

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Vitamin A Water-miscible, Type 100

#### 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 (UK) Ltd.  
Heanor Gate  
αGB061EI0017  
Delves Road  
GB-DE75 7SG Heanor

Telephone : +441773536500  
Telefax : +441773536600  
E-mail address : sds.nutritionalproducts@dsm.com  
Responsible/issuing person

#### 1.4 Emergency telephone number

+441773536623 / +41628662314

### 2. Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)


||| Reproductive toxicity, Category 1B H360D: May damage the unborn child.

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

Toxic to Reproduction Category 2 R61: May cause harm to the unborn child.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

||| Hazard pictograms : 

||| Signal word : Danger

||| Hazard statements : H360D May damage 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.  
P281 Use personal protective equipment as required.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

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### Storage:

P405

Store locked up.

### Disposal:

P501

Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

79-81-2 retinyl palmitate (vitamin A palmitate)

### Additional Labelling:

Restricted to professional users.

## 2.3 Other hazards

Women of childbearing age must avoid any overexposure.

## 3. Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing active ingredient and auxiliary substances  
aqueous dispersion

### 3.2 Mixtures

#### Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
retinyl palmitate (vitamin A palmitate)	79-81-2 201-228-5 01-2119480425-37	Repr.Cat.2; R61 Xi; R38 R53	Repr. 1B; H360D Aquatic Chronic 4; H413	>= 5 - < 10

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### Further ingredients

Chemical Name	CAS-No. EC-No. Registration number	Classification	GHS Classification	Concentration [%]
glycerol	56-81-5 200-289-5			>= 10 - <= 20

## 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

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- In case of skin contact : Take off contaminated clothing and shoes immediately.  
Wash off with soap and plenty of water.
- In case of eye contact : Flush eyes with water as a precaution.  
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 : 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)

### 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  
Alcohol-resistant foam  
Dry chemical  
Use extinguishing measures that are appropriate to local  
circumstances and the surrounding environment.

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : None known.

### 5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : The product itself does not burn.  
Collect contaminated fire extinguishing water separately. This  
must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must  
be disposed of in accordance with local regulations.

## 6. Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Evacuate personnel to safe areas.  
Use personal protective equipment.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

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Ensure adequate ventilation.

### 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

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
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 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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Protect against light.  
Keep under inert gas.  
: Keep container tightly closed.  
Prevent unauthorized access.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature : < 15 °C

### 7.3 Specific end use(s)

Specific use(s) : not applicable

## 8. Exposure controls/personal protection

### 8.1 Control parameters

Components	CAS-No.	Value (Form of exposure)	Control parameters	Update	Basis
glycerol	56-81-5	TWA	10 mg/m <sup>3</sup>	2005-04-06	GB EH40
	:	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used			
retinyl palmitate	79-81-2	TWA	0,37 mg/m <sup>3</sup>		DSM Internal Limit

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

	:   established for men				
		TWA	0,09 mg/m <sup>3</sup>		DSM Internal Limit
	:   established for women				

### DNEL

vitamin A palmitate

: Skin contact, Workers: 1,6 mg/kg bw/d  
Potential health effects: Systemic effects, long-term

Inhalation, Workers: 0,55 mg/m<sup>3</sup> ( 8 h)

Potential health effects: Systemic effects, long-term

### PNEC

vitamin A palmitate

: Fresh water: 0,1 mg/l

Fresh water sediment: The equilibrium partitioning method is not applicable.

Marine water: 0,01 mg/l

Marine sediment: The equilibrium partitioning method is not applicable.

Soil: The equilibrium partitioning method is not applicable.

Sewage treatment plant: 10 mg/l

## 8.2 Exposure controls

### Personal protective equipment

Respiratory protection : Breathing apparatus needed only when aerosol or mist is formed.

