



化学品安全说明书

(MSDS)

本报告依据的样品成分由申请者提供并确认

THIS MSDS IS AUTHORED BASED ON THE DATA SUPPLIED BY
AND IDENTIFIED ON BEHALF OF THE CLIENT.

样品名称: 新型冠状病毒抗原检测试剂盒(胶体金法)

SAMPLE NAME: SARS-CoV-2 ANTIGEN RAPID TEST KIT (Colloidal Gold)

委托单位: 正元盛邦(天津)生物科技有限公司

CLIENT NAME: JOYSBIO(TIANJIN) BIOTECHNOLOGY CO., LTD.

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MSDS 编号: MSDS NO.: ZKGCX20210204-10-01-001

签发日期: 2021 年 02 月 08 日

ISSUE DATE: FEB.08,2021

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安全技术说明书

Material Safety Data Sheet

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化学品及企业标识

SECTION 1: Identification

产品名称:	新型冠状病毒抗原检测试剂盒(胶体金法)		
Product name:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)		
供应商:	正元盛邦(天津)生物科技有限公司		
Supplier:	JOYSBIO (Tianjin) Biotechnology CO., LTD.		
技术说明书编码:	ZKGCX20210204-10-01-001		
MSDS NO.:	ZKGCX20210204-10-01-001		
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Company mailbox:		Zip code:	

成分/组成信息

SECTION 2: Composition/information on ingredients

物质名称	Pure chemicals	√混合物	mixture	规格	规格	规格	主要成分
Name	Specifications	Specifications	Specifications	Specifications	Specifications	Specifications	Main components



检测卡 Test card	5人份 / 盒 5Tests/Kit (1Test/bag ×5Bags)	10人份 / 盒 10Tests/Kit (1Test/bag ×15Bags)	10人份 / 盒 20Tests/Kit (1Test/bag ×20 Bags)	
干燥剂 Desiccant	5包 5 packs	10包 10 packs	20包 20 packs	硅胶 Silica Gel
缓冲液 Buffer	5支*550μL/支 550μL /bottle×5 bottles	10支*550μL/支 550μL /bottle×10 bottles	20支*550μL/支 550μL /bottle×20 bottles	0.01M tris 缓冲液
提取管 Extraction tube	5个一次性提取管, 每个提取管带有一个喷嘴盖 5 single-use reaction tubes, each with 1x nozzle cap	10个一次性提取管, 每个提取管带有一个喷嘴盖 10 single-use reaction tubes, each with 1x nozzle cap	20个一次性提取管, 每个提取管带有一个喷嘴盖 20 single-use reaction tubes, each with 1x nozzle cap	/
收集袋 specimen collection bags	5个无菌、一次性标本采集袋 5 sterile, single use specimen collection bags	10个无菌、一次性标本采集袋 10 sterile, single use specimen collection bags	20个无菌、一次性标本采集袋 20 sterile, single use specimen collection bags	/
滴管 Dropper	5个一次性滴管 5 single-use droppers	10个一次性滴管 10 single-use droppers	20个一次性滴管 20 single-use droppers	/

试剂盒需要但不提供的材料

Materials required but not provided with the kit:

SARS-CoV-2 (+)
1 each - individually wrapped for single-use

非传染性, 重组病毒蛋白抗原, 低于 0.1% 的前蛋白 300。

Non-infectious, recombinant viral protein antigen with less than 0.1% Proclin 300.



SARS-CoV-2 (-)

1个- 一次性拭子, 单独包装
1 each - individually wrapped for single-use

拭子中含有少于0.1%前蛋白的缓冲液。
Buffer with less than 0.1% Proclin 300.

危险性概述

SECTION 3: Hazards identification

物质分类: Classification of the substance or mixture:	本品未列入《危险化学品名录》中。 This product is not included in the List of Hazardous Chemicals.
标签要素: Label elements:	无特殊危险标签 No special danger label
健康危害: Health hazards:	正常使用无特殊危害 Normal use has no special hazards
燃爆危险: Fire and explosion danger:	外包装遇明火可燃 The outer package is combustible in case of open fire.
环境危害: Environmental hazards:	本品不允许直接排入环境中。 This product is not allowed to be directly discharged into the environment.

