



规格单 SPECIFICATION SHEET

CR0120-20250521

品名 Product Name: Omega 369 Softgel Omega 369 软胶囊		原产国 Country Of Origin: China	
形状 Shape: 20# Oblong			
有效成分 Active Ingredients		辅料 Excipient	
名称 Name	添加量 Quantity	名称 Name	添加量 Quantity
鱼油 Fish Oil (EPA18%/DHA12%, EE)	400mg±7.5%	明胶 Gelatin	400mg±7.5%
亚麻籽油 Flaxseed Oil (50% ALA)	300mg±7.5%		
葵花籽油 Sunflower Seed Oil	287.5mg±7.5%	甘油 Glycerin	
维生素 E (dl- α -生育酚醋酸酯) Vitamin E (dl-alpha Tocopherol Acetate)	12.5mg±7.5%	纯水 Pure Water	
检测项目 Testing Item	规格 Specification	检测方法 Test Method	
Physicals & Chemicals			
外观和颜色 Appearance And Color	Transparent Softgel With Light Yellow Liquid Inside	Organoleptic	
装量 Filling Weight Variation	1000mg±7.5%	USP-2021<2091>	
总重 Total Weight Variation	1400mg±7.5%	USP-2021<2091>	
胶皮水分 Moisture Of Shell	7.0%-13.0%	GB 5009.3	
崩解时限 Disintegration Time	≤30min	BP-2021<Appendix XII A>+Disks	
酸值 Acid Value	≤3mgKOH/g	USP-2021<401>	
过氧化值 Peroxide Value	≤10mmol/kg	USP-2021<401>	
茴香胺值 Anisidine Value	≤20.0	USP-2021<401>	
总氧化值 TOTOX	≤16.0	USP-2021<401> Note: Totox≤16 When Production Is Completed, Totox Will Increase Over Time But Totox ≤26 Can Be Guaranteed During Shelf Life.	
Assays			
二十碳五烯酸 EPA (As Area)	≥7.2%	USP-2021<401>	
二十二碳六烯酸 DHA (As Area)	≥4.8%	USP-2021<401>	
α -亚麻酸 ALA (As Area)	≥15%	GB 5009.168	
亚油酸 Linoleic Acid	≥20%	GB 5009.168	
油酸 Oleic Acid	≥15%	GB 5009.168	
Heavy Metals			
砷 Arsenic	≤0.1mg/kg	USP-2021<233>	
铅 Lead	≤0.1mg/kg	USP-2021<233>	
镉 Cadmium	≤0.1mg/kg	USP-2021<233>	
汞 Mercury	≤0.1mg/kg	USP-2021<233>	
Microbiologicals			
菌落总数 Aerobic Plate Count	≤1,000cfu/g	ISO 4833-1	
霉菌及酵母菌 Moulds And Yeasts	≤100cfu/g	GB 4789.15	
大肠菌群 Coliforms	<10cfu/g	GB 4789.3	
大肠杆菌 E.Coli	<10cfu/g	ISO 16649-2	
沙门氏菌 Salmonella	Not Detected/25g	GB 4789.4	

金黄色葡萄球菌 Staphylococcus Aureus	Not Detected/25g	GB 4789.10
黄曲霉毒素 Aflatoxins	≤2µg/kg	HPLC
Polycyclic Aromatic Hydrocarbons(PAH)		
苯并芘 4 项 Sum Of Benz(a)anthracene, Chrysene, Benzo(a)pyrene, Benzo(b)fluoranthene	<10µg/kg	GC-MS
苯丙 A 芘 Benzo(a)pyrene	<2µg/kg	GC-MS
Pesticide Residue		
二噁英与类二噁英多氯联苯总和 Sum Of Dioxins And Dioxin-Like PCBS (WHOPCDD/F-PCBTEQ)	<6.0pg/g	GC-MS/MS
多氯联苯 Sum Of PCB28, PCB52, PCB101, PCB138, PCB153 And PCB180	<200ng/g	GC-MS/MS
二噁英 Sum Of Dioxins (WHO-PCDD/F-TEQ)	<1.75pg/g	GC-MS/MS
有效期 Shelf Life	3 Years When Properly Stored. 1. Bulk-Packaged Product Is Recommended To Be Packaged Into Retail Packaging Within Six (6) Months After The Manufacture Date. 2. The Overall Product Shelf Life Is Three (3) Years After The Manufacture Date If The Product Is Stored At The Storage Conditions Shown Herein And Packaged Into Retail Packaging As Described Immediately Above.	
储存条件 Storage	The Product Should Be Stored In A Sealed Container, Temperature: 15-25°C, Humidity: 35-65%. Keep Away From Strong Light And Heat.	
包装 Package	5000pcs/Carton.	

Allergens:- When purchased in bulk size original packaging, manufacturer allergen policy will apply. When purchased in quantities that need re-packaging, our allergen policy will apply.						
Component	Manufacturer			Nuts in Bulk (Applies when bought in small quantities that need re-packaging)		
	In Product	Processed in Same Equipment	Handled on Site	In Product	Processed in Same Equipment	Handled on Site
Cereals containing GLUTEN and products thereof	NO	NO	NO	NO	YES	YES
EGGS or its derivatives	NO	NO	NO	NO	NO	NO
FISH or its derivatives	NO	NO	NO	NO	NO	NO
CRUSTACEANS / SHELLFISH	NO	NO	NO	NO	NO	NO
MOLLUSCS	NO	NO	NO	NO	NO	NO
PEANUTS or derivatives	NO	NO	NO	NO	YES	YES
SOYA BEANS or derivatives	NO	NO	NO	NO	YES	YES
MILK (LACTOSE) or its derivatives	NO	NO	NO	NO	YES	YES
NUTS , tree nuts:	NO	NO	NO	NO	YES	YES
CELERY, including celeriac and its derivatives	NO	NO	NO	NO	YES	YES
MUSTARD, referring to all parts of the plant and derivatives thereof	NO	NO	NO	NO	YES	YES
SESAME SEEDS or derivatives	NO	NO	NO	NO	YES	YES
SULPHITES >10ppm – Sulphite quantity to be given in ppm	NO	NO	NO	NO	YES	YES
LUPIN seeds or derivatives	NO	NO	NO	NO	NO	NO