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CHEMICAL MFG CORP

进口药用辅料供应商
Pharmaceutical excipients supplier
全面支持共同审评与一致性评价

spectrum[®] *Macco*
CHEMICAL MFG CORP

无机盐辅料

Mineral

全面支持共同审评
与一致性评价

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Spectrum China Ltd.

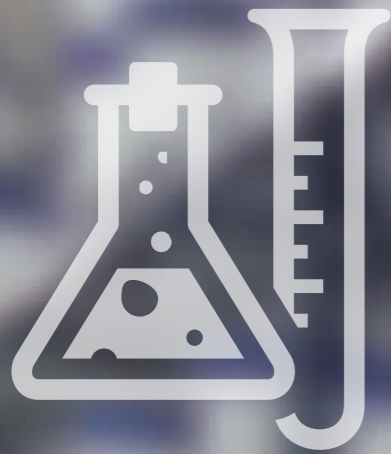
美国斯百全化学中国分公司
斯百全化学(上海)有限公司



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进口药用
辅料供应商
Pharmaceutical excipients
supplier

美国斯百全化学
SPECTRUM CHEMICAL



美国斯百全简介

spectrum[®]
CHEMICAL MFG CORP

Spectrum Chemical Profile

Spectrum Chemical Mfg. Corp. 位于美国加州, 成立于1971年, 在美国有近50年的历史了。我们是FDA认证注册的化学品和实验室产品的生产商和供应商。美国斯百全化学在化工行业是独特的存在, 我们可以毫不谦虚的讲, 我们可以提供最多品种的精化化学品, 现已发展成为化学工业中以客户为中心的高质量化学品、实验室用品和设备的全球领先供应商, 并且是很多食品、药品和个人保健品企业的唯一供应商。Spectrum Chemical 目前在全球有四个公司, 除总部加州外, 在美国新泽西和亚利桑那, 中国上海有三处分公司。

Spectrum Chemical Mfg. Corp. is unique in the chemical industry, boasting one of the largest selections of fine chemicals while also remaining a family-owned business for nearly fifty years. We are an FDA registered manufacturer and distributor of fine chemicals and laboratory products with the largest selection of USP-NF-FCC chemicals for manufacture of food, drug and personal care products available from a single source. Our multi-decade progress and continued business success stems from our dedication to providing more for our customers each year. The Spectrum family works hard to earn the trust and confidence of the people we serve, and we appreciate the opportunity to continue providing outstanding service to these important industries.

质量优先 Quality - Priority

美国斯百全的所有全球制造和分销点均已通过**FDA**注册, 并严格按照**cGMP**分包、仓储、运营管理。All of Spectrum's global manufacturing and distribution sites are FDA registered and operate under current Good Manufacturing Practices (cGMP).

美国斯百全的设施通过**ISO 9001:2015**质量标准认证。All Spectrum facilities are certified to the current ISO 9001:2015 quality standard.

美国斯百全中国实验室通过了**ISO 17025**质量标准认证, 是一个独立的第三方测试实验室。Spectrum's Shanghai, China analytical laboratory is certified to the ISO 17025:2005 quality standard as an independent third-party testing laboratory.

美国斯百全在**DEA**注册了受控物质制造商。Spectrum is registered with the DEA as a manufacturer of Controlled Substances.

美国斯百全定期对供应商**现场审核**, 以确保产品质量的稳定和一致性。Spectrum regularly performs manufacturer site audits to ensure batch-to-batch consistency.

美国斯百全积极支持国际药品供应链联盟**Rx-360**, 并支持供应链的透明度。Spectrum actively supports Rx-360, an international pharmaceutical supply chain consortium, and supports transparency in the supply chain.