急救措施

SECTION 4: First aid measures

皮肤接触: Skin contact:	脱去污染的衣着, 用肥皂水和清水彻底冲洗皮肤。 Remove contaminated clothes and rinse the skin thoroughly with soapy water and clean water.
眼睛接触: Eye contact:	尽量避免直接接触眼睛, 如误接触眼睛应立即提起眼睑, 用流动清水或生理盐水冲洗。 Try to avoid direct contact with eyes. If you accidentally contact eyes, immediately lift your eyelids and rinse them with running water or normal saline.
吸入: Inhaled:	此情况一般不会发生, 如果吸入, 迅速脱离现场至空气新鲜处。保持呼吸道通畅。 This does not usually happen, if inhaled, quick release from site to fresh air. Keep the airways open.
食入: Swallowed:	一般不会出现这种情况; 如有发生, 饮足量温水或牛奶, 就医。 This is not usually the case, if it happens, drink plenty of warm water or milk, and seek medical advice.

消防措施

SECTION 5: Firefighting measures

危险特性: Hazard characteristics:	遇明火可燃 In case of open fire, it can burn.
有害燃烧产物: Harmful combustion products:	无资料 No data available



灭火方法: 根据周围环境选择合适的灭火材料。用水雾、沙土、干粉或二氧化碳灭火剂灭火。

Fire extinguishing method: Choose suitable fire-extinguishing materials according to the surrounding environment. Put out the fire with water mist, sand, dry powder or carbon dioxide.

泄露应急处理

SECTION 6: Accidental release measures

应急处理: 尽可能切断泄漏源。远离热源/火花/明火/热表面。

Emergency handling: Cut off the source as much as possible. Keep from heat/spark/open flame/hot surface.

尽可能将泄漏物收集在可密闭的容器中。勿使泄漏物与易燃物、火源接触。

Collect the leakage in a closed container as much as possible.

勿使泄漏物与易燃物、火源接触。尽量收集回收或运至废物处理场所处置。

Do not make the leakage contact with inflammables and source of ignition. Try to collect, recycle or transport to waste disposal sites for disposal.

与人相关的安全防护措施: 无关人员从侧风、上风向撤离至安全区。

Unrelated persons from the side of the wind, upwind evacuation to a safe area.

建议应急处理人员戴携气式呼吸器, 穿防护服, 戴橡胶手套。

Human related safety protection measures: Fire fighters are required to wear air-carrying respirators. Wear a full-body fire suit. Wear rubber gloves.

在进入封闭空间前先通风, 禁止接触或跨越泄漏物。

Ventilate a confined space before entering, it is forbidden to touch or cross the leakage.

环境保护措施: 收容泄漏物, 避免污染环境。无相关政府许可, 不允许将该物质随意释放到环境中。

Environmental precautions: Collecting leaks to avoid environmental pollution. Disposing this product into the environment without permission of the local government is prohibited.

操作处置与储存

SECTION 7: Handling and storage

安全操作的注意事项: 仅供体外诊断使用, 仅供专业人士使用。个体防护措施参见第8部分。

Precautions for safe handling: For in vitro diagnostic use only, for professional use only. See section 8 for individual protective measures.

在15到20分钟之间阅读测试结果。20分钟后不要阅读结果。

Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

切勿在气流较强的房间进行测试, 例如电风扇或冷气较强的房间。

Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning.

避免与还原剂等禁配物接触(禁配物参见第10部分)。

Separate from reducing agent. Mixed storage is not allowed (see Section 10 for incompatible materials.)

搬运时要轻装轻卸, 防止包装及容器损坏。

Handle with care to preempt package or container breakage.



禁止在工作场所进饮食。远离火种、热源, 工作场所严禁吸烟。

Prohibit the intake of food in the workplace. Keep away from fire and heat source.

Smoking is strictly prohibited in the workplace.

配备相应品种和数量的消防器材及泄漏应急处理设备。

Equipped with the corresponding variety and quantity of fire fighting equipment and leakage emergency treatment equipment.

安全储藏条件:

在24个月的有效期内, 在2~30°C的温度下储存在密封袋里, 禁止冷冻。

Conditions for safe storage:

Store at 2~30°C in the sealed pouch up to the expiration date and the validity is tentatively 24 months. Do not freeze.

避光保存, 远离水分、热源。保持容器密封。包装件应堆放整齐。

Keep away from sunlight, moisture, and heat. Keep the container sealed. The packaging should be stacked neatly.

新鲜采集的标本应在1小时内处理。储区应有泄漏应急处理设备和合适的收容材料。

Freshly collected specimens should be processed within 1 hour. The storage area should be equipped with emergency leakage treatment equipment and appropriate shelter materials.

应与氧化剂、食用化学品分开存放, 切忌混储(禁配物参见第10部分)。

Separate from oxidants chemicals. Mixed storage is not allowed (see section 10 for incompatible materials.)

