

# Material Safety Data Sheet

## RETIN-A Cream

Version 1.0

Revision Date 2014/02/17

Print Date 2014/02/17

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : RETIN-A Cream

Substance name : tretinoin  
cream  
0,1% 0,05% 0,025% 0,01%

Chemical nature : Mixture

Manufacturer or supplier's details

Company name of supplier : Janssen Ortho LLC

Address : State Road #2 Km 45.6  
Manati 00674-0463  
PR

Telephone : +18097878541800

**Emergency telephone number** : **+32 14 60 24 44**

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product, Pharmacotherapeutic group: Anti-acne preparations, This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.  
This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

E-mail address :

Responsible/issuing person : SDSJanssen@its.jnj.com

### SECTION 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Form	cream
Colour	light yellow
Odour	no data available
Hazard Summary	This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

#### GHS Classification

Reproductive toxicity : Category 1B

#### GHS Label element


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- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H360 May damage fertility or the unborn child.
- Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves/ protective clothing.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
**Storage:**  
P405 Store locked up.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Self-Ignitable : no data available

### Potential Health Effects

- Aggravated Medical Condition : None known.
- Symptoms of Overexposure : Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.  
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

### Carcinogenicity:

- OSHA** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
- NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Pure substance/mixture : Mixture

Chemical nature : Mixture

### Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	>= 0.1 - < 1 %

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TRETINOIN

302-79-4

>= 0.1 - < 1 %

### SECTION 4. FIRST AID MEASURES

- If inhaled : If breathed in, move person into fresh air.  
Consult a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.  
Wash off with soap and water.  
If symptoms persist, call a physician.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,  
for at least 5 minutes.  
Remove contact lenses.  
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is  
conscious).  
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Repeated or prolonged skin contact may cause allergic  
reactions with susceptible persons.  
Consult the patient packaging insert for more information  
about this Finished Pharmaceutical Product.
- Notes to physician : Treat symptomatically.  
Consult the patient packaging insert for more information  
about this Finished Pharmaceutical Product.

### SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local  
circumstances and the surrounding environment.
- Hazardous combustion products : No hazardous combustion products are known.
- Specific extinguishing methods : No information available.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response  
team must respond based on a risk assessment and use  
personal protective equipment as appropriate.  
Evacuate personnel to safe areas.
- Environmental precautions : Should not be released into the environment.  
Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material.  
Keep in properly labelled containers.  
Small spills: Gently cover the spill with an absorbent towel or  
pad.

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Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

### SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.  
To avoid thermal decomposition, do not overheat.  
For personal protection see section 8.  
Avoid inhalation, ingestion and contact with skin and eyes.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.  
Store in original container.  
Keep containers tightly closed in a dry, cool and well-ventilated place.  
Keep away from heat and sources of ignition.
- Materials to avoid : None known.
- Storage temperature : <= 25 °C

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Form of exposure	Permissible concentration	Basis
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	TWA	10 mg/m <sup>3</sup>	ACGIH
TRETINOIN	302-79-4	TWA	0.003 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		STV	0.03 mg/100cm <sup>2</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J OEL/PBOEL HHC
Further information:	J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B.			
				J&J OEL/PBOEL HHC
Further information:	Notation SKIN: has the potential for absorption via the skin. Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			

- Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

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### Personal protective equipment

Respiratory protection	: Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present. No personal respiratory protective equipment normally required.
Hand protection	: No special precautions required.
Remarks	: No special precautions required.
Eye protection	: No special precautions required.
Skin and body protection	: No special precautions required.
Protective measures	: The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: cream
Colour	: light yellow
Odour	: no data available
Odour Threshold	: no data available
pH	: 2.7 - 4.7
	: no data available
	: no data available
Flash point	: no data available
Evapouration rate	: no data available
Auto-flammability	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Solubility(ies)	
Water solubility	: no data available

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Solubility in other solvents	: no data available
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Thermal decomposition	: no data available
Viscosity	
Viscosity, dynamic	: no data available
Viscosity, kinematic	: no data available
Explosive properties	: no data available
Oxidizing properties	: no data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: Exposure to sunlight. To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	: None known.
Hazardous decomposition products	: None known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

##### Product

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
Acute dermal toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method

##### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Acute oral toxicity	: LD50 rat: > 2,000 mg/kg  LD50 rabbit: > 2,000 mg/kg
Acute inhalation toxicity	: no data available

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Acute dermal toxicity : no data available

### **TRETINOIN :**

Acute oral toxicity : LD50 Oral rat: 2,000 mg/kg

LD50 Oral mouse: 1,100 mg/kg

Acute dermal toxicity : May be harmful if absorbed through skin.

Acute toxicity (other routes of administration) : LD50 mouse: 208 mg/kg  
Application Route: intraperitoneal; injection made in the abdominal area

LD50 mouse: 92 mg/kg  
Application Route: intravenous injection

LD50 mouse: 53 mg/kg  
Application Route: Subcutaneous; injection made in the back or neck of animal

### **Skin corrosion/irritation**

#### **Components:**

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**  
no data available

**TRETINOIN :**  
no data available

### **Serious eye damage/eye irritation**

#### **Components:**

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**  
no data available

**TRETINOIN :**  
no data available

### **Respiratory or skin sensitisation**

#### **Product**

Species: human  
Result: May cause sensitisation by skin contact.

