

Customer:	ACEF SPA	Product Size:	00
Product Name:	DRCAPS 00 BIANCO	Type:	Coni-Snap
Product Code	001522-79	Print Type:	Non Print
<b>BODY</b>		<b>CAP</b>	
Code:	V44.700	Code:	V44.700
Name:	WHITE.OP.V700	Name:	WHITE.OP.V700
<b>IMPRINTING</b>			

### Qualitative and Quantitative composition \*

#### Composition per unprinted capsule part

Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (V44.700)		Cap (V44.700)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Hypromellose	Structure	qsp100	65.9018	qsp100	43.9345	qsp100	109.8363
Gellan gum	Gelling agent	5.0000	3.5400	5.0000	2.3600	5.0000	5.9000
Titanium dioxide	Opacifier	1.9184	1.3582	1.9184	0.9055	1.9184	2.2637
		100	70.8000	100	47.2000	100	118.0000

\*The quantities given are based on the theoretical calculations of the average specification weight of the capsules.

\*Due to the nature of raw materials, their sourcing and technology improvements, the dyestuff content data indicated are target values and actual values may vary.

### Additional information

Specifications :	These capsules conform to the specifications as defined in the current edition of the Capsugel "TECHNICAL REFERENCE FILE".
Packaging information :	Standard packaging consists of protective, food antistatic bags inside robust cardboard cartons.
Storage information :	Capsugel recommends that our capsules be stored in the closed containers in which they are dispatched in areas where the ambient temperature is 15°C to 25°C and the relative humidity 35% to 65%.
General commitment :	As the supplier of this product, Capsugel will notify of any significant changes that would affect the integrity of the product. Typically this is defined as Level II changes by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.
Shelf life :	Capsugel continues a global stability program and maintains data supporting 5 years shelflife of our capsules.

### Manufacturing Processes

No Addition Of Preservatives  
 No Ethylene Oxide Treatment  
 No Irradiation Treatment

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**Regulatory information**

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Name of excipient(s)	E Nr	C.I. Nr	Function	Reference / Monograph standard
Hypromellose	E464		Structure	(EU) 231/2012,, EP, JP, USP/NF
Gellan gum	E418		Gelling agent	(EU) 231/2012, JSFA, 21 CFR
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF

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**Date: Oct 14, 2019****Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France****Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium**