



TOXICOLOGY/REGULATORY SERVICES, INC.

CONFIDENTIAL

Interpolymer Cosmetic Ingredient Safety Dossier

Product Identification:	Syntran [®] PC 5320
INCI Designation:	Polyquaternium 37
CAS Number:	Trade Secret
Other Designations:	Syntran [®] EX120

Typical Composition:	
Water:	57.5%
Acrylate Copolymer:	39.15%
1,3-Butanediol:	1.0%
Sodium Laurylpolyethoxyethanol Sulfate:	0.6%
Preservatives:	0.20% methyl paraben/0.15% propyl paraben
Sodium Salts/Primary Sodium Sulfate:	1.4%
Residual Monomer:	< 5 ppm
Molecular Weight:	Mn = 8500 Da; Mw = 26,000 Da

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.

A topical application ocular irritation screening assay using the EpiOcular[™] human cell construct was conducted to evaluate the potential toxicity of the test article for various exposure times (4, 8, 16 and 24 hours). The duration of exposure resulting in a 50% decrease MTT conversion in test article-treated EpiOcular[™] human cell constructs, relative to control cultures, was determined (ET₅₀). This study resulted in an ET₅₀ value of 5.3 hours, with 5.1% 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, 2005).

The lack of ocular irritation potential established by the ET₅₀ values also indicates that the product is not likely to produce dermal irritation or sensitization, since skin is less susceptible to irritation than eye tissue. In addition, a human repeated insult patch test (HRIPT) was conducted with this product in 101 male and female volunteer subjects to evaluate skin sensitization potential definitively. Observations throughout the test interval were negative, therefore, it may be concluded that this product does not produce dermal irritation or allergic contact sensitization following repetitive dermal exposure (CPTC, 2006).

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 in the mutagenicity and confirmatory tests for this product under the conditions of the bacterial reverse mutation assay both with and without metabolic activation (BioReliance, 2006).

Human Toxicity Profile:

The manufacturer is not aware of any adverse health effects that have been reported from using Syntran[®] PC 5320 for its intended applications or from processing it in accordance with current industrial practice.

Conclusion:

Syntran[®] PC 5320 is considered safe for use in cosmetic applications when formulated to avoid irritation. The history of this product, along with the results of the studies conducted using it, support the current use pattern.



Andrey I. Nikiforov, Ph.D.
Toxicology Consultant to Interpolymer Corporation

References

IIVS [Institute for In Vitro Sciences, Inc.] (2005) Topical application ocular irritation screening assay using the EpiOcular[™] human cell construct with Syntran PC 5320 and Syntran EX120. Unpublished Report (Study No. 05AF25-AF26.015001) dated October 24, 2005, submitted to Interpolymer Corporation.

CPTC [Consumer Product Testing Company] (2006) Human Repeated Insult Patch Test with Syntran EX120. Unpublished Report (Study No. C05-1042) dated March 3, 2006, submitted to Interpolymer Corporation.

BioReliance (2006) Bacterial Reverse Mutation Assay of Syntran EX120. Unpublished Report (Study No. AB18YJ.503.BTL) dated March 9, 2006, submitted to Interpolymer Corporation.