

## ANA T-fill

Revision date: 06.03.2017

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

ANA T-fill

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

medical use

**Uses advised against**

No information available.

**1.3. Details of the supplier of the safety data sheet**

Company name:	dent a pharm Produktionsges.mbH	
Street:	Schusterring 35	
Place:	D-25355 Barmstedt	
Telephone:	+49 (0) 4123-9225-0	Telefax: +49 (0) 4123-9228-49
e-mail:	info@dent-a-pharm.de	
e-mail (Contact person):	info@dent-a-pharm.de	
Internet:	www.wpdental.de	
Responsible Department:	info@dent-a-pharm.de	

**1.4. Emergency telephone number:** +49(0) 551 - 1 92 40 (GIZ-Nord, 24h)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Hazardous to the aquatic environment: Aquatic Acute 1

Hazardous to the aquatic environment: Aquatic Chronic 1

Hazard Statements:

Causes serious eye damage.

Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard components for labelling**

Zinc sulfate monohydrate

**Signal word:** Danger**Pictograms:****Hazard statements**

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

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P310 present and easy to do. Continue rinsing.  
 Immediately call a POISON CENTER/doctor.  
 P501 Dispose of contents/container to ....

**2.3. Other hazards**

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
1314-13-2	zinc oxide			20-30 %
	215-222-5	030-013-00-7	01-2119463881-32	
	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H400 H410			
7446-19-7	Zinc sulfate monohydrate			4-6 %
	231-793-3		01-2119474684-27	
	Acute Tox. 4, Eye Dam. 1, Aquatic Chronic 1; H302 H318 H410			

Full text of H and EUH statements: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

No special measures are necessary.

**After inhalation**

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap.

In case of skin irritation, consult a physician.

**After contact with eyes**

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Consult an ophthalmologist.

**After ingestion**

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

Do NOT induce vomiting.

**4.2. Most important symptoms and effects, both acute and delayed**

No known symptoms to date.

**4.3. Indication of any immediate medical attention and special treatment needed**

First Aid, decontamination, treatment of symptoms.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**Water spray jet, Carbon dioxide (CO<sub>2</sub>), Foam, Dry extinguishing powder, alcohol resistant foam

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**Unsuitable extinguishing media**

High power water jet

**5.2. Special hazards arising from the substance or mixture**

No known hazardous decomposition products.

**5.3. Advice for firefighters**

Co-ordinate fire-fighting measures to the fire surroundings.

In case of fire: Wear self-contained breathing apparatus.

**Additional information**

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Dispose of waste according to applicable legislation.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

See protective measures under point 7 and 8.

Personal protection equipment: see section 8

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

**6.3. Methods and material for containment and cleaning up**

Take up mechanically, placing in appropriate containers for disposal.

**6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Avoid contact with eyes and skin.

Wear personal protection equipment (refer to section 8).

Keep container tightly closed.

**Advice on protection against fire and explosion**

Usual measures for fire prevention.

**Further information on handling**

No information available.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

No special technical protective measures are necessary.

Keep/Store only in original container.

**Advice on storage compatibility**

Keep away from food, drink and animal feedingstuffs.

**Further information on storage conditions**

Keep away from:

Frost

Heat

Humidity

**7.3. Specific end use(s)**

No information available.

**SECTION 8: Exposure controls/personal protection**

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**8.1. Control parameters****DNEL/DMEL values**

CAS No	Substance		
DNEL type	Exposure route	Effect	Value
1314-13-2	zinc oxide		
Worker DNEL, long-term	inhalation	systemic	5 mg/m <sup>3</sup>
Worker DNEL, long-term	inhalation	local	0,5 mg/m <sup>3</sup>
Worker DNEL, long-term	dermal	systemic	83 mg/kg bw/day
Consumer DNEL, long-term	inhalation	systemic	2,5 mg/m <sup>3</sup>
Consumer DNEL, long-term	dermal	systemic	83 mg/kg bw/day
Consumer DNEL, long-term	oral	systemic	0,83 mg/kg bw/day
7446-19-7	Zinc sulfate monohydrate		
Worker DNEL, long-term	inhalation	systemic	1 mg/m <sup>3</sup>
Worker DNEL, long-term	dermal	systemic	8,3 mg/kg bw/day
Consumer DNEL, long-term	inhalation	systemic	1,25 mg/m <sup>3</sup>
Consumer DNEL, long-term	dermal	systemic	8,3 mg/kg bw/day
Consumer DNEL, long-term	oral	systemic	0,83 mg/kg bw/day