美国斯百全产品和服务

Spectrum Chemical Products and Services



美国斯百全特色

Spectrum Chemical Capabilities

实施供应商星级制度, 更好的合作经验
Implement supplier star system, better cooperation experience

新功能设备, 优良的存储能力
New functional facility, excellent storage ability

经验丰富的物流, 处理特殊运输需求的设备和产品
Experienced logistics, deal with equipments and products with special shipment requirement

专业的销售和客户服务团队, 与客户进行良好的沟通
Dedicated sales & customer service team, good communication with customers

有经验的测试中心, 控制产品质量
Experienced testing center, controlling product quality

斯百全中国简介

spectrum[®]

CHEMICAL MFG CORP

Spectrum China Profile

斯百全化学(上海)有限公司(Spectrum China Ltd.)是Spectrum Chemical的中国分公司, 成立于2003年。是一家以药用辅料为主, 化学试剂及实验室消耗品为辅的专业化进口药用辅料供应商。斯百全药用辅料覆盖亚太地区, 是行业内规模大, 品种齐全的专业化公司。斯百全化学CNAS实验室汇聚了行业检测精英, 控制产品的质量, 并且支持客户的检测服务。

斯百全化学始终贯彻美国总部“质量是第一关注要点”的企业宗旨, 为全球制药企业精选全球优质的药用辅料、精细化学品、实验室试剂等, 为您解决后顾之忧! 同时可以配合客户制剂辅料的共同审评, 以达到中国药监局法规的要求。斯百全化学承诺提供优质产品和服务, 为您选择优质的制剂辅料。

Spectrum China Ltd. was founded in 2003 as a pharmaceutical excipients and chemical reagents supplier. Operational since 2005, Spectrum Shanghai lab has a team of well-educated and experienced chemist half of whom with master degree or higher in the related fields. The center was ISO 9001 and ISO 17025 certified. The center not only takes charge of controlling the quality of chemicals, but also provides technical support to customers at any time. In the future, Spectrum China will provide our customer the better corporation experience with high quality products, competitive price and remarkable services!

质量承诺 Quality Commitment

斯百全中国通过**ISO9001:2015**认证;
Spectrum China have ISO 9001:2015 Certificate;

斯百全中国**ISO 17025**认证,是**CNAS**实验室;
Spectrum China have ISO 17025 Certificate , have independent CNAS Lab;

斯百全化学**有危险化学品经营许可证**;
Spectrum China have dangerous chemicals business license;

斯百全化学是**IPEC中国的高级会员**。
Spectrum China is IPEC China Senior member.

优势 Superiority

精选全球优质药用辅料,产品品种齐全,包装规格多种化;
Select the world's high-quality pharmaceutical excipients, product variety, packaging specifications diversified.

独立的法规注册部门,全面支持共同审评和一致性评价;
The independent registration department supports comprehensive review and consistency evaluation.

药用辅料都有相应的资质文件, cGMP/COA/BSE/TSE/Residual Solvent Statement等文件;
Have cGMP/COA/BSE/TSE/Residual Solvent Statement and other documents.

强大的售后技术团队支持,对文件审计和检测方法、配方研究等都能提供一定的支持;
Strong after-sales technical team support, document audit and testing methods, formulation research can provide some support.

在美国、欧洲、亚洲等市场有众多合作伙伴,货源丰富,可以提供优质的代购服务;
In the United States, Europe, Asia and other markets have a large number of partners, rich supply, can provide quality consignment Services.

“We distribute pharmaceutical excipients and fine chemicals - with quality and delivery you can count on every time”

BRINGING
MINERALS
TO LIFE...



