

**CERTIFICATE OF ANALYSIS
CANDURIN® PEARL EFFECT COLOR
Orange Amber**

<u>ANALYTICAL DATA</u>	<u>SOP's</u>	<u>SPECS</u>	<u>RESULTS</u>
Color and Appearance	Merck KGaA		Conforms
Content of Mica**	Merck KGaA	53.0 – 62.0	56.3%
Content of Fe2O3	Merck KGaA	38.0 – 47.0	43.7%
Particle size distribution (80% within 10-60 µm)	Laser Diffraction		Conforms
Median particle size (D50)	Laser Diffraction	18.0 – 25.0	21.7 µ
pH (10% aqueous suspension)	ISO 787-9	3.0 – 7.0	3.9
Loss on drying (2 hrs. 105°C)	Merck KGaA	</=0.5	</=0.5

<u>Microbial Purity</u>	<u>USP or EP or JP</u>
Total Viable Aerobic Count	< 100 CFU/g
E. coli	Absent in 1g
Pseudomonas aeruginosa	Absent in 1g
Staphylococcus aureus	Absent in 1g
Salmonella species	Absent in 10g
Candida albicans	Absent in 1g

<u>Heavy Metals</u>		<u>Modified CTFA/Internal</u>			
Arsenic	≤ 3 ppm	Barium	≤ 25 ppm	Cadmium	≤ 2 ppm
Chromium	≤ 100 ppm	Copper	≤ 25 ppm	Mercury	≤ 1 ppm
Nickel	≤ 50 ppm	Lead	≤ 4 ppm	Zinc	≤ 25 ppm

This article is in compliance with EU food additive regulations and conforms with 21 CFR Part 73.

* Data based on manufacturer's document

John

Quality Control