**PNEC values**

CAS No	Substance	
Environmental compartment	Value	
1314-13-2	zinc oxide	
Freshwater	0,0206 mg/l	
Marine water	0,0061 mg/l	
Freshwater sediment	117,8 mg/kg	
Marine sediment	56,5 mg/kg	
Soil	35,6 mg/kg	
7446-19-7	Zinc sulfate monohydrate	
Freshwater	0,0206 mg/l	
Marine water	0,0061 mg/l	
Freshwater sediment	117,8 mg/kg	
Marine sediment	56,5 mg/kg	
Soil	35,6 mg/kg	

**8.2. Exposure controls****Appropriate engineering controls**

No special measures are necessary.

**Protective and hygiene measures**

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Avoid contact with skin, eyes and clothes.

**Eye/face protection**

goggles

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**Hand protection**

Tested protective gloves must be worn: DIN EN 374

Suitable material:

NBR (Nitrile rubber)

Butyl caoutchouc (butyl rubber)

**Skin protection**

Only wear fitting, comfortable and clean protective clothing.

**Respiratory protection**

Usually no personal respirative protection necessary.

**Environmental exposure controls**

See section 7. No additional measures necessary.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	Paste
Colour:	light beige
Odour:	characteristic

**Test method**

pH-Value:	not determined
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**Changes in the physical state**

Melting point:	not applicable
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Initial boiling point and boiling range:	not determined
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Flash point:	not determined
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**Flammability**

Solid:	not determined
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Gas:	not applicable
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**Explosive properties**

not explosive according to EU A.14

Lower explosion limits:	not applicable
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Upper explosion limits:	not applicable
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**Auto-ignition temperature**

Solid:	not applicable
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Gas:	not applicable
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Decomposition temperature:	not applicable
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**Oxidizing properties**

Not oxidising.

Vapour pressure:	not determined
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Density:	not determined
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Water solubility:	partially soluble
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**Solubility in other solvents**

No information available.

Partition coefficient:	not determined
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Vapour density:	not determined
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Evaporation rate:	not determined
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**9.2. Other information**

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No information available.

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No information available.

**10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

**10.3. Possibility of hazardous reactions**

No information available.

**10.4. Conditions to avoid**

No information available.

**10.5. Incompatible materials**

No information available.

**10.6. Hazardous decomposition products**

No information available.

**Further information**

No information available.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

Based on available data, the classification criteria are not met.

CAS No	Chemical name			
	Exposure route	Dose	Species	Source
1314-13-2	zinc oxide			
	oral	LD50 > 2000 mg/kg	Rat	OECD Guideline 423
	dermal	LD50 > 2000 mg/kg	Rat	OECD Guideline 402
	inhalative (4 h) aerosol	LC50 >5,7 mg/l	Rat	
7446-19-7	Zinc sulfate monohydrate			
	oral	ATE 500 mg/kg		

**Irritation and corrosivity**

Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

**Sensitising effects**

Based on available data, the classification criteria are not met.

**Carcinogenic/mutagenic/toxic effects for reproduction**

Based on available data, the classification criteria are not met.

**STOT-single exposure**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Additional information on tests**

No information available.

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**Practical experience****Observations relevant to classification**

No information available.

**Other observations**

No information available.

**Further information**

There are no data available on the preparation/mixture itself.

