

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

Name of the substance	Aminophyllin wfr.
Identification number	206-264-5 (EC number)
Registration number	-
Synonyms	None.
Material Number(s)	704152, 704161
Issue date	31-July-2016
Version number	01
Revision date	-
Supersedes date	-

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

Identified uses	Pharmaceutical agent.
Uses advised against	None known.

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

Company name	Siegfried PharmaChemikalien Minden GmbH
Address	Karlstrasse 15 32423 Minden Germany
Telephone	+49 571 391-0
e-mail	she@siegfried.ch

1.4 Emergency telephone number

+44 8 08 189 0979. Access Code: 334531.
For Chemical Emergency ONLY, call 3E at (+)1 760 476 3961. Access Code: 334531

General in EU	112 (Available 24 hours a day. SDS/Product information may not be available for the Emergency Service.)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended**Health hazards**

Acute toxicity, oral	Category 3	H301 - Toxic if swallowed.
Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 1	H318 - Causes serious eye damage.

Hazard summary

May form explosible dust-air mixture if dispersed. Toxic if swallowed. Causes serious eye damage. Causes skin irritation. Exposure to powder or dusts may be irritating to eyes, nose and throat. Dangerous for the environment if discharged into watercourses.

2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

Contains: Aminophylline

Hazard pictograms

Signal word: Danger

Hazard statements

H301: Toxic if swallowed.

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements

Prevention

P264 Wash thoroughly after handling.
P280 Wear protective gloves and eye/face protection.

Response

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

Storage

P405 Store locked up.

Disposal

Not available.

Supplemental label information None.

2.3. Other hazards May form explosible dust-air mixture if dispersed.

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Aminophylline	100	317-34-0 206-264-5	-	-	
Classification:	Acute Tox. 3;H301, Skin Irrit. 2;H315, Eye Dam. 1;H318				

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact Wash affected eyes for at least 15 minutes under running water with eyelids held open. Seek medical attention.
Ingestion Rinse mouth. Drink plenty of water. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Call a physician or poison control centre immediately.

4.2. Most important symptoms and effects, both acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dusts may irritate the respiratory tract, skin and eyes. Skin irritation. May cause redness and pain. Overexposure may cause: vomiting, cyanosis, death, anorexia, dehydration, restlessness, shock, nausea, fever.

4.3. Indication of any immediate medical attention and special treatment needed Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Firefighting measures

General fire hazards May form explosible dust-air mixture if dispersed. May form combustible dust concentrations in air.

5.1. Extinguishing media

Suitable extinguishing media Water spray. Alcohol-resistant foam. Dry chemical powder. Carbon dioxide (CO₂). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed such as: Toxic gases/vapors.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent product from entering drains. Stop the flow of material, if this is without risk.

Large Spills: Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

6.4. Reference to other sections

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Minimise dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Avoid dust formation. Do not get in eyes. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see section 10 of the SDS). Protect from light. Protect from moisture. Protect from temperatures above: 30 °C.

7.3. Specific end use(s)

Pharmaceutical agent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no effect levels (DNELs)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information	Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eyeface protection	Wear safety glasses with side shields (or goggles). (EN 166)
Skin protection	
- Hand protection	Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc.
- Other	Wear suitable protective clothing. Wash hands thoroughly after handling.
Respiratory protection	Breathing protection if breathable aerosols/dust are formed. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
Environmental exposure controls	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.
Colour	White to slight yellow.
Odour	Odourless.
Odour threshold	not determined
pH	9 (approximate)
Melting point/freezing point	270 - 274 °C (518 - 525.2 °F) (approximate)
Initial boiling point and boiling range	dropped
Flash point	not determined
Evaporation rate	Not available.
Flammability (solid, gas)	Not determined.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	not determined
Flammability limit - upper (%)	not determined
Explosive limit - lower (%)	not determined
Explosive limit – upper (%)	not determined

Vapour pressure	dropped
Vapour density	not determined
Relative density	Study does not need to be conducted.
Solubility(ies)	200 g/l (20 °C)
Partition coefficient (n-octanol/water)	-0.28
Auto-ignition temperature	> 610 °C (> 1130 °F)
Decomposition temperature	No decomposition if stored and handled as prescribed/indicated.
Viscosity	Not available.
Explosive properties	Product is not explosive, however a dust explosion could result from an air/dust mixture.
Oxidising properties	Not oxidising.

