

1. Product and company identification

Product identifier

Trade name: 85F1 - Plaster Parting Agent

This safety data sheet pertains to the following products:
85F1 = Gipstrennflüssigkeit

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

General use: Release agent for plaster and acryl for orthopedic procedures.
For commercial user only.

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Postal Code, city: Salt Lake City, UT 84120
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Department responsible for information:

Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

Additional information:

Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: liquid

Color: white

milky

Odor: No data available

Classification: Eye Irritation - Category 2A. Aquatic toxicity - chronic - Category 3.

Hazard symbols:



Signal word:

Warning

Hazard statements: Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

Precautionary statements: Wash hands and face thoroughly after handling.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 107-21-1	Ethenediol	1 - 3 %	Acute Toxicity - oral - Category 4. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
CAS 69011-36-5	Isotridecanol, ethoxylated	< 3 %	Acute Toxicity - oral - Category 4. Eye Damage - Category 1.
CAS 1314-13-2	Zinc oxide	< 2.5 %	Aquatic toxicity - acute - Category 1 (M-factor = 1). Aquatic toxicity - chronic - Category 1 (M-factor = 1).
CAS 1336-21-6	Ammonia, aqueous solution	< 1 %	Skin Corrosion - Category 1B. Eye Damage - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3. Aquatic toxicity - acute - Category 1 (M-factor = 1). Aquatic toxicity - chronic - Category 2.
CAS 2634-33-5	1,2-Benzisothiazol-3(2H)-one	< 0.005 %	Acute Toxicity - oral - Category 4. Skin Irritation - Category 2. Eye Damage - Category 1. Sensitization - skin - Category 1. Aquatic toxicity - acute - Category 1 (M-factor = 1). Aquatic toxicity - chronic - Category 2.
CAS 2682-20-4	2-Methyl-2H-isothiazol-3-one	< 0.0015 %	Acute Toxicity - oral - Category 3. Acute Toxicity - dermal - Category 3. Acute Toxicity - inhalative - Category 2. Skin Corrosion - Category 1B. Eye Damage - Category 1. Sensitization - skin - Category 1A. Aquatic toxicity - acute - Category 1 (M-factor = 10). Aquatic toxicity - chronic - Category 1 (M-factor = 1).

Additional information: Contains 2-(2-Ethoxyethoxy)ethanol: The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures

General information: If medical advice is needed, have product container or label at hand. Take off contaminated clothing and wash it before reuse.

In case of inhalation: Provide fresh air.
If the symptoms persist, seek medical attention.

Following skin contact: Immediately clean with water and soap followed by thorough rinsing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
Subsequently consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person.
Rinse mouth and drink large quantities of water.
Seek medical treatment in case of troubles.

Most important symptoms/effects, acute and delayed

Causes serious eye irritation. May cause allergic reactions in already sensitized persons.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range: No data available

Auto-ignition temperature: not self-igniting

Suitable extinguishing media: Water spray jet, alcohol resistant foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons: Full water jet

Specific hazards arising from the chemical

In case of fire may be liberated: carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Cool endangered containers with water spray and, if possible, remove from danger zone.
Suppress gases/vapors/mists with water spray jet.
Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions: Do not breathe mist/vapors/spray. If possible, eliminate leakage. Provide adequate ventilation.
Wear appropriate protective equipment. Keep unprotected people away. Take off contaminated clothing and wash it before reuse.

Environmental precautions:

Do not allow to enter into ground-water, surface water or drains.
If necessary, notify appropriate authorities.

Methods for clean-up:

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance. Final cleaning.

Additional information:

Special danger of slipping by leaking/spilling product.

7. Handling and storage

Handling

Advices on safe handling:

Provide adequate ventilation, and