Macco

生产商简介

Welcome to the World of Mineral Salts

Manufacturer Profile

1986年, Macco公司成立于加拿大瓦利菲尔德Valleyfield(Quebec),最初是以生产丙酸酯、苯甲酸盐和醋酸盐为主的化工生产公司。自此, Macco公司在食品和制药行业生产经验稳步成长,生产能力惊人增长,现已成为领先的无机盐生产商和供应商。1988年, Macco公司开发了一项革命性的生产技术,将所有成分干燥和处理成无尘而不结块,并且能自由流动的粉末的生产技术。今天, Macco公司是静脉注射和透析液、药物、生物技术、婴儿配方、营养补充剂、兽医制剂、矿化水和瓶装水的无机盐主要生产商和供应商。

因其独一无二的生产技术生产的优质无尘无机盐, Macco公司享誉全球。Macco公司生产设备设施通过GMP Q7审核,并严格遵守GFSI FSSC 22000标准,通过ISO 9001认证,并拥有加拿大API健康制造许可证。

公司非常重视产品的质量,反映在授予Macco公司的认证和注册以及Macco公司遵守的生产流程和文件标准中。

Formed in 1986, Macco Organiques Inc. acquired the assets of a long-standing chemical manufacturing company in Valleyfield(Quebec) producing propionates, benzoates and acetates. Since this time Macco has experienced steady growth and an impressive increase in capacity focusing predominantly on the Food and Pharmaceutical Industries. In 1988, Macco Organiques Inc. developed a revolutionary technology to dry and process all ingredients into a dustfree powder form that remains free flowing without caking or clumping for extended lengths of time. Today, Macco Organiques s.r.o. is a leading producer and supplier of mineral salts for IV and dialysis solutions, pharmaceuticals, biotechnology, infant formulas, nutritional supplements, veterinarian preparations, mineralised and bottled water.

Macco has received and maintained worldwide recognition for producing high quality dust free products with their unique technology and has been awarded ISO 9001 certification and adheres strictly to FSSC 22000 standards. The facility is FDA audited according to GMP Q7 guidelines and has API manufacturing license from the Health Canada.

We take great care in maintaining our high levels of quality, this is reflected in the certification and registrations awarded to Macco Organiques, s.r.o. and the documented standards that we adhere to.



认证注册

Certifications and registrations

- GMP ICH Q7A
- FSSC 22000
- ISO 9001
- FDA inspected
- Registrations at MHLW & PMDA Japan
- CoS/CEP
- US DMF
- Jap DMF
- ASMF Halal
- Kosher

无机盐系列辅料目录 mineral salt contents

Name	CAS NO	Formula	Quality Standard
二水氯化钙 Calcium Chloride Dihydrate	10035-04-8	$\text{CaCl}_2 \cdot 2 \text{H}_2\text{O}$	EP, BP, USP, JP
六水氯化镁 Magnesium Chloride Hexahydrate	7791-18-6	$\text{MgCl}_2 \cdot 6 \text{H}_2\text{O}$	EP, BP, USP, JPC
氯化钾 Potassium Chloride	7447-40-7	KCl	EP, BP, USP
七水硫酸镁 Magnesium Sulphate Heptahydrate	10034-99-8	$\text{MgSO}_4 \cdot 7 \text{H}_2\text{O}$	EP, BP, USP
硫酸镁 Magnesium Sulphate Dried	22189-08-8	$\text{MgSO}_4 \cdot x \text{H}_2\text{O}$	BP or USP
七水硫酸锌 Zinc Sulphate Heptahydrate	7446-20-0	$\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$	EP, BP, USP
一水硫酸锌 Zinc Sulphate Monohydrate	7446-19-7	$\text{ZnSO}_4 \cdot \text{H}_2\text{O}$	EP, BP, USP
硫酸铵 Ammonium Sulphate	7783-20-2	$(\text{NH}_4)_2\text{SO}_4$	USP
无水硫酸钠 Sodium Sulphate Anhydrous	7757-82-6	Na_2SO_4	EP, BP, USP

硫酸铵 Ammonium Sulphate

产品名称 (Chemical name)	Ammonium Sulphate
CAS No.	7783-20-2
化学式 (Chemical formula)	(NH ₄) ₂ SO ₄
分子量 (Molecular weight)	132.14
铵含量 (Contents of Ammonium)	27.2 g in 100 g of (NH ₄) ₂ SO ₄
保存期限 (Shelf life)	5 years
物理性质 (Physical properties)	
外观 (Appearance)	Inorganic colourless or white crystalline
密度 (Density)	1.769 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	75.16 g/1000 g
熔点 (Melting point)	235°C
应用 (Applications)	
生物制药 Biopharmaceutical	
证书 (Certificates)	
ISO 9001:2016 / ISO 22000:2006 / Kosher including for Passover days / HALAL	

