



TOXICOLOGY/REGULATORY SERVICES, INC.

CONFIDENTIAL

Interpolymer Cosmetic Ingredient Safety Dossier

Product Identification:	Syntran [®] PC 5117
INCI Designation:	Polyacrylate-18 (and) Polyacrylate-19
CAS Number:	848236-12-4
Other Designations:	107.15BM (dry) and 107.16 BMD (wet) Syntran [®] EX 107
Typical Composition:	
Water:	64-65%
Acrylate Copolymer:	31-33%
1,3-Butanediol:	2-3%
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 by weight of approximately 19% concentrate, 91% of which was Syntran[®] EX 107, and approximately 81% solvent/propellant. The mean aerosol particle diameter was 45.1 µm and approximately 95% of the particles had a diameter greater than 10 µm. Since particles with diameters greater than 10 µm are not respirable to humans, similar aerosol formulations of Syntran[®] PC 5117 do not pose an acute inhalation hazard.

A topical application ocular irritation screening assay using the EpiOcular[™] human cell construct was conducted using the dry form of the polymer to evaluate the potential toxicity of the test article for various exposure times (1, 2, 4, 8 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[™] human cell constructs, relative to control cultures, was determined (ET₅₀). This study resulted in an ET₅₀ value of 3.3 hours, with 15.2% 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, 2004a).

A topical application ocular irritation screening assay using the EpiOcular[™] human cell construct was conducted using the wet form of the polymer 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 MTT conversion in test article-treated EpiOcular[™] human cell constructs, relative to control cultures, was determined (ET₅₀). This study

