

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

Hazardous according to the criteria of Worksafe Australia

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

1.1 Product identifier

Trade name : Tretinoin
Substance name : 2,4,6,8-Nonatetraenoic acid, 3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-, (all-E)-
CAS-No. : 302-79-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Ingredient for pharmaceutical products

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Ltd.
PO Box 2676
CH-4002 Basel
Telephone : +41618158888
Telefax : +41618157253
E-mail address : sds.nutritionalproducts@dsm.com
Responsible/issuing person

1.4 Emergency telephone number

+41 62 866 2314

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Chronic aquatic toxicity, Category 2	H411: Toxic to aquatic life with long lasting effects.
Reproductive toxicity, Category 1A	H360D: May damage the unborn child.

Classification (67/548/EEC, 1999/45/EC)

Toxic to Reproduction Category 1	R61: May cause harm to the unborn child.
Irritant	R36/37/38: Irritating to eyes, respiratory system and skin.
Dangerous for the environment	R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

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Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
302-79-4 tretinoin

2.3 Other hazards

Risk of dust explosion.
Women of childbearing age must avoid any overexposure.

3. Composition/information on ingredients

Synonyms : all-trans-Retinoic acid
all-trans-vitamin A acid

Brief description of the product : Substance

Molecular formula : C₂₀ H₂₈ O₂

3.1 Substances

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
tretinoin	302-79-4 206-129-0	Repr.Cat.1; R61 Xi; R36/37/38 N; R51-R53	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 Aquatic Chronic 2; H411 Repr. 1A; H360D	>= 97,5

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

4. First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
After any accidental exposure women should seek medical advice from a physician.
- If inhaled : Move to fresh air in case of accidental inhalation of dust or fumes from overheating or combustion.
If symptoms persist, call a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours), Skin irritation

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water
Foam

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

be disposed of in accordance with local regulations.
Consider dust explosion hazard.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
Ensure adequate ventilation.
Evacuate personnel to safe areas.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.
Avoid exposure - obtain special instructions before use.
For personal protection see section 8.
Dispose of rinse water in accordance with local and national regulations.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.
Take precautionary measures against static discharges.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Protect from humidity.
Protect against light.
: Keep container tightly closed and dry.
Prevent unauthorized access.
Storage temperature : < 15 °C

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

7.3 Specific end uses

Specific use(s) : not applicable

8. Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value	Control parameters	Update	Basis
tretinoin	302-79-4	TWA	0,02 mg/m ³		DSM Internal Limit
		established for men			
		TWA	0,001 mg/m ³		DSM Internal Limit
		established for women			

8.2 Exposure controls

Personal protective equipment

- Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
- Hand protection : Glove material: for example nitrile rubber
: Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
- Eye protection : Safety glasses with side-shields
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Avoid contact with skin, eyes and clothing.
Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : crystalline, powder
- Colour : yellow - light orange
- Odour : characteristic, pleasant
- Odour Threshold : No information available.
- pH : no data available
- Melting point/range : ca. 182 °C
- Boiling point/boiling range : not determined
- Flash point : not applicable
- Flammability (solid, gas) : Not classified as supporting combustion according to the

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

	transport regulations.
Vapour pressure	: < 0,001 hPa (at 25 °C)
Relative vapour density	: not applicable
Density	: not determined
Water solubility	: (20 °C) practically insoluble
Solubility in other solvents	: Propylene glycol: slightly soluble n-Octanol: slightly soluble Ethanol: slightly soluble Glycerol: insoluble Chloroform: soluble
Partition coefficient: n-octanol/water	: log Pow 6,3
Autoignition temperature	: no data available
Thermal decomposition	: no data available
Explosive properties	: no data available
Oxidizing properties	: no data available

9.2 Other information

Combustibility index for deposited dust	: 3 (ca. 21 °C)
Dust explosion class	: St(H)2 (The value was determined in the modified Hartmann tube.)
Molecular Weight	: 300,44 g/mol
Dissociation constant	: pKa 4,2 (25 °C, calculated value)

10. Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Strong acids
Bases
Strong oxidizing agents
Copper
Copper alloys

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

Iron
Iron salts

10.6 Hazardous decomposition products

No decomposition if used as directed.

