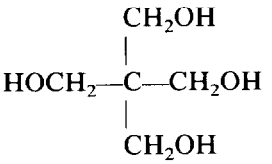

Impurities

No data are available on the impurities of Pentaerythritol Rosinate.

USE

Cosmetic

United States

Pentaerythritol Rosinate is used as a skin conditioning agent and as a viscosity increasing agent (nonaqueous) (Nikitakis, 1988).

The product formulation data submitted to the Food and Drug Administration (FDA) in 1992 reported that Pentaerythritol Rosinate was used in a total of four mascaras (Table 1) (FDA, 1992). Concentration of use values are no longer reported to the FDA by the cosmetic industry (Federal Register, 1992). However, product formulation data submitted to the FDA in 1984 stated that Pentaerythritol Rosinate was used at concentrations up to 10% in mascaras (FDA, 1984).

International

Pentaerythritol Rosinate is approved for use in Japan [Cosmetic, Toiletry and Fragrance Association (CTFA), 1983].

Noncosmetic

The Pentaerythritol Ester of Rosin is a direct food additive used as a plasticizing material in chewing gum base (Rothschild, 1990; Furia, 1977).

TABLE 1. *Product formulation data for pentaerythritol rosinate (Food and Drug Administration, 1992)*

Product category	Total no. of formulations in category	Total no. of formulations containing ingredient
Mascara	247	4
Total		4

ABSORPTION, METABOLISM, AND EXCRETION

No studies on the absorption, metabolism, or excretion of Pentaerythritol Rosinate were available.

ANIMAL TOXICOLOGY

Subchronic Oral Toxicity

In a 90-day toxicity study, groups of 20 Sprague-Dawley albino rats were fed diets containing 0.010, 0.050, 0.20, 1.0, and 5.0% (wt/wt) Pentaerythritol Rosinate in corn oil by weight. The percentage of corn oil in the diet was balanced in the three lowest-dose groups in proportion to that of the 1.0% group. Two control groups of 20 rats were fed the basic diet with the same total percentage of corn oil as the 1.0% diet. The animals were monitored throughout the study for changes in body weight, weight gain, feed consumption, and behavior. Blood and urine samples were analyzed every 30 days and necropsy was performed on all of the rats.

No serious signs of toxicity were observed during the study. The rats of the high-dose group consumed slightly less feed than that of the control animals, and their weight was slightly reduced at the beginning of the test. However, this reduction was not statistically significant, and the authors attributed it to the palatability of the treated feed. No significant incidence of mortality occurred in any of the treatment groups and hematological data and urinalyses were normal. Minor gross pathological changes were found in the treated rats, but the incidence of these changes was not significantly different from that of the controls. The only consistent changes in organ weight were an increase in the absolute liver weights, the liver/body weight ratio, and the liver/brain ratio of the high-dose group. No other evidence of toxicity was observed (Industrial Bio-Test Laboratories, Inc., 1960).

Chronic Oral Toxicity

In a 2-year feeding study, a group of 30 male and 30 female Sprague-Dawley albino rats were fed a diet containing 0.050% Pentaerythritol Rosinate and 2.33% corn oil by weight. Two control groups of 30 male and 30 female rats each were fed the basic diet and with the same percentage of corn oil only. The animals were monitored throughout the study for signs of toxicity, and hematological studies and urinalyses were conducted every 3 months. After 1 year, five male and five female rats were necropsied for interim gross and microscopic pathological studies. The other animals were necropsied when they died during the study or when they were killed after 2 years.

No treatment-related deaths occurred, and no significant adverse changes were observed in any of the parameters studied. The body weight and weight gain of the treated animals were comparable to those of the controls, and their behavior appeared normal. Hematological and urinalyses values were also within normal range. Tumor incidence was not treatment related, being consistent with that seen in the controls. No significant changes were observed upon gross or microscopic examination. A few differences in organ weight and ratio data were noted, but

these were not considered treatment related (Industrial Bio-Test Laboratories, Inc., 1962a).

A 2-year study was also conducted with use of dogs. Three male and three female beagles were fed a diet containing 0.050% Pentaerythritol Rosinate and 2.33% corn oil by weight. A control group of six male and six female dogs were fed the diet with the 2.33% corn oil only. Feed consumption, body weight, and weight gain were within normal limits throughout the study, and hematological studies, urinalyses, and liver and kidney function tests conducted at 90-day intervals were within normal limits. Necropsy was performed on all of the animals at the end of the study and no significant pathological changes were observed (Industrial Bio-Test Laboratories, Inc., 1962b).

Developmental Toxicology

No studies on the developmental toxicity of Pentaerythritol Rosinate were available.

CARCINOGENICITY

There was no evidence of carcinogenicity during the chronic oral studies (described previously) with rats or dogs fed Pentaerythritol Rosinate at 0.050% of their diet for 2 years (Industrial Bio-Test Laboratories, Inc., 1962a; b).

SUMMARY

Pentaerythritol Rosinate is the ester of rosin acids derived from Rosin with the polyol, pentaerythritol. The only reported cosmetic use of Pentaerythritol Rosinate is in mascaras. In a subchronic toxicity study with rats, a diet containing 5.0% Pentaerythritol Rosinate (the highest dose tested) caused an increase in hepatic weights. At lower doses, no significant signs of toxicity were observed. In chronic studies, 0.050% Pentaerythritol Rosinate in the diet was neither toxic nor carcinogenic to rats or dogs.

DISCUSSION

Section 1, paragraph (p) of the Cosmetic Ingredient Review (CIR) Procedures states that "a lack of information about an ingredient shall not be sufficient to justify a determination of safety." In accordance with Section 30(j)(2)(A) of the Procedures, the Expert Panel informed the public of its decision that the data on Pentaerythritol Rosinate were not sufficient for determining whether the ingredient, under relevant conditions of use, was either safe or unsafe. The Panel released a Notice of Insufficient Data on September 8, 1992, outlining the data needed to assess the safety of Pentaerythritol Rosinate. No comments regarding the data requested were received during the 90-day public comment period. The following data are necessary to make a safety assessment: a) concentration of use, b) source and method of manufacture, c) chemistry (UV spectral analysis, pH, and impurities), d) ocular irritation, e) human dermal irritation and sensitization,

and f) photosensitization (only if Pentaerythritol Rosinate absorbs UVA or UVB light).

It was also noted that the carcinogenic potential of Pentaerythritol Rosinate is still of concern because the concentration tested (0.050%) in the chronic/carcinogenicity study was low.

The Expert Panel will issue the Final Report in accordance with Section 45 of the CIR Procedures. When new data are available, the Expert Panel will reconsider the Final Report in accordance with Section 46 of the CIR Procedures, Amendment of a Final Report.

CONCLUSION

The CIR Expert Panel concludes that the data available on Pentaerythritol Rosinate are insufficient to support the safety of this ingredient as used in cosmetic products.

Acknowledgment: Susan N. J. Pang, Scientific Analyst and Writer, prepared this report.

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