



TOXICOLOGY/REGULATORY SERVICES, INC.

CONFIDENTIAL

Interpolymer Cosmetic Ingredient Safety Dossier

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| Product Identification: | Syntran 5190 |
| INCI Designation: | Acrylates Copolymer (and) Propylene Glycol (and) Sodium Laureth (12) Sulfate |
| CAS Number: | 25035-69-2 |
| Typical Composition: | |
| Water: | 54 – 55% |
| Acrylate Copolymer: | 39 – 40% |
| 1,2-Propanediol: | 4 – 5% |
| Sodium Laurylpolyethoxyethanol Sulfate: | 1% |
| Bacterial Preservative: | 0.20% methylparaben; 0.15% propylparaben; 0.10% EDTA; 0.30% potassium sorbate |
| Residual Monomer: | < 5 ppm |
| Molecular Weight: | n > 100 |

General Toxicity:

Acute Toxicity Profile:

Because the large molecular size of this polymer limits its bioavailability and none of the components are considered to be acutely hazardous, little or no systemic toxicity would be expected by the oral, dermal and inhalation routes of exposure.

Instillation of the acrylate copolymer into the eyes of rabbits produced only slight conjunctival redness in one animal at one hour post instillation. Acrylate copolymer was considered not irritating to the rabbit eye (Austrian Research Centers, 2001a). The lack of eye irritation potential established in the rabbit also indicates that the product is not likely to produce skin irritation, since skin is less susceptible to irritation than eye tissue.

A guinea pig maximization skin sensitization test was conducted using 20 females in the test substance group. A negative control group also was used. The study utilized two induction exposures (intradermal and topical). The animals were exposed to acrylate copolymer at concentrations of 2.5, 80 and 5% (v/v) for the intradermal induction, topical induction and challenge dose, respectively. No evidence of dermal irritation was observed at a concentration of 5%. None of the animals revealed positive skin sensitization reactions to the test substance 24 or 48 hours following the challenge application (Austrian Research Centers, 2001b).

Genetic Toxicity Profile:

A reverse mutation assay using the direct plate incorporation method was conducted using acrylate copolymer in *Salmonella typhimurium* strains TA97a, TA98, TA100, TA102 and TA1535 both with and without metabolic activation. Acrylate copolymer was negative in the test for mutagenicity at concentrations up to 5000 µg/plate (Austrian Research Centers, 2001c).

Human Toxicity Profile:

This type product has been safely used in leave-on cosmetic products for over 25 years.

Conclusion:

Acrylate copolymers are considered safe for use in cosmetic formulations when formulated to avoid irritation. The history of this product, along with the results of the studies conducted using the closely related product, Syntran 5009, support the current use pattern for Syntran 5190.



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References

Austrian Research Centers (2001a) "SYNTRAN 5009": Acute eye irritation/corrosion study with rabbits. Unpublished Report (Study No. OEFZ-UL-0008) submitted to Interpolymer Corporation, dated January 18.

Austrian Research Centers (2001b) "SYNTRAN 5009": Skin sensitisation study (guinea pig maxmisation test). Unpublished Report (Study No. OEFZ-UL-0017) submitted to Interpolymer Corporation, dated January 25.

Austrian Research Centers (2001c) "SYNTRAN 5009": *Salmonella typhimurium* reverse mutation test. Unpublished Report (Study No. OEFZ-UL-0029) submitted to Interpolymer Corporation, dated February 2.