#### **Components:**

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**  
no data available

**TRETINOIN :**  
no data available

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### Germ cell mutagenicity

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Germ cell mutagenicity-  
Assessment : No information available.

##### **TRETINOIN :**

Genotoxicity in vitro : Type: Ames test  
Result: negative

: Type: A mouse lymphoma test  
Result: positive

Genotoxicity in vivo : Type: In vivo micronucleus test  
Test species: mouse Result: negative

Germ cell mutagenicity-  
Assessment : Not mutagenic in Ames Test.

### Carcinogenicity

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Carcinogenicity -  
Assessment : No information available.

##### **TRETINOIN :**

Carcinogenicity -  
Assessment : No information available.

### Reproductive toxicity

#### Components:

##### **TRETINOIN :**

Reproductive toxicity -  
Assessment : No information available.

### Reproductive Toxicity/Development/Teratogenicity

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Teratogenicity - Assessment : No information available.

##### **TRETINOIN :**

Species: rat  
Application Route: Oral  
>= 1 mg/kg  
positive

Species: Monkey  
Application Route: Oral  
>= 5 mg/kg  
positive

Teratogenicity - Assessment : May damage the unborn child.



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### STOT - single exposure

#### Components:

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Remarks: no data available

**TRETINOIN :**

Remarks: no data available

### STOT - repeated exposure

no data available

### Aspiration toxicity

no data available

### Further information

#### Product

Photosensitizer - causes sensitization to light.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Toxicity to fish : (Fish): 0.199 mg/l  
Exposure time: 96 h  
Test Method: LC50

Toxicity to algae : EC50 : 0.758 mg/l  
Exposure time: 96 h

**TRETINOIN :**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 0.163 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

NOEC (Danio rerio (zebra fish)): 0.136 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.2 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 0.0366 mg/l  
Exposure time: 48 h

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata): > 0.102 mg/l  
Test Method: Growth inhibition  
Method: OECD Test Guideline 201

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NOECr (Pseudokirchneriella subcapitata (green algae)): 0.102 mg/l

Test Method: Growth inhibition

Method: OECD Test Guideline 201

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 0.102 mg/l

Test Method: Cell multiplication inhibition test

Method: OECD Test Guideline 201

NOECb (Pseudokirchneriella subcapitata (green algae)): 0.102 mg/l

Test Method: Cell multiplication inhibition test

Method: OECD Test Guideline 201

### Persistence and degradability

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Biodegradability : no data available

##### **TRETINOIN :**

Biodegradability : no data available

### Bioaccumulative potential

#### Product:

Partition coefficient: n-octanol/water : no data available

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Bioaccumulation : Bioconcentration factor (BCF): 598.4

##### **TRETINOIN :**

Bioaccumulation : Accumulation in aquatic organisms is expected.

Partition coefficient: n-octanol/water : Pow: 6.3

### Mobility in soil

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Mobility : no data available

##### **TRETINOIN :**

Mobility : no data available

### Results of PBT and vPvB assessment

#### Components:

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Assessment : No information available.

##### **TRETINOIN :**

Assessment : No information available.

### Other adverse effects

#### Product:

Ozone-Depletion Potential Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

List

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Group  
Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

### **Components:**

#### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- :**

Environmental fate and pathways : no data available

#### **TRETINOIN :**

Environmental fate and pathways : no data available

Additional ecological information : no data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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## SECTION 14. TRANSPORT INFORMATION

### **International transport regulations**

#### **ADR**

Not dangerous goods

#### **RID**

Not dangerous goods

#### **DOT**

Not dangerous goods

#### **IATA**

Not dangerous goods

#### **IMDG**

Not dangerous goods

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## SECTION 15. REGULATORY INFORMATION

### **EPCRA - Emergency Planning and Community Right-to-Know Act**

#### **SARA 302**

: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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**SARA 313** : SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

### Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

#### Pennsylvania Right To Know

Purified water, USP	7789-20-0	50 - 70 %
Octadecanoic acid	57-11-4	10 - 20 %
Tetradecanoic acid, 1-methylethyl ester	110-27-0	10 - 20 %
		5 - 10 %
1-Octadecanol	112-92-5	1 - 5 %

#### New Jersey Right To Know

Purified water, USP	7789-20-0	50 - 70 %
Octadecanoic acid	57-11-4	10 - 20 %
Tetradecanoic acid, 1-methylethyl ester	110-27-0	10 - 20 %
		5 - 10 %
1-Octadecanol	112-92-5	1 - 5 %

#### California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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## SECTION 16. OTHER INFORMATION

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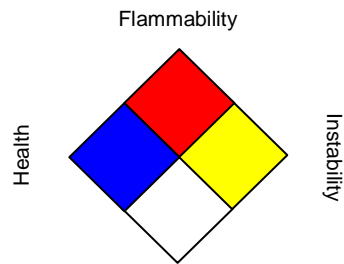
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### Further information

#### NFPA:



#### HMIS III:

<b>HEALTH</b>	
<b>FLAMMABILITY</b>	
<b>PHYSICAL HAZARD</b>	

0 = not significant, 1 = Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

### Date and Number Formats

This document uses the following notation for printing dates and numbers:

**Date:** Dec 31th, 2012 as 2012/12/31

**Numbers:** 123456,78 as 123,456.78

Prepared by: