# SAFETY DATA SHEET



# 1. Identification

1. Identification		
Product identifier	Acitretin Related Compour	nd A
Other means of identification		
Catalog number	1011018	
CAS number	69427-46-9	
Synonyms	13-cis-Acitretin * Isoacitretin	
Chemical name	(2Z,4E,6E,8E)-9-(4-methoxy	-2,3,6-trimethylphenyl)-3,7-dimethylnona-2,4,6,8-tetraenoic acid
Recommended use	Specified quality tests and as	ssay use only.
Recommended restrictions	Not for use as a drug. Not fo	r administration to humans or animals.
Manufacturer/Importer/Supplier/	Distributor information	
Manufacturer		
Company name Address	U. S. Pharmacopeia 12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887
2. Hazard(s) identification		
Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger	
Hazard statement	May damage fertility or the u	nborn child.
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/containe	er in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Pharmaceutical related compound of unknown potency.	

# 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Acitretin Related Compound A	13-cis-Acitretin Isoacitretin	69427-46-9	100
4. First-aid measures			
nhalation	Move to fresh air. Call a physician if symptom	ns develop or persist.	
Skin contact	Wash off with soap and water. Get medical a	ttention if irritation develops and	persists.
Eye contact	Rinse with water. Get medical attention if irrit	ation develops and persists.	
ngestion	Rinse mouth. Get medical attention if sympto	ms occur.	
Most important symptoms/effects, acute and delayed	Reproductive system effects. Pharmaceutica known if occupational exposure may cause p		potency. It is not
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and tre	at symptomatically.	
General information	Remove from exposure. Remove contaminat an occupational health physician or other lice chemical exposures. In the United States, the 1-800-222-1222. If person is not breathing, g oxygen if available. Persons developing serior receive immediate medical attention.	ensed health-care provider familia e national poison control center p ive artificial respiration. If breathi	ar with workplace whone number is ng is difficult, give
5. Fire-fighting measures			
Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire- materials.	extinguishing media appropriate	for surrounding
Unsuitable extinguishing media	None known.		
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.		
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.		
Fire fighting equipment/instructions	Use water spray to cool unopened containers Firefighters should use self-contained breath		
Specific methods	Use standard firefighting procedures and con	sider the hazards of other involv	ed materials.
General fire hazards	No unusual fire or explosion hazards noted.		
6. Accidental release meas	sures		
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear ap inhalation of dust from the spilled material. Do unless wearing appropriate protective clothin protection, see section 8 of the SDS.	o not touch damaged containers	or spilled material
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up suitable container for disposal. Clean surface waste disposal, see section 13 of the SDS.	<ul> <li>Sweep up or vacuum up spilla thoroughly to remove residual of</li> </ul>	ge and collect in contamination. For
Environmental precautions	Avoid discharge into drains, water courses or	onto the ground.	
7. Handling and storage	-	-	
Precautions for safe handling	As a general rule, when handling USP Refere dust, mists, and/or vapors associated with the suitable detergent or solvent after use. After thoroughly. Select and use containment devic risk assessment of material potency and exp	e material. Clean equipment and removing gloves, wash hands ar ces and personal protective equi	work surfaces with d other exposed ski
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP label instructions to ensure product integrity.	•	ndled and stored pe
8. Exposure controls/perse	onal protection		
Occupational exposure limits	No exposure limits noted for ingredient(s).		
Biological limit values	No biological exposure limits noted for the inc		

## **Biological limit values** No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls	Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.
Individual protection measures,	such as personal protective equipment
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.
Other	Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.
Respiratory protection	Choose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. Pharmacological effects may be seen with occupational exposure.

# 9. Physical and chemical properties

5. Thysical and chemical	
Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Crystalline powder.
Color	Yellow.
Odor	Not available.
Odor threshold	Not available.
рН	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or exp	plosive limits
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Retinoid.

Molecular formula	C21H26O3
Molecular weight	326.44

# 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents. Strong bases.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

## Information on likely routes of exposure

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Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Related material: Dehydration. Dry mouth. Dry skin. Runny nose. Hair loss. Bone pain. Joint pain. Muscle pain. Headache. Gastrointestinal disturbances. Behavior, mood, or mental changes.
-formation on toxical add	inste

## Information on toxicological effects

	mornation on toxicological enects		
	Acute toxicity	Not known.	
	Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
	Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
	Respiratory or skin sensitization		
	Respiratory sensitization	Knowledge about health hazard is incomplete.	
	Skin sensitization	Knowledge about health hazard is incomplete.	
	Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
	Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
	IARC Monographs. Overall E	valuation of Carcinogenicity	
	Not listed. OSHA Specifically Regulated	d Substances (29 CFR 1910.1001-1052)	
Not regulated. US. National Toxicology Program (NTP) Report on Carcinogens Not listed.		gram (NTP) Report on Carcinogens	
	Reproductive toxicity	May damage fertility or the unborn child. Therapeutic use of a related material during pregnancy has been associated with adverse reproductive effects. A related material has caused birth defects in animals.	
	Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
	Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
	Aspiration hazard	Based on available data, the classification criteria are not met.	
	Further information	Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.	
	12. Ecological information		
	Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
	Persistence and degradability	No data is available on the degradability of this substance.	

Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

#### 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

Transport in bulk according to	Not applicable.
Annex II of MARPOL 73/78 and	
the IBC Code	

**General information** 

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US** federal regulations Standard, 29 CFR 1910.1200. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. Superfund Amendments and Reauthorization Act of 1986 (SARA) SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous Yes chemical Classified hazard Reproductive toxicity categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act Not regulated. (SDWA)

#### **US state regulations**

#### **California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

#### **International Inventories**

Country(s) or region	Inventory name On inventory (y	es/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No
** ** *		

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date	11-23-2004
Revision date	09-30-2019
Version #	03
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