硫酸镁 Magnesium sulphate x-hydrate

产品名称 (Chemical name)	Magnesium sulphate x-hydrate
CAS No.	22189-08-8
化学式 (Chemical formula)	MgSO ₄ ·xH ₂ O
分子量 (Molecular weight)	120.37 (as anhydrous form)
镁含量 (Contents of Magnesium)	13.2 g in 100 g of MgSO ₄ ·xH ₂ O (BP monograph) 15.0 g in 100 g of MgSO ₄ ·xH ₂ O (USP monograph)
保存期限 (Shelf life)	3 years

物理性质 (Physical properties)

外观 (Appearance)	Inorganic white crystalline
密度 (Density)	2.63 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	374.0 g/1000 g
熔点 (Melting point)	1185°C

应用 (Applications)

医药/注射剂 Pharmaceuticals/ Injections

证书 (Certificates)

GMP according ICH Q7A / FSSC 22000 / ISO 9001:2016
Kosher including for Passover days / HALAL

无水硫酸钠 Sodium Sulfate Anhydrous

产品名称 (Chemical name)	Sodium sulfate
CAS No.	7757-82-6
化学式 (Chemical formula)	Na ₂ SO ₄
分子量 (Molecular weight)	142.04
镁含量 (Contents of Magnesium)	16.2 g in 100 g of Na ₂ SO ₄
保存期限 (Shelf life)	3 years
物理性质 (Physical properties)	
外观 (Appearance)	Inorganic colourless crystals or as a fine, white, crystalline powder
密度 (Density)	2.664 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	19.2 g/1000 g
熔点 (Melting point)	884°C
应用 (Applications)	
医药 Pharmaceuticals / 维生素 Vitamins	
证书 (Certificates)	
ISO 9001:2016 / Kosher including for Passover days / HALAL	

一水硫酸锌 Zinc sulfate monohydrate

产品名称 (Chemical name)		Zinc sulfate monohydrate
CAS No.	7446-19-7	
化学式 (Chemical formula)	ZnSO ₄ ·H ₂ O	
分子量 (Molecular weight)	179.47	
锌含量 (Contents of Zinc)	36.4 g in 100 g of ZnSO ₄ ·H ₂ O	
保存期限 (Shelf life)	3 years	
物理性质 (Physical properties)		
外观 (Appearance)	Inorganic colorless or white crystalline	
密度 (Density)	3.195 kg/dm ³	
溶解度 (20°C水) Solubility in water at 20°C	91.6 g/100 g	
熔点 (Melting point)	280°C	
脱水温度 (Temperature of dehydration)	238°C	
应用 (Applications)		
OTC		
证书 (Certificates)		
HACCP / ISO 9001:2016 / Kosher including for Passover days / HALAL		
声明 (Statement)		
在生产和配送过程中，原料中没有动物或人类来源的原料。产品有BSE/TSE，GMO，无过敏原声明。 No material of animal or human origin is used in the raw materials, in the production and distribution process. Product is BSE/TSE, GMO, allergen free.		

七水硫酸锌 Zinc sulfate heptahydrate

产品名称 (Chemical name)		Zinc sulfate heptahydrate
CAS No.	7446-20-0	

化学式 (Chemical formula)	ZnSO ₄ ·7H ₂ O
分子量 (Molecular weight)	287.53
锌含量 (Contents of Zinc)	22.7 g in 100 g of ZnSO ₄ ·7H ₂ O
保存期限 (Shelf life)	3 years
物理性质 (Physical properties)	
外观 (Appearance)	Inorganic colorless or white crystalline
密度 (Density)	1.957 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	165.63 g/100 g
熔点 (Melting point)	100°C
应用 (Applications)	
OTC	
证书 (Certificates)	
GMP according to ICH Q7A / HACCP / ISO 9001:2016 Kosher including for Passover days / HALAL	
声明 (Statement)	
在生产和配送过程中，原料中没有动物或人类来源的原料。产品有BSE/TSE，GMO，无过敏原声明。 No material of animal or human origin is used in the raw materials, in the production and distribution process. Product is BSE/TSE, GMO, allergen free.	