**SECTION 12: Ecological information****12.1. Toxicity**

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h]   [d]	Species	Source
1314-13-2	zinc oxide				
	Acute fish toxicity	LC50 4,92 mg/l	96 h	Danio rerio	ECHA
	Acute algae toxicity	ErC50 0,21 mg/l	72 h	Selenastrum capricornutum	
	Acute crustacea toxicity	EC50 7,5 mg/l	48 h	Daphnia magna	OECD Guideline 202
	Fish toxicity	NOEC >= 0,54 mg/l	32 d	Danio rerio	OECD Guideline 210
	Algae toxicity	NOEC 0,024 mg/l	3 d	Selenastrum capricornutum	OECD Guideline 201
	Crustacea toxicity	NOEC 0,058 mg/l	21 d	Daphnia magna	OECD Guideline 211
	Acute bacteria toxicity	(5,2 mg/l)	3 h	activated sludge of a predominantly domestic sewage	OECD Guideline 209

**12.2. Persistence and degradability**

No information available.

**12.3. Bioaccumulative potential****BCF**

CAS No	Chemical name	BCF	Species	Source
1314-13-2	zinc oxide	28960	Palaemon elegans	ECHA

**12.4. Mobility in soil**

No information available.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

**12.6. Other adverse effects**

No information available.

**Further information**

No information available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

Dispose of waste according to applicable legislation.

**Contaminated packaging**

Dispose of waste according to applicable legislation.

**SECTION 14: Transport information****Land transport (ADR/RID)**

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<b><u>14.1. UN number:</u></b>	UN 3077
<b><u>14.2. UN proper shipping name:</u></b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide, Zinc sulfate monohydrate)
<b><u>14.3. Transport hazard class(es):</u></b>	9
<b><u>14.4. Packing group:</u></b>	III
Hazard label:	9
Classification code:	M7
Special Provisions:	274 335 375 601
Limited quantity:	5 kg
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	E

**Inland waterways transport (ADN)**

<b><u>14.1. UN number:</u></b>	UN 3077
<b><u>14.2. UN proper shipping name:</u></b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide, Zinc sulfate monohydrate)
<b><u>14.3. Transport hazard class(es):</u></b>	9
<b><u>14.4. Packing group:</u></b>	III
Hazard label:	9
Classification code:	M7
Special Provisions:	274 335 375 601
Limited quantity:	5 kg
Excepted quantity:	E1

**Marine transport (IMDG)**

<b><u>14.1. UN number:</u></b>	UN 3077
<b><u>14.2. UN proper shipping name:</u></b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide, Zinc sulfate monohydrate)
<b><u>14.3. Transport hazard class(es):</u></b>	9
<b><u>14.4. Packing group:</u></b>	III
Hazard label:	9
Marine pollutant:	PP
Special Provisions:	274, 335, 966, 967, 969
Limited quantity:	5 kg
Excepted quantity:	E1
EmS:	F-A, S-F

**Air transport (ICAO-TI/IATA-DGR)**

<b><u>14.1. UN number:</u></b>	UN 3077
<b><u>14.2. UN proper shipping name:</u></b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide, Zinc sulfate monohydrate)
<b><u>14.3. Transport hazard class(es):</u></b>	9
<b><u>14.4. Packing group:</u></b>	III
Hazard label:	9
Special Provisions:	A97 A158 A179 A197
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y956
Excepted quantity:	E1
IATA-packing instructions - Passenger:	956
IATA-max. quantity - Passenger:	400 kg
IATA-packing instructions - Cargo:	956



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IATA-max. quantity - Cargo: 400 kg

**14.5. Environmental hazards**ENVIRONMENTALLY HAZARDOUS: yes  
Danger releasing substance: zinc oxide, Zinc sulfate monohydrate**14.6. Special precautions for user**

No information available.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

No information available.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water contaminating class (D): 3 - highly water contaminating

**15.2. Chemical safety assessment**

For the following substances of this mixture a chemical safety assessment has been carried out:

zinc oxide

Zinc sulfate monohydrate

**SECTION 16: Other information****Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer  
(Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organization  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures,  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
EC50: Effectice concentration, 50 percent  
DNEL: Derived No Effect Level  
PNEC: Predicted No Effect Concentration  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

**Relevant H and EUH statements (number and full text)**

H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

# Safety Data Sheet



according to Regulation (EC) No 1907/2006

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*