11. Toxicological information

11.1 Information on toxicological effects

- Acute oral toxicity : LD50 (rat): 2 000 mg/kg
: LD50 (mouse): 2 200 mg/kg
- Skin corrosion/irritation : Severe skin irritation (mouse)
: May cause skin irritation and/or dermatitis.
- Serious eye damage/eye irritation : Eye irritation
- Germ cell mutagenicity
Genotoxicity in vitro : not mutagenic, not genotoxic (Various test systems)
- Genotoxicity in vivo : not genotoxic (mouse, oral, Mutagenicity (micronucleus test))
- Carcinogenicity : No indication for carcinogenicity known.
- Teratogenicity : Teratogenic
embryotoxic
(several species)
Assessment: Teratogenic
- STOT - single exposure : May cause respiratory irritation.
- STOT - repeated exposure : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
- Aspiration toxicity : No aspiration toxicity classification
- Further information : Irritating to mucous membranes
: May cause irritation of respiratory tract.
- Experience with human exposure : Overexposure may provoke the following symptoms:
Symptoms of hypervitaminosis A

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

- Experience with human exposure: Skin contact : Skin irritation
- Experience with human exposure: Ingestion : Acute overdose produces the following symptoms:
: Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours)

12. Ecological information

12.1 Toxicity

- Toxicity to daphnia and other aquatic invertebrates. : Daphnia magna (Water flea)
EC50 (48 h) 3,1 mg/l
(OECD Test Guideline 202)
: EC0 (48 h) 1,8 mg/l
- Toxicity to algae : Scenedesmus capricornutum (fresh water algae)
ErC50 (72 h) > 100 mg/l
(nominal concentration)
(OECD Test Guideline 201)
: NOEC (72 h) 80 mg/l
- Toxicity to bacteria : activated sludge
Concentration of the substance (28 d) 30 mg/l
No inhibition was observed under the biodegradation test conditions.
(OECD Test Guideline 302C)

12.2 Persistence and degradability

- Biodegradability : Inherently biodegradable.
54 % (28 d)
(OECD Test Guideline 302C)

12.3 Bioaccumulative potential

- Partition coefficient: n-octanol/water : log Pow 6,3

12.4 Mobility in soil

- Distribution among environmental compartments : no data available

12.5 Results of PBT and vPvB assessment

- Assessment : This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
: This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects

- Additional ecological information : Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

13. Disposal considerations

13.1 Waste treatment methods

- Product : Discharge into the environment must be avoided.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed disposal company.
- Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

14. Transport information

14.1 UN number

- ADR : 3077
RID : 3077
IMDG : 3077
IATA : 3077

14.2 Proper shipping name

- ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tretinoin)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tretinoin)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tretinoin)
IATA : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tretinoin)

14.3 Transport hazard class

- ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

- ADR
Packaging group : III
Classification Code : M7
Hazard identification No : 90
Labels : 9
Tunnel restriction code : (E)
RID
Packaging group : III
Classification Code : M7
Hazard identification No : 90
Labels : 9
IMDG
Packaging group : III
Labels : 9
EmS Number : F-A, S-F

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

Print Date 24.06.2014

IATA

Packing instruction (cargo aircraft) : 956
Packaging group : III
Labels : 9

14.5 Environmental hazards

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : no

IATA

Environmentally hazardous : yes

14.6 Special precautions for user

No additional requirements.

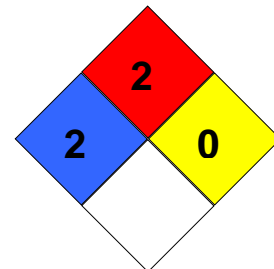
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

NFPA Classification : Health hazard: 2
Fire Hazard: 2
Reactivity Hazard: 0



15.2 Chemical Safety Assessment

16. Other information

Full text of R-phrases referred to under sections 2 and 3

R36/37/38 Irritating to eyes, respiratory system and skin.
R51 Toxic to aquatic organisms.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R53 May cause long-term adverse effects in the aquatic environment.
R61 May cause harm to the unborn child.

Full text of H-Statements referred to under sections 2 and 3.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tretinoin

0418099

Version 1.2

Revision Date 30.09.2011

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H411	Toxic to aquatic life with long lasting effects.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Abbreviations: 67/548/EEC= Dangerous Substances Directive. 1999/45/EC= Dangerous Preparations Directive. Regulation (EC) No. 1272/2008= Regulation on classification, labelling and packaging of substances and mixtures. DNEL= Derived No-Effect Level. PNEC= Predicted No-Effect Concentration. NFPA= National Fire Protection Association. IATA= International Air Transport Association. IMDG= International Maritime Dangerous Goods. RID= International Rule for Transport of Dangerous Substances by Railway; ADR= European Agreement concerning the International Carriage of Dangerous Goods by Road. TWA= Time Weighted Average. STEL= Short term exposure limit.