Hand protection : Chloroprene  
Nitrile rubber  
Latex gloves

: 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 : liquid, emulsion

Colour : green - yellow

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

Odour	: No information available.
Odour Threshold	: No information available.
pH	: 6,0 - 7,5
Melting point/range	: not determined
Boiling point/boiling range	: not determined
Flash point	: does not flash
Evaporation rate	: not determined
Flammability (solid, gas)	: Not classified as supporting combustion according to the transport regulations.
Lower explosion limit	: not determined
Upper explosion limit	: not determined
Vapour pressure	: not determined
Relative vapor density	: not applicable
Density	: 1,04 - 1,06 g/cm <sup>3</sup> (at 20 °C)
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: not applicable
Auto-ignition temperature	: no data available
Ignition temperature	: not determined
Thermal decomposition	: no data available
Viscosity, dynamic	: not determined
Explosive properties	: no data available
Oxidizing properties	: no data available

### 9.2 Other information

no data available

## 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

Possible incompatibility with materials listed under section 10.5.

### 10.4 Conditions to avoid

Heat.

### 10.5 Incompatible materials

Strong acids and strong bases  
Strong oxidizing agents

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

### 10.6 Hazardous decomposition products

No decomposition if used as directed.

## 11. Toxicological information

### 11.1 Information on toxicological effects

- Skin irritation  
retinyl palmitate : Mild skin irritation (rabbit, OECD Test Guideline 404)
- : no phototoxic skin reaction (guinea pig)
- Genotoxicity in vivo  
retinyl palmitate : not genotoxic (In vivo micronucleus test, mouse)
- Teratogenicity  
retinyl palmitate : Teratogenic  
embryotoxic  
(several species)
- Further information  
retinyl palmitate : Danger of cumulative effects.
- Experience with human exposure  
retinyl palmitate : RDA (Recommended Daily Allowance) 0,8 mg pure vitamin A (retinol) per day established for men  
RDA (Recommended Daily Allowance) ca. 0,7 mg pure vitamin A (retinol) per day established for women
- Experience with human exposure: Ingestion  
retinyl palmitate : 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

No data is available on the product itself.

### 12.2 Persistence and degradability

- Biodegradability  
retinyl palmitate : Not readily biodegradable.  
40 - 50 % (28 d)  
(OECD Test Guideline 301F)

No data is available on the product itself.

### 12.3 Bioaccumulative potential

- Bioaccumulation : no data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

Partition coefficient: n-octanol/water : not applicable

### 12.4 Mobility in soil

Distribution among environmental compartments : no data available

### 12.5 Results of PBT and vPvB assessment

Assessment : This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).  
: This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

### 12.6 Other adverse effects

Additional ecological information : There is no data available for this product.

## 13. Disposal considerations

### 13.1 Waste treatment methods

Product : 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

Not dangerous goods

#### RID

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

### 14.2 Proper shipping name

#### ADR

Not dangerous goods

#### RID

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

### 14.3 Transport hazard class

#### ADR

Not dangerous goods



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

### RID

Not dangerous goods

### IMDG

Not dangerous goods

### IATA

Not dangerous goods

#### 14.4 Packing group

### ADR

Not dangerous goods

### RID

Not dangerous goods

### IMDG

Not dangerous goods

### IATA

Not dangerous goods

#### 14.5 Environmental hazards

### ADR

Not dangerous goods

### RID

Not dangerous goods

### IMDG

Not dangerous goods

### IATA

Not dangerous goods

#### 14.6 Special precautions for user

Not classified as dangerous in the meaning of transport regulations.

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

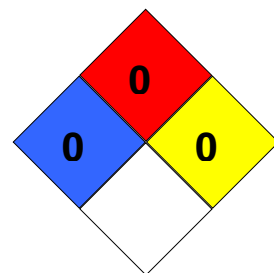
no data available

### 15. Regulatory information

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

##### NFPA Classification

: Health hazard: 0  
Fire Hazard: 0  
Reactivity Hazard: 0



#### 15.2 Chemical Safety Assessment

not applicable

### 16. Other information

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Vitamin A Water-miscible, Type 100

0421316

Version 3.0

Revision Date 13.08.2012

Print Date 26.06.2014

R38	Irritating to skin.
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.

H360D	May damage the unborn child.
H413	May cause long lasting harmful effects to aquatic life.

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 (USA). 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.