

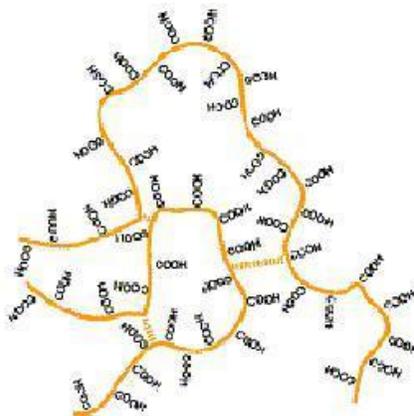
Comparative Summary SWELL vs. Carbopol Analogues

SWELL

SWELL PS-100 (“SWELL”) is an ultra high molecular weight, ingestible, pharmaceutical-grade, bioinert, carbomer fiber (CAS No: 9003-01-4) used as a temporary gastric bulking agent determined to be useful as a weight management adjunct. SWELL is comprised of polymerized side chains of the sodium salt of poly(acrylic acid), lightly cross-linked with non-branched intermediate molecular weight polyethylene glycol. SWELL is manufactured using a highly proprietary supercritical fluid technology protocol to form superabsorbent microspheres under fully compliant cGMP regulations. SWELL is self-determined to be GRAS and is currently commercialized in capsule form. SWELL is sold in the United States and elsewhere labeled as a dietary supplement; and meets all current regulatory standards established for this designation, as well as the FDA’s newly proposed NDI guidelines.

Analogous Carbomers

Analogous carbomers include the Carbopol polymers; which are cross-linked homopolymers of polyacrylic acid. They are produced from primary polymer particles of about 0.2 to 6.0 micron average diameter. The flocculated agglomerates cannot be broken into the ultimate particles when produced. Each particle can be viewed as a network structure of polymer chains interconnected via cross-linking. Carbomers were first prepared and patented in 1957. Since then, a number of extended release tablet formulations, which involve carbomer matrices, have been patented. Carbomers readily absorb water, get hydrated and swell. In addition to their hydrophilic nature, their cross-linked structure is essentially insolubility in water, making Carbopols ideal for use in controlled release drug delivery systems, dentifrices, and other ingestible forms.

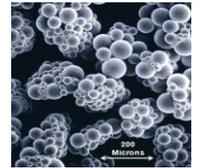
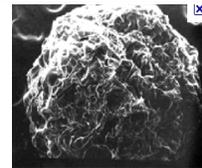
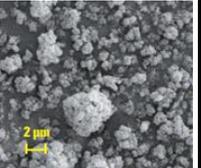
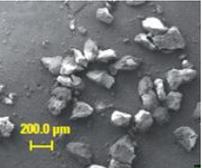


Schematic of Carbopol Structure

Comparison of Analogous Carbomers

The following chart summarizes the characteristics and properties of SWELL vs. three Carbomer analogues. As can be readily appreciated, the similarities among the comparators are evident, especially with regard to their safety characteristics.

Comparison of Properties and Specifications SWELL vs. Carbopol Analogues

Properties/Specifications	SWELL PS-100	Carbopol Analogues		
		974P	971P	71G NF
Powder				
Electronmicrograph				
CAS No.	9003-04-07	9003-01-4		
Safety	Self-directed GRAS	Self-directed GRAS		
Avg Mol Weight	Billions of Daltons	Billions of Daltons		
Side Chains	Polyacrylic Acid	Polyacrylic Acid		
PAA Oral LD50 Rat	No Data Available	No Data Available		
Cross-linker	PEG 600	allyl penta erythritol		
Cross-link MW	600	114.1		
Cross-Link Oral LD50 Rat	30g/kg	19.5g/kg		
Cross-link Density	1% to 10%	25% to 50%	15% to 25%	15% to 25%
Absorptive Rate	1 - 2 minutes	30 - 60 minutes		
Absorptive Capacity (DI H₂O)	Up to 1,000 g/g	Up to 1,000 g/g		
Gastric pH Optimized	Yes	No		
Bioadhesive Rating	0 (5 max)	3 to 4 (5 Max)	2 to 3 (5 Max)	2 to 3 (5 Max)
90% Particle Size Retention	80 Mesh	240 Mesh	240 Mesh	150 Mesh
Solvent	Supercritical CO ₂	Ethyl Acetate		
Monomer Content	<20 ppm	<1,000 ppm		
Ash Content	0.008 ppm (average) **	<20,000 ppm		
Heavy Metals	<0.1 ppm	<20 ppm		
Appearance	Fine, white, granular	Fluffy, white, powder	Fluffy, white, powder	White, granular powder
Bulk Density	73 kg/m ³	208 kg/m ³	208 kg/m ³	325-400 kg/m ³
Specific gravity	1.84	1.41	1.41	1.41
Moisture content	2.0% (max)	2.0% (max)	2.0% (max)	2.0% (max)
Equilibrium moisture content	8.3% (@ 50% rh)	8-10% (@ 50% rh)	8-10% (@ 50% rh)	8-10% (@ 50% rh)
pKa	5.5 ± 0.5	6.0 ± 0.5	6.0 ± 0.5	6.0 ± 0.5
pH of 1.0% water dispersion	3.0	2.5 - 3.0	2.5 - 3.0	2.5 - 3.0
Glass transition temperature	104C (219F)	100-105C (212-221F)	100-105C (212-221F)	100-105C (212-221F)

Disclaimer

The Company expends an abundance of care with respect to its products. Although the SWELL carbomer has been determined to be GRAS, it has not been subjected to clinical studies under all conditions with all people. Therefore, there can be no assurance that, under unusual circumstances or idiopathic situations, SWELL could not be found to have detrimental effects on the environment or human health.

However, given: 1) our understanding of the chemistry involved in carbomers in general, 2) the long history of safety of analogous, GRAS-designated carbomers used as ingestible materials, and 3) our considerable clinical, experimental and commercial knowledge of SWELL in particular; we believe that the chance that a materially significant, latent, undetected or detrimental effect has remained undocumented - is highly unlikely.

Attested:



Signed



September 12, 2011
Date

Name: Dr. Richard Davis, MD

Title: President and Chief Science Officer

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