

Safety Data Sheet

according to Regulation (EC) No 1907/2006 and 1272/2008

HOMBITAN AFDC, AFDC200, AFDC300, AC360, FF-Pharma, FG, AZ

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

1.1 Product identifier

Product Code: HOMBITAN AFDC, AFDC200, AFDC300, AC360, FF-Pharma, FG, AZ

Types:

REACH Registration No.: 01-2119489379-17-0005
01-2119489379-17-0006
01-2119489379-17-0018

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

Relevant identified uses:

White pigment for cosmetics, food and pharmaceutical applications

Uses advised against:

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1.3 Details of the supplier of the safety data sheet

Manufacturer / supplier: Sachtleben Chemie GmbH
Dr.-Rudolf-Sachtleben-Str. 4
D-47198 Duisburg, Germany



American International Chemical, Inc.
135 Newbury St. Framingham, MA 01701
800-238-0001

www.aicma.com

Manufacturing Sites:

► Sachtleben Pigments Oy
Titaanitie, 28840 Pori, Finland
Phone: +358 10 430 1000

► Sachtleben Pigment GmbH
47829 Krefeld, Germany
Phone: +49 2151 4797-5230

► Sachtleben Chemie GmbH
47198 Duisburg, Germany

Phone:

+49 2066 22-0

Fax:

+49 2066 22-2000

Mail:

info@sachtleben.de

Product Safety:

product-safety@sachtleben.com

1.4 Emergency telephone number

+49 30 30686 790 Giftnotruf Berlin (German/English)
+1 800 255 3924 CHEMTEL (U S A)
+358 9 471 977 or +358 9 4711 Poison Information Center
(Finland) Emergency Number: Chemtrec 800-424-9300
703-527-3887

2. POSSIBLE HAZARDS

2.1 Classification of the substance or mixture

The product is not classified hazardous according to the Regulation (EC) No 1272/2008 and the Council Directives 67/548/EEC and 1999/45/EEC. Therefore no obligation exists to issue a

safety data sheet according to REACH Art. 31.

- **2.2. Label elements**
No special labelling required
- **2.3 Other hazards**
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3. COMPOSITION/INFORMATION ON INGREDIENTS

- **3.1 Chemical Characterisation (Substance)**

Classification according to DSD -DPD / CLP

Substance identification	ID Numbers		Classification	Hazard Statemernts (R/H)
Titanium Dioxide	CAS. EINECS INDEX: REACH Color Index	13463-67-7 236-675-5 - 01-2119489379-17-0005 01-2119489379-17-0006 01-2119489379-17-0018 C.I. 77891 Pigment white 6	-	-

- **3.2 Chemical Characterisation (Mixture)**

Description: No mixture
Hazardous components: -

4. FIRST AID MEASURES

- **4.1 Description of first aid measures**

General indications: No hazards which require special first aid measures.
Inhalation: Move to fresh air. Give symptomatic treatment as necessary.
Skin contact: Wash with soap and water.
Eye contact: Wash with water or neutral eyewash solution.
Ingestion: Do not induce vomiting. Give up to 200 ml water. In case of persistent symptoms, consult a doctor.

- **4.2 Most important symptoms and effects, both acute and delayed**
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- **4.3 Indication of any immediate medical attention and special treatment needed**
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5. FIREFIGHTING MEASURES

- **5.1 Extinguishing media**
No restrictions
- **5.2 Special hazards arising from the substance or mixture**
The product itself does not burn. Product is inert, not flammable and incombustible.
- **5.3 Advice for firefighters**
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6. ACCIDENTAL RELEASE MEASURES

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid dust formation. Ensure adequate ventilation.
- **6.2 Environmental precautions**

Avoid dust dispersion to the environment. Dust may cause the surroundings to become white.
Prevent
leakages from entering drains and ditches that lead to natural waterways.

- **6.3 Methods and material for containment and cleaning up**
Use any suitable mechanical means (e.g. vacuum, sweeping), but avoid dusting during clean-up.
- **6.4 Reference to other sections**
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7. HANDLING AND STORAGE

- **7.1 Precautions for safe handling**
Avoid dust formation during handling. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. In case of insufficient ventilation, wear suitable respiratory equipment.
- **7.2 Conditions for safe storage, including any incompatibilities**
Fire Precautions: The product is not flammable
Storage conditions/ packing material: Keep in a dry place.
Incompatible products: No restrictions
- **7.3 Specific end use(s)**
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- **8.1 Control parameters**

Substance CAS No.	Titanium dioxide 13463-67-7		Dust, inhalable		Dust, respirable	
	Limit value - Eight hours mg/m ³	Limit value - Short term mg/m ³	Limit value - Eight hours mg/m ³	Limit value - Short term mg/m ³	Limit value - Eight hours mg/m ³	Limit value - Short term mg/m ³
Austria			10	20	5	10
Belgium	10		10		3	
Canada - Québec	10					
Denmark	6 total dust	12 total dust	10	20		
European Union						
France	11 inhalable aerosol		10		5 respirable aerosol	
Germany (AGS)			10	20	3	6
Germany (DFG)			4		1,5	
Hungary			10		6	
Italy						
Japan						
Poland	10	30				
Spain	10 inhalable aerosol		10		3	
Sweden	5 inhalable aerosol		10		5	
Switzerland	3 respirable aerosol		10		3	
The Netherlands						
USA - OSHA	15 total dust		15		5	
United Kingdom	10 inhalable aerosol					
	4 respirable aerosol					

