



MATERIAL SAFETY DATA SHEET

物料安全数据表

Material Name/物料名称: Oseltamivir Phosphate Capsules USP,
30mg/45mg/75mg 磷酸奥司他韦胶囊 USP, 30mg/45mg/75mg

Doc. No.编号: MSDS-OSP03-01

Version/版本号: 01

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

化学品/配置品以及公司/企业名称

Sunshine Lake Pharma Co., Ltd
Northern Industry Road 1#,
SongShanLake
Dongguan, Guangdong, China.

广东东阳光药业有限公司
中国, 广东省, 东莞市,
松山湖, 工业北路1号

Emergency telephone number/紧急联系电话:

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guozhi@hec.cn

Material Name: Oseltamivir Phosphate Capsules USP, 30mg/45mg/75mg

产品名称: 磷酸奥司他韦胶囊 USP, 30mg/45mg/75mg

Appearance

75mg:

Capsule cap is light green and imprinted S2 with black ink, body is white and without any imprint; the contents is white or almost white granules.

囊帽淡绿色, 印有黑色字体“S2”, 囊体白色, 无印字; 胶囊内容物应为白色或类白色颗粒。

45mg:

Capsules cap is buff and imprinted S4 with blue ink, body is white and without any imprint; the contents is white or almost white granules.

囊帽淡黄色, 印有蓝色字体“S4”, 囊体白色, 无印字; 胶囊内容物应为白色或类白色颗粒。

30mg:

Capsules cap and body are opaque white, cap imprinted S5 with black ink, body without any imprint; the contents is white or almost white granules.

囊帽和囊体均为不透明白色; 囊帽印字黑色字体“S5”, 囊体无印字; 胶囊内容物应为白色或类白色颗粒。

Trade Name/商品名称:

Oseltamivir Phosphate Capsules USP, 30mg/45mg/75mg

磷酸奥司他韦胶囊 USP, 30mg/45mg/75mg

Chemical Family/化学族:

Mixture/混合物

Intended Use/用途:

This product is applicable to the treatment and prevention of influenza A and B.
本品适用于治疗和预防甲型和乙型流感治疗。

2. HAZARDS IDENTIFICATION

危害描述

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

药品代理-处理本产品的最终形式, 职业接触风险最小。

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

患者/消费者: 根据医生的指示使用本产品时, 请参阅产品说明书或产品标签, 以获取有关本产品适合消费者的特定信息。

Classification 分类

Not classified 未分类

Label elements 标签元素

Not classified 未分类

Other Hazards 其他危害

No information available 无可用信息

Unknown acute toxicity 未知毒性

No information available 无可用信息

3. COMPOSITION/INFORMATION ON INGREDIENTS

组成成分

Hazardous/危险的

Ingredient 物质	CAS Number CAS 号	EU EINECS/ELINCS List 欧洲已存在商业/已报告化学 物品目录	GHS Classification GHS 分类	%
Oseltamivir Phosphate 磷酸奥司他韦	204255-11-8	616-396-9	Not Listed	40
Pregelatinized Starch 预胶化淀粉	9005-25-8	232-679-6	Not Listed	*
Croscarmellose Sodium 交联羧甲基纤维素钠	74811-65-7	1312995-182-4	Not Listed	*





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Povidone 聚维酮	9003-39-8	1312995-182-4	Not Listed	*
Sodium Stearyl Fumarate 硬脂富马酸钠	4070-80-8	223-781-1	Not Listed	*
Talc 滑石粉	14807-96-6	238-877-9	Not Listed	*
Gelatin hollow capsule 明胶空心胶囊	Not Listed	Not Listed	Not Listed	*
Additional Information: 其他信息	*Proprietary/专有 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. 标记为危险的物质已经在国际工作场所安全标准下进行评估。			

4. DESCRIPTION OF FIRST AID

急救措施

Eye Contact

眼接触:

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

立即用大量的水冲洗,也在眼皮下冲洗至少15分钟。冲洗时眼睛睁得大大的。取下隐形眼镜(如果有,而且容易取下)。继续冲洗。如果刺激持续发展,请就医。不要摩擦患处。

Skin Contact

皮肤接触:

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

立即用肥皂和大量水冲洗至少15分钟。如果刺激持续发展,请就医。

Ingestion

摄入:

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. Do not vomit. Use water to clean mouth, then drink plenty of water. Do not give food to a person who is unconscious. Call a physician.

Remove to fresh air. Get medical attention immediately if symptoms occur. 移至空气新鲜处。如果出现症状,立即就医。

5. FIRE FIGHTING MEASURES 消防措施

a) Suitable Extinguishing Media

Media

灭火介质:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

采用适合当地情况和周围环境的灭火措施。

Unsuitable Extinguishing Media

不合适的灭火介质

None known.

未知

b) Fire hazard

火灾危险

Not flammable.

不易燃。

Explosive hazard

爆炸危险

Not an explosive.

不是爆炸物。

Reactivity

反应性

Hazardous reactions will not occur under normal conditions.

在正常情况下不会发生危险反应。

Hazardous combustion products

危险燃烧产物

Carbon oxides. Oxides of sulfur. Nitrogen oxides (NOx). Sulfur compounds.

Hydrogen sulfide. 碳氧化物。硫氧化物。氮氧化物 (NOx)。含硫化合物。硫化氢。

c) Fire Fighting Instructions

消防说明:

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

消防员应穿戴自给式呼吸器和全套消防装备。

6. ACCIDENTAL RELEASE MEASURES

泄露应急处理措施

Personal precautions, protective equipment and emergency procedures 个人预防措施, 防护设备和应急程序

Personal precautions: Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

个人注意事项: 避免接触皮肤、眼睛或衣服。确保通风良好。按要求使用个人防护设备。

For non-emergency personnel 非应急人员

Personal Protective Equipment: Use personal protective equipment as required.

个人防护用品: 按要求使用个人防护用品。

Emergency procedures: Evacuate personnel to safe areas.

应急程序: 将人员疏散到安全区域。

For emergency responders 应急响应人员



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Personal Protective Equipment: Use personal protective equipment as required.

个人防护用品: 按要求使用个人防护用品。

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

应急程序: 将人员疏散到安全区域。使该区域通风。在安全的情况下, 排除所有火源。

Environmental precautions/环境预防措施

Prevent further leakage or spillage if safe to do so.

在安全的情况下, 防止进一步泄漏或溢出。

Methods and material for containment and cleaning up/控制和清理的方法和材料

Methods for containment: Prevent further leakage or spillage if safe to do so.

控制方法: 在安全的情况下防止进一步泄漏或溢出。

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

清理方法: 使用适当的个人防护设备(PPE)。小心地铲起或清扫溢出的材料, 并放入适当的容器中。避免产生灰尘。对于泄漏: 用惰性吸收剂吸收。使用干净的无火花工具收集吸收的材料。避免吸入灰尘或喷雾。

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

预防二次危害: 彻底遵守环境法规, 清洁受污染的物体和区域。

7. HANDLING AND STORAGE

操作处置和储存

Precautions for safe handling/安全搬运注意事项

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

患者/消费者: 根据医生的指示使用时, 患者应遵守产品说明书或产品标签中提供的有关本产品的消费者特定信息的说明。

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.

安全处理建议: 按照良好的工业卫生和安全惯例进行处理。避免接触皮肤、眼睛或衣服。使用本产品时请勿进食、饮水或吸烟。脱掉被污染的衣服和鞋子。脱下被污染的衣服, 清洗后再使用。

Conditions for safe storage, including any incompatibilities/安全储存条件, 包括任何不相容性

Storage Conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Protect from moisture. Keep out of the reach of children. Store locked up.

