



# Toxicology Regulatory Services

## CONFIDENTIAL

### Interpolymer Cosmetic Ingredient Safety Dossier

Product Identification:	Syntran <sup>®</sup> PC 5100
INCI Designation:	Polyacrylate-21 (and) Acrylates/Dimethylaminoethyl Methacrylate Copolymer
CAS Number:	68541-61-7 and 26316-50-7
Other Designations:	100.58BM

Typical Composition:	
Water:	72 – 73%
Acrylate Copolymers:	23 – 24%
1,3-Butanediol:	2%
C11-C15 Pareth-7	1%
Sodium Laurylpolyethoxyethanol Sulfate:	1%
Bacterial Preservative:	0.20% methylparaben; 0.15% propylparaben
Residual Monomer:	< 5 ppm
Molecular Weight:	n > 50

#### 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. The airborne particle size distribution of this product after spraying from a commercial aerosol can was evaluated. The aerosol formulation consisted of 65% concentrate, approximately half of which was Syntran<sup>®</sup> PC 5100, and 35% 152A propellant. The mean aerosol particle diameter was 54.7  $\mu\text{m}$  and approximately 97% of the particles had a diameter greater than 10  $\mu\text{m}$ . Since particles with diameters greater than 10  $\mu\text{m}$  are not respirable to humans, similar aerosol formulations of Syntran<sup>®</sup> PC 5100 do not pose an acute inhalation hazard.

A topical application ocular irritation screening assay using the EpiOcular<sup>™</sup> human cell construct was conducted to evaluate the potential toxicity of the test article for various exposure times (2, 4, 8, 16 and 24 hours). The duration of exposure resulting in a 50% decrease in 3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide (MTT) conversion in test article-treated EpiOcular<sup>™</sup> human cell constructs, relative to control cultures, was determined (ET<sub>50</sub>). This study resulted in an ET<sub>50</sub> value of 16.7 hours, with - 8.5% cell viability at the 24-hour exposure period. Based on the results of this study, this product is classified as non-irritating to the eye (IIVS, 2004).

The lack of ocular irritation potential established by the ET<sub>50</sub> value also indicates that the product is not likely to produce dermal irritation or sensitization, since skin is less

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susceptible to irritation than eye tissue. In addition, a human repeated insult patch test (HRIPT) was conducted with this product in 100 male and female volunteer subjects to evaluate skin sensitization potential definitively. Observations throughout the test interval were within normal limits, therefore, it may be concluded that this product does not produce allergic contact sensitization following repetitive dermal exposure (CPTC, 2005).

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**Genetic Toxicity Profile:**

A reverse mutation assay using the direct plate incorporation method was conducted with this product in *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* WP2 *uvrA* both with and without metabolic activation. The dose levels tested were 1.5, 5.0, 15, 50, 150, 500, 1500, and 5000 µg per plate. Results were negative for this product under the conditions of the bacterial reverse mutation assay both with and without metabolic activation (BioReliance, 2005).

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**Human Toxicity Profile:**

The manufacturer is not aware of any adverse health effects that have been reported from using Syntran<sup>®</sup> PC 5100 for its intended applications or from processing it in accordance with current industrial practice.

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**Conclusion:**

Polyacrylate-21 (and) Acrylates/Dimethylaminoethyl Methacrylate Copolymer is 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 Syntran<sup>®</sup> PC 5100 support the current use pattern.



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**References**

BioReliance (2005) Bacterial Reverse Mutation Assay of Syntran<sup>®</sup> PC 5100. Unpublished Report (Study No. AB06EX.501028.BTL) submitted to Interpolymer Corporation, dated March 24, 2005.

CPTC [Consumer Product Testing Company] (2005) Syntran<sup>®</sup> PC 5100: Human Repeated Insult Patch Test. Unpublished Report (Study No. C05-0090.01) submitted to Interpolymer Corporation, dated May 2, 2005.

IIVS [Institute for In Vitro Sciences] (2004) "100.58BM" Topical application ocular irritation screening assay using the EpiOcular<sup>™</sup> human cell construct. Unpublished Report (Study No. 04AA73.015001) submitted to Interpolymer Corporation, dated June 3, 2004.