9.2. Other information

Bulk density	290 kg/m ³ (approximate)
Dust explosion properties	
Kst	>0 up to 200 bar m s ⁻¹

St class	1 Weak explosion.
Dynamic viscosity	Not relevant
Kinematic viscosity	Not relevant

Self ignition: not determined

Fire promoting properties: not fire-propagating

Flammability of Aerosol Products: not applicable, the product does not form flammable aerosols.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Dust may form explosive mixture with air.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimise dust generation and accumulation. Electrostatic Discharge. Eliminate all sources of ignition. Exposure to moisture. Light.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye damage.
Ingestion	Toxic if swallowed.

Symptoms Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dusts may irritate the respiratory tract, skin and eyes. Skin irritation. May cause redness and pain. Overexposure may cause: vomiting, cyanosis, death, anorexia, dehydration, restlessness, shock, nausea, fever.

11.1. Information on toxicological effects

Acute toxicity Toxic if swallowed.

Product	Species	Test results
Aminophylline (CAS 317-34-0)		
Acute		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg, (Internal testing)
<i>Inhalation</i>		
LC50	Rat	> 5.3 mg/l, 4 h, (OECD Guideline 403)
<i>Oral</i>		
LD50	Rat	247 mg/kg, (Internal testing)
<i>Other</i>		
LC50	Mouse	218 mg/kg, (calculated)
Skin corrosion/irritation	Causes skin irritation. Skin corrosion/irritation rabbit: Irritant. (Internal testing)	
Serious eye damage/eye irritation	Causes serious eye damage. Serious eye damage/irritation rabbit: irreversible damage (Draize test)	
Respiratory sensitisation	The chemical structure suggests a sensitizing effect.	
Skin sensitisation	The chemical structure suggests a sensitizing effect.	
Germ cell mutagenicity	The substance was not mutagenic in bacteria.	
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.	
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.	
Aspiration hazard	Not relevant, due to the form of the product.	

Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Harmful to aquatic life.

Product		Species	Test results
Aminophylline (CAS 317-34-0)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Scenedesmus subspicatus	> 100 mg/l, 72 h (growth rate)
Crustacea	EC50	Daphnia magna	> 10 < 100 mg/l, 48 h (static)
Fish	LC50	Leuciscus idus	> 100 < 220 mg/l, 96 h (DIN 38412 Part 15, static)
Other	EC20	Activated sludge	> 100 mg/l, 0.5 h (aerobic)
Other			
<i>Acute</i>			
Bacteria	EC10	Pseudomonas putida	0.93 mg/l, 17 h (DIN 38412 Part 8, aerobic)

12.2. Persistence and degradability Not readily biodegradable (by OECD criteria). Biodegradable. The product has not been tested. The statement has been derived from the properties of the individual components. Elimination information: > 60 % (28 d) (aerobic) Biodegradable.

12.3. Bioaccumulative potential The product is not expected to bioaccumulate.

**Partition coefficient
n-octanol/water (log Kow)**
-0.28

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Absorption to solid soil phase is not expected.

**12.5. Results of PBT
and vPvB
assessment** Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

12.7. Additional information The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN2811
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. (AMINOPHYLLINE)
14.3. Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Label(s)	6.1

Hazard No. (ADR)	60
Tunnel restriction code	E
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

RID

14.1. UN number	UN2811
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. (AMINOPHYLLINE)
14.3. Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Label(s)	6.1
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

ADN

14.1. UN number	UN2811
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. (AMINOPHYLLINE)
14.3. Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Label(s)	6.1
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

14.1. UN number	UN2811
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. (Aminophylline)
14.3. Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	No.
ERG Code	6L
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

14.1. UN number	UN2811
14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. (Aminophylline)
14.3. Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-A
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

EC50: Effective Concentration 50%.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
STEL: Short term exposure limit.
TWA: Time weighted average.

References

Not available.

Information on evaluation method leading to the classification of mixture

Not applicable.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.

Training information

Follow training instructions when handling this material.

Disclaimer

Siegfried PharmaChemikalien Minden GmbH cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.