贮存条件: 将容器密封在干燥、凉爽、通风良好的地方。避光。防潮。放在孩子够不到的地方。上锁管理。

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

特定最终用途: 药品。仅按指示使用。有关使用说明和产品信息, 请参阅产品说明书。

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

暴露控制/个人防护

Control parameters/控制参数

Exposure Limits: No information available

接触限值: 无可用信息

Exposure controls/接触控制

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

适当的工程控制: 应进行现场特定风险评估, 以确定适当的暴露控制措施。如适用, 使用工艺外壳、局部排气通风或其他工程控制, 以保持空气中的水平低于建议的暴露限值。

Individual protection measures, such as personal protective equipment/个人防护措施, 如个人防护装备

Hand protection: Wear suitable gloves. Impervious gloves.

手部防护: 戴上合适的手套。不透水手套。

Eye/face protection: If splashes are likely to occur, wear safety glasses with side-shields.

眼睛/面部防护: 如果可能发生飞溅, 请佩戴带侧护板的安全眼镜。

Skin and body protection: Wear suitable protective clothing. Long sleeved clothing.

皮肤和身体保护: 穿戴合适的防护服。长袖衣服。

Respiratory protection: Use appropriate respiratory protection.

呼吸防护: 使用适当的呼吸防护。

General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or



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clothing.

一般卫生注意事项: 使用本产品时请勿进食、饮水或吸烟。休息前和处理产品后立即洗手。戴上合适的手套和眼睛/面部防护装置。避免接触皮肤、眼睛或衣服。

9. PHYSICAL AND CHEMICAL PROPERTIES 物理和化学属性

a) Information on Basic Physical and Chemical Properties 基本理化性质信息

75mg:

Capsule cap is light green and imprinted S2 with black ink, body is white and without any imprint; the contents is white or almost white granules.

囊帽淡绿色, 印有黑色字体“S2”, 囊体白色, 无印字; 胶囊内容物应为白色或类白色颗粒。

45mg:

Capsules cap is buff and imprinted S4 with blue ink, body is white and without any imprint; the contents is white or almost white granules.

囊帽淡黄色, 印有蓝色字体“S4”, 囊体白色, 无印字; 胶囊内容物应为白色或类白色颗粒。

30mg:

Capsules cap and body are opaque white, cap imprinted S5 with black ink, body without any imprint; the contents is white or almost white granules.

囊帽和囊体均为不透明白色; 囊帽印字黑色字体“S5”, 囊体无印字; 胶囊内容物应为白色或类白色颗粒。

10. STABILITY AND REACTIVITY

稳定性和反应活性

Reactivity 反应性

Hazardous reactions will not occur under normal conditions.

在正常情况下不会发生危险反应。

Chemical stability 化学稳定性

Stable under normal conditions.

正常情况下稳定。

Possibility of hazardous reactions 危险反应的可能性

None under normal processing.

正常处理下无。

Conditions to avoid 应避免的条件

Extremes of temperature and direct sunlight.

极端的温度和阳光直射。

Incompatible materials 不相容材料

Strong acids. Strong bases. Strong oxidizing agents.

强酸。强碱。强氧化剂。

Hazardous decomposition products 有害分解产物

Decomposition will not occur under normal conditions.

正常情况下不会发生分解。

11. TOXICOLOGICAL INFORMATION

毒理学信息

Carcinogenesis, Mutagenesis, Impairment of Fertility

致癌、突变、生育能力受损

In 2-year carcinogenicity studies in mice and rats given daily oral doses of the prodrug oseltamivir phosphate up to 400 mg/kg and 500 mg/kg, respectively, the prodrug and the active form oseltamivir carboxylate induced no statistically significant increases in tumors over controls. The mean maximum daily exposures to the prodrug in mice and rats were approximately 130- and 320-fold, respectively, greater than those in humans at the recommended clinical dose based on AUC comparisons. The respective safety margins of the exposures to the active oseltamivir carboxylate were 15- and 50-fold.