接触控制和个体防护

SECTION 8: Exposure controls/personal protection

工程控制:

作业场所建议与其它作业场所分开。加强通风。

Appropriate engineering controls:

Workplace recommendations are separate from other workplaces. Strengthen ventilation.

设置红色区域警示线、警示标识和中文警示说明, 并设置通讯报警系统。

Set up red area warning line, warning sign and Chinese warning description, and set up communication alarm system.

排风系统应设有导除静电的接地装置。禁止使用易产生火花的设备和工具。

The air conditioning system shall pair with a grounding device. Use non-sparking equipment and tools.

设置应急撤离通道和必要的泄险区。提供安全淋浴和洗眼设备。

Emergency evacuation passage and necessary evacuation area shall be set up. Provide safe shower and eye washing equipment.

呼吸系统防护:

佩戴医用防护型口罩。

Respiratory protection:

Wear medical protective mask.

眼睛防护:

佩戴全面防护型面罩。

Eye protection:

Wear full protective mask.

手防护:

佩戴一次性手套, 并经常更换。

Hand protection:

Wear disposable gloves and change frequently.



个人防护:	佩戴工作帽, 穿工作服, 穿防护服及工作鞋
Body protection:	Wear work caps, work clothes, protective clothing and work shoes.
其他防护:	工作现场禁止吸烟、进食和饮水。工作完毕, 彻底清洗。
Other protection:	Smoking, eating and drinking are prohibited at work. After work, clean it thoroughly.

理化特性

SECTION 9: Physical and chemical properties

包装规格:	5人份/盒(1人份/袋×5袋), 10人份/盒(1人份/袋×10袋), 20人份/盒(1人份/袋×20袋)
Packing specifications:	5Tests/box (1Test/bag ×5 Bags), 10Tests/box (1Test/bag ×10 Bags), 20Tests/box (1Test/bag ×20 Bags)
主要用途:	用于体外定性检测新型冠状病毒肺炎(COVID-19)感染或疑似患者出现症状5天内唾液样本中的新型冠状病毒(SARS-CoV-2)核衣壳蛋白。产品仅提供给临床实验室或医护人员用于即时测试, 不可家用自测。
Main uses:	For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days after onset of symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, not for at-home testing.

稳定性和反应活性

SECTION 10: Stability and reactivity

化学稳定性:	在包装标识的效期内保存, 本品稳定。检测卡从铝箔袋中取出后1小时内使用。
Chemical stability:	To be kept within the period of validity of the packing mark, this product is stable. The test card should be used within 1 hour after taking out from the aluminum foil bag.
禁配物:	强氧化剂、强酸、强碱。
Prohibited substances:	Strong oxide, strong acid, strong base.
应避免的条件:	光照、高热、明火
Conditions to avoid:	Light, high heat, open fire
聚合危害:	无资料
Polymerization harm:	No data available
分解产物:	自然分解, 产物未知。
Decomposition products:	Natural decomposition, unknown product

毒理学资料

SECTION 11: Toxicological information

急性毒性:	无资料
Acute toxicity:	No data available
刺激性:	无资料
Irritation:	No data available



致敏性:	无资料
Sensitization:	No data available
致畸性:	无资料
Teratogenicity:	No data available
致癌性:	无资料
Carcinogenicity:	No data available

生态学资料

SECTION 12: Ecological information

生态毒理毒性:	无资料
Ecological Toxicity:	No data available
潜在的生物累积性:	无资料
Bio-accumulative potential:	No data available
土壤中的迁移性:	无资料
Mobility in soil:	No data available

废弃处置意见

SECTION 13: Disposal considerations

废弃化学品:	将使用后的产品以不低于 850℃ 的高温在焚烧炉中进行焚烧, 焚烧后的炉渣和飞灰经固化后安全填埋; 或是在高温消毒舱中经高温蒸汽 (不低于 134℃) 60-90 分钟的消毒灭菌, 实现无害化, 破碎后再二次处理。
Waste chemicals:	The product after use shall be incinerated in the incinerator at a high temperature of no less than 850 °C, and the incinerated slag and fly ash shall be safely buried after solidification; or in the high-temperature disinfection cabin, it shall be sterilized by high-temperature steam (no less than 134 °C) for 60-90 minutes to realize harmless treatment, and then it shall be treated again after crushing. 剩余产品和不能回收的产品应由持牌的废物处置承包商进行处理。 Surplus products and unrecyclable products should be disposed of by licensed waste disposal contractors.
污染包装物:	将容器返还生产商或按照国家和地方法规处置。
Contaminated packaging:	Return containers to the manufacturer or dispose the container in accordance with national and local regulations.
废弃注意事项:	处理所有用于进行测试的标本和材料, 作为生物危险废物。
Discarded notices:	Dispose of all specimens and materials used to perform the test as biohazardous waste. 废弃处置前应参阅国家和地方有关法规。处置人员的安全防范措施参见第 8 部分。 Dispose according to national and local regulations. See section 8 for personal security precautions during waste disposal.