Remarks:

Austria

*STV 15 minutes average

France	*Bold type: Restrictive statutory limit values	value *Bold type: Restrictive statutory limit values
Germany(AGS)	*15 minutes average value, insoluble particulates	*15 minutes average value, insoluble particulates
Germany(DFG)	*long term exposure level, insoluble particulates	*insoluble particulates

(Source: GESTIS - Internationale Grenzwerte für chemische Substanzen - Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA))

- 8.2 Exposure controls

Engineering measures: None required

Personal Protection Equipment

Industrial hygiene measures: Maintain exposures below applicable exposure limits:
Respiratory protection: A respirator must be used if the dust concentration is likely to exceed the occupational exposure limit. At higher concentrations wear particle filter DIN EN 143 - P2.
Hand protection: Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.
Eye protection: The use of an approved dustproof goggles is recommended if the dust concentration is likely to exceed the occupational exposure limit
Skin protection: TiO₂ pigments are not irritant but as with all fine powders can adsorb moisture and natural oils from the surface of the skin during prolonged exposure. Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Information on basic physical and chemical properties

Appearance

Physical State: powder

Colour: white

Odour: none

Critical Data

Melting point or range: > 1,800°C
Boiling point or range: not applicable
Flash point: not flammable
Ignition temperature: not flammable
Auto-ignition temperature: not flammable
Oxidizing properties: none
Explosive properties: no danger of explosion.
Explosivity or flammability limit -
in air:
Vapour pressure: not applicable
Density: approx. 3,9 g/ml
Solubility: practically insoluble
pH-value: approx. 4 - 9
Partition coefficient: not applicable
Viscosity: not applicable

- 9.2 Other information

10. STABILITY AND REACTIVITY

- 10.1 Reactivity

No special reactivity known

- 10.2 Chemical stability

Stable under normal use conditions

- **10.3 Possibility of hazardous reactions**
No hazardous reactions known
 - **10.4 Conditions to avoid**
Stable under normal use conditions
 - **10.5 Incompatible materials**
None known
 - **10.6 Hazardous decomposition products**
No hazardous decomposition products known.
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11. TOXICOLOGICAL INFORMATION

- **11.1 Information on toxicological effects**
 - **Acute toxicity:**
Acute toxicity: LD_{50} (rats, oral) > 10,000 mg/kg
Inhalative LC_{50} /4 hrs (Rat): > 6.8 mg/l
 - **Irritation/corrosion:**
Titanium dioxide is not irritating
 - **Sensitisation:**
No sensitisation known
 - **Chronic Toxicity:**
Non genotoxic.
 - **Further information:**
Health injuries are not known under normal use. Tumours produced in rats on inhalation of very high concentrations of titanium dioxide are believed to be the result of prolonged "lung overload" and are not considered relevant to man.
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12. ECOLOGICAL INFORMATION

- **12.1 Toxicity**
Aquatic toxicity: Fish LC_0 (Leuciscus idus, 48h): > 1000 mg/l
 - **12.2 Persistence and degradability**
Methods for the determination of biodegradability are not applicable to inorganic substances.
 - **12.3 Bioaccumulative potential**
The product is practically insoluble in water and not biodegradable.
 - **12.4 Mobility in soil**
No data
 - **12.5 Results of PBT and vPvB assessment**
According to Annex XIII of regulation (EC) 1907/2006 a PBT and vPvB assessment shall not be conducted for inorganic substances. Titanium Dioxide is an inorganic substance, thus a PBT and vPvB assessment is not required.
 - **12.6 Other adverse effects**
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13. DISPOSAL CONSIDERATIONS

- **13.1 Waste treatment methods**
Product: No hazardous waste according to European Directive 2000/532/EC. Place in an appropriate disposal facility in compliance with local and national regulations.

Contaminated packaging:	Containers that cannot be cleaned must be treated as waste and disposed of in an approved industrial incineration facility. The empty and clean containers may be reused in conformity with regulations.
Cleanser:	water

14. TRANSPORT INFORMATION

- **14.1 UN number**
The product is not classified as a hazardous material according to the ADR/RID, IMDG, IATA on the transport of dangerous or hazardous goods.
 - **14.2 UN proper shipping name**
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 - **14.3 Transport hazard class(es)**
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 - **14.4 Packing group**
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 - **14.5 Environmental hazards**
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 - **14.6 Special precautions for user**
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 - **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
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15. REGULATORY INFORMATION

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Inhalation of TiO₂ dust: In February 2006 IARC concluded, "There is inadequate evidence in humans for the carcinogenicity of titanium dioxide." Based on rat inhalation studies IARC concluded that there is, "sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide," IARC's overall evaluation was that, "Titanium dioxide is possibly carcinogenic to humans (Group 2B)".
This conclusion was based on IARC's guidelines which require such a classification if two or more independent studies in one species carried out of different times or in different laboratories or under different protocols show evidence of tumors .
 - **National Regulations**
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 - **15.2 Chemical safety assessment**
The substance has undergone a safety assessment.
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16. OTHER INFORMATION

- **Changes against last version**
Integration of Sachtleben Pigment GmbH site products.
 - **Hazard information which is referred to in section 2 or 3**
According to Regulation (EC) No 1272/2008:
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According to Directive (EC) 67/548/EWG:
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(2011-TI-001-EN)

The data given here are based on current knowledge and experience. The purpose of this Material Safety Data Sheet is to describe the product in terms of its safety requirements. The data do not signify any warranty with regard to the product's properties.