在对小鼠和大鼠进行的为期2年的致癌性研究中, 前药磷酸奥司他韦每日口服剂量分别高达400 mg/kg和500 mg/kg, 前药和活性形式羧酸奥司他韦比对照组在肿瘤方面没有显著增加。根据AUC比较, 在推荐的临床剂量下, 小鼠和大鼠每日前药的平均最大暴露量分别约为人类的130倍和320倍。活性奥司他韦羧酸盐暴露的安全边际分别为15倍和50倍。

Oseltamivir was found to be non-mutagenic in the Ames test and the human lymphocyte chromosome assay with and without enzymatic activation and negative in the mouse micronucleus test. It was found to be positive in a Syrian Hamster Embryo (SHE) cell transformation test. Oseltamivir carboxylate was non-mutagenic in the Ames test and the L5178Y mouse lymphoma assay with and without enzymatic activation and negative in the SHE cell transformation test.

在Ames试验和人类淋巴细胞染色体试验中发现奥司他韦无致突变性, 无论是否有酶激活, 在小鼠微核试验中均为阴性。在叙利亚仓鼠胚胎(SHE)细胞转化试验中发现它是阳性的。在Ames试验和L5178Y小鼠淋巴瘤试验中, 无论有无酶激活, 奥司他韦羧酸盐均无致突变性, 在SHE细胞转化试验中均为阴性。

In a fertility and early embryonic development study in rats, doses of oseltamivir at 50, 250, and 1500 mg/kg/day were administered to females for 2 weeks before mating, during mating and until day 6 of pregnancy. Males were dosed for 4 weeks before mating, during mating, and for 2 weeks after mating. There were no effects on fertility, mating performance or



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early embryonic development at any dose level. The highest dose in this study was approximately 100 times the human systemic exposure (AUC0-24h) of oseltamivir carboxylate that occurs after administration of the maximum recommended human dose.

在一项大鼠生育力和早期胚胎发育研究中, 雌性大鼠在交配前、交配期间和怀孕第6天服用剂量分别为50、250和1500毫克/千克/天的奥司他韦2周。雄性在交配前、交配期间和交配后给药4周。在任何剂量水平下都不会对生育能力、交配性能或早期胚胎发育产生影响。本研究中的最高剂量约为服用最大推荐人体剂量后人体全身暴露量 (AUC0-24h) 的100倍。

12. ECOLOGICAL INFORMATION

生态学信息

Ecotoxicity:生态毒性

No information available.

无可用信息。

Persistence and Degradability:

韧性和可降解性

No information available.

无可用信息。

Bioaccumulative Potential:

潜在的生物累积性:

No information available.

无可用信息。

Mobility in Soil:

土壤流动性:

No information available.

无可用信息。

Other adverse effects

其他不良反应

No information available.

无可用信息。

13. Disposal Considerations 处置注意事项

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable.

Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

根据适用的当地、地区、国家和国际法规处理内含物/容器。根据环境法规处理废物。不要冲入地表水或下水道系统。

14. Transport Information 运输信息

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

运输要求可根据许多因素而变化, 如地区法规和装运量。运输组织有责任确保遵守有关本产品运输的所有适用法律法规。

15. REGULATORY INFORMATION

法规信息

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

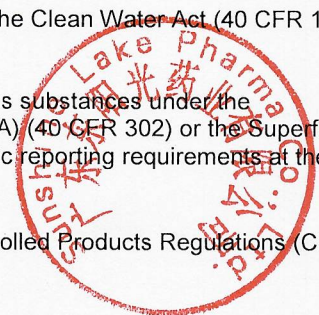
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.



16. OTHER INFORMATION

其他信息

Data Sources

数据来源:

Safety data sheets for individual ingredients. HEC proprietary drug development information.

单个物质的安全数据表。HEC 专有的药物研发信息。



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Reasons for Revision

N/A

修订原因:

无

Company Policy or Disclaimer 公司政策或免责声明: :

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Role 责任人	Draft 起草人	Review 审核人	Approve 批准人
Dept. 部门	TD	TD	QA
Name 姓名	彭昶	刘宁	郭智
Signature 签名	彭昶/2023-02-22	刘宁/2023-02-22	郭智/2023-02-24