运输信息

SECTION 14: Transport information

联合国危险货物编号: 无



UN number: None

联合国运输名称: 无

United Nations transport name: None

包装标识:

Packaging marking:

包装规格:

Packing specifications:

包装方法:

Packing method:

运输注意事项:

Matters of attention to transportation:



20 人份/盒 (1 人份/袋×20 袋)、40 人份/盒 (1 人份/袋×40 袋)

20 Tests/Box(1 Test/Pouch ×20 Pouches), 40 Tests/Box(1 Test/Pouch ×40 Pouches)

按照生产商推荐的方法进行包装

Pack as instructed by the manufacturer

在运输过程中应防漏、防破损。中途停留时应远离火种、热源、高温区。

Leakage and breakage shall be prevented during transportation. Keep from fire, heat and high temperature areas during stopovers.

运输车辆应配备相应品种和数量的消防器材及泄漏应急处理设备。

Transport vehicles should be equipped with enough amount of proper fire-fighting equipment and equipment for emergency leakage control.

禁止使用易产生火花的机械设备和工具装卸。

Use non-sparking mechanical equipment and tools to handle this product.

夏季最好早晚运输。运输途中应防暴晒、雨淋，防高温。

It is better to transport in the morning and evening in summer. Prevent overexposure to sunlight, rain and high temperature during transport.

法规信息

SECTION 15: Regulatory information

法规信息:

Regulatory information:

本安全技术说明书符合(EC) No. 1907/2006, 1272/2008. 管理规范

This safety data sheet complies with the requirements of Regulation(EC) No. 1907/2006, 1272/2008.

专门对此物质或混合物的安全, 健康和环境的规章 / 法规。

Safety, health and environment regulations/legislation which regulates this substance or its mixture. 化学品安全评估 Chemical Safety Assessment

其他信息

SECTION 16: Other information

编写和修订信息:

Abbreviations and acronyms:

缩略语和首字母缩写:

Abbreviations and acronyms:

参考文献:

本版为第 1.0 版, 按照 GB/T 16483-2008、GB/T 17519-2013、GB 30000 系列分类标准编制。

This is version 1.0 in compliance with GB/T 16483-2008, GB/T 17519-2013 and GB 30000 classification standards.

CAS: CAS 登录号

CAS: CAS login number

【1】国际化学品安全规划署: 国际化学品安全卡 (ICSC)



References:

网址: <http://www.ilo.org/dyn/icsc/showcard.home>

International Programme on Chemical Safety: International Chemical Safety Card (ICSC) Website: <http://www.ilo.org/dyn/icsc/showcard.home>

【2】国际癌症研究机构, 网址: <http://www.iarc.fr/>

International Agency for Research on Cancer Website: <http://www.iarc.fr/>

【3】OECD 全球化学品信息平台, 网址:

http://www.chemportal.org/chemportal/index?pageID=0&request_locale=en
The OECD Global portal to Information on Chemical Substances

Website: http://www.chemportal.org/chemportal/index?PageID=0&request_locale=en

【4】美国 CAMEO 化学物质数据库, 网址:

<http://cameochemicals.noaa.gov/search/simple>

The CAMEO Chemicals Database,

Website: <http://cameochemicals.noaa.gov/search/simple>

【5】美国医学图书馆: 化学品标识数据库

网址: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>

United States National Library of Medicine: Chemical Database

Website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>

【6】美国环境保护署: 综合危险性信息系统, 网址: <http://cfpub.epa.gov/iris/>

United States Environmental Protection Agency:

Integrated Risk Information System (epa) : integrated risk information system,

Website: <http://cfpub.epa.gov/iris/>

【7】美国交通部: 应急响应指南, 网址: <http://www.phmsa.dot.gov/hazmat/library/erg>

U.S. Department of Transportation: Emergency Response Guidelines,

Website: <http://www.phmsa.dot.gov/hazmat/library/erg>

【8】德国 GESTIS-有害物质数据库, 网址: <http://gestis-en.itrust.de/>

GESTIS – Databases on Hazardous Substances, Website: <http://gestis-en.itrust.de/>

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