七水硫酸镁 Magnesium sulfate heptahydrate

产品名称 (Chemical name)		Magnesium sulfate heptahydrate
CAS No.	10034-99-8	
化学式 (Chemical formula)	MgSO ₄ ·7H ₂ O	
分子量 (Molecular weight)	246.47	
镁含量 (Contents of Magnesium)	9.7 g in 100 g of MgSO ₄ ·7H ₂ O	
保存期限 (Shelf life)	PHARMA quality - 3 years	
物理性质 (Physical properties)		
外观 (Appearance)	Inorganic white crystalline	

密度 (Density)	2.63 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	374.0 g/1000 g
熔点 (Melting point)	1185°C
应用 (Applications)	
医药/注射剂 Pharmaceuticals/ Injections	
证书 (Certificates)	
GMP according ICH Q7A / ISO 9001:2016 Kosher including for Passover days / HALAL	

六水氯化镁 Magnesium chloride hexahydrate

产品名称 (Chemical name)	Magnesium chloride hexahydrate
CAS No.	7791-18-6
化学式 (Chemical formula)	MgCl ₂ ·6H ₂ O
分子量 (Molecular weight)	203.303
镁含量 (Contents of Magnesium)	11.8 g in 100 g of MgCl ₂ ·6H ₂ O
保存期限 (Shelf life)	3 years
物理性质 (Physical properties)	
外观 (Appearance)	Inorganic colourless crystalline
密度 (Density)	1.57 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	3043.05 g/1000 g
熔点 (Melting point)	117°C
脱水温度 (Temperature of dehydration)	500°C
应用 (Applications)	
透析液Dialysis Solution / 输液溶液Infusion Solutions / 生物制药Pharmaceutical	
证书 (Certificates)	
GMP according to ICH Q7A / HACCP / ISO 9001:2016 / CEP Kosher including Passover days / HALAL	

声明 (Statement)

在生产和配送过程中，原料中没有动物或人类来源的原料。产品有BSE/TSE，GMO，无过敏原声明。
No material of animal or human origin is used in the raw materials, in the production and distribution process. Product is BSE/TSE, GMO, allergen free.

二水氯化钙 Calcium chloride dihydrate

产品名称 (Chemical name)	Calcium chloride dihydrate
CAS No.	10035-04-8
化学式 (Chemical formula)	CaCl ₂ ·2H ₂ O
分子量 (Molecular weight)	147.02
钙含量 (Contents of Calcium)	27.2 g in 100 g of CaCl ₂ ·2H ₂ O
保存期限 (Shelf life)	4 years
物理性质 (Physical properties)	
外观 (Appearance)	Inorganic colorless crystalline
密度 (Density)	1.85 kg/dm ³
溶解度 (20°C水) Solubility in water at 20°C	1301.0 g/1000 g
熔点 (Melting point)	176°C
脱水温度 (Temperature of dehydration)	260°C
应用 (Applications)	
透析液Dialysis Solution / 输液溶液Infusion Solutions / 生物制药Pharmaceutical	
证书 (Certificates)	
GMP according to ICH Q7A / HACCP / ISO 9001:2016 / CEP Kosher including Passover days / HALAL	
声明 (Statement)	
在生产和配送过程中，原料中没有动物或人类来源的原料。有BSE/TSE，GMO，无过敏原声明。 No material of animal or human origin is used in the raw materials, in the production and distribution process. Product is BSE/TSE, GMO, allergen free.	