

SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.0
Creation Date: July 15, 2019
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SECTION 1: Identification

1.1 GHS Product identifier

Product name Isotretinoin

1.2 Other means of identification

Product number -

Other names cis-retinoic acid; 13-cis-ra; 13-cis-Retinoic acid

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research use.

Uses advised against no data available

1.4 Supplier's details

Company Shanghai Baishun Biotechnology Co., Ltd
Address No. 26, Lane 918, Lianye Road, Zhelin Town, Fengxian District, Shanghai, 201400, China
Telephone +86-21-37581181

1.5 Emergency phone number

Emergency phone number +86-21-37581181

Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Reproductive toxicity, Category 1B

Hazardous to the aquatic environment, short-term (Acute) - Category Acute 1

Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 1

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Danger

Hazard statement(s) H360 May damage fertility or the unborn child
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

Precautionary statement(s)

Prevention	P203 Obtain, read and follow all safety instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/... P273 Avoid release to the environment.
Response	P318 IF exposed or concerned, get medical advice. P391 Collect spillage.
Storage	P405 Store locked up.
Disposal	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Isotretinoin	Isotretinoin	4759-48-2	225-296-0	100%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound may include dryness and itching of the skin and conjunctivitis. It can also cause pruritus, epistaxis, dry nose and mouth, rash, temporary thinning of the hair, cheilitis, fatigue, skin fragility, skeletal hyperostosis, musculoskeletal symptoms and chest pain. Other symptoms, rarely seen, include peeling of the palms and soles, skin infections, nonspecific urogenital findings, nonspecific gastrointestinal symptoms and increased susceptibility to sunburn. This compound has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension) characterized by the following symptoms: headache, papilledema, nausea, vomiting and visual disturbances. It can also cause fetal abnormalities if ingested while pregnant. Other symptoms include ocular irritation, blurred vision, arthralgias, facial dermatitis, xerosis, minor nosebleed inflamed urethral meatus and urethritis.
ACUTE/CHRONIC HAZARDS: This compound may cause eye irritation. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Emergency and supportive measures; Maintain an open airway and assist ventilation if necessary. Treat coma, seizures, hypotension, and arrhythmias if they occur. Treat nausea and vomiting with metoclopramide and fluid loss caused by gastroenteritis with intravenous crystalloid fluids. Bone marrow depression should be treated with the assistance of an experienced hematologist or oncologist. 5. Extravasation. Immediately

stop the infusion and withdraw as much fluid as possible by negative pressure on the syringe. Then give the following specific treatment. Dactinomycin, daunorubicin, doxorubicin, idarubicin, mitomycin-C, mitoxantrone, and plicamycin. Apply ice compresses to the extravasation site for 15 minutes 4 times daily for 4 days. Topical application of dimethyl sulfoxide (DMSO) may be beneficial. Mechlorethamine (and concentrated dacarbazine and cisplatin); apply ice compresses for 6-12 hours. Etoposide, paclitaxel, vincristine, or vinblastine. Place a heating pad over the area and apply heat intermittently for 24 hours; elevate the limb. /Antineoplastic Agents, Retnoic acid/.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Fires involving this material can be controlled with a carbon dioxide, dry chemical or Halon extinguisher. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this material are not available; however, it is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

PRECAUTIONS FOR CYTOTOXIC AND HAZARDOUS DRUGS:/ Spills. Emergency procedures to cover spills or inadvertent release of hazardous drugs should be included in the facility's overall health and safety program. Incidental spills and breakages should be cleaned up immediately by a properly protected person trained in the appropriate procedures.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

PRECAUTIONS FOR CYTOTOXIC AND HAZARDOUS DRUGS:/ Facilities (eg, shelves, carts, counters, and trays) for storing hazardous drugs are designed to prevent breakage and to limit contamination in the event of leakage. Bins, shelves with barriers at the front, or other design features that reduce the chance of drug containers falling to the floor should be used. Hazardous drugs requiring refrigeration should be stored separately from nonhazardous drugs in individual bins designed to prevent breakage and to contain leakage.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	PHYSICAL DESCRIPTION: Yellow-orange to orange crystalline powder; orange-brown chunky solid. (NTP, 1992)
Colour	Reddish-orange plates from isopropyl alcohol
Odour	no data available
Melting point/freezing point	175°C(lit.)
Boiling point or initial boiling point and boiling range	106°C/3.5mmHg(lit.)
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flash point	117°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 72° F (NTP, 1992)
Partition coefficient n-octanol/water	no data available
Vapour pressure	1.0X10 ⁻⁷ mm Hg @ 25 deg C /Estimated/
Density and/or relative density	1.011 g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

An organic acid and unsaturated aliphatic hydrocarbon. Carboxylic acids donate hydrogen ions if a base is present to accept them. They react in this way with all bases, both organic (for example, the amines) and inorganic. Their reactions with bases, called "neutralizations", are accompanied by the evolution of substantial amounts of heat.

Neutralization between an acid and a base produces water plus a salt. Insoluble carboxylic acids react with solutions of cyanides to cause the release of gaseous hydrogen cyanide. Flammable and/or toxic gases and heat are generated by the reaction of carboxylic acids with diazo compounds, dithiocarbamates, isocyanates, mercaptans, nitrides, and sulfides. Carboxylic acids, especially in aqueous solution, also react with sulfites, nitrites, thiosulfates (to give H₂S and SO₃), dithionites (SO₂), to generate flammable and/or toxic gases and heat. Their reaction with carbonates and bicarbonates generates a harmless gas (carbon dioxide) but still heat. Like other organic compounds, carboxylic acids can be oxidized by strong oxidizing agents and reduced by strong reducing agents. These reactions generate heat. A wide variety of products is possible. Like other acids, carboxylic acids may initiate polymerization reactions; like other acids, they often catalyze (increase the rate of) chemical reactions.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

SECTION 11: Toxicological information

Acute toxicity

- Oral: LD₅₀ Rat oral greater than 4 g/kg
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN1759 (For reference only, please check.)

IMDG: UN1759 (For reference only, please check.)

IATA: UN1759 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: CORROSIVE SOLID, N.O.S. (For reference only, please check.)

IMDG: CORROSIVE SOLID, N.O.S. (For reference only, please check.)

IATA: CORROSIVE SOLID, N.O.S. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 8 (For reference only, please check.)

IMDG: 8 (For reference only, please check.)

IATA: 8 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: I (For reference only, please check.)

IMDG: I (For reference only, please check.)

IATA: I (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: Yes

IMDG: Yes

IATA: Yes

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Isotretinoin	Isotretinoin	4759-48-2	225-296-0
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.
Korea Existing Chemicals List (KECL)			Listed.

SECTION 16: Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>

- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Any questions regarding this SDS, Please send your inquiry to sds@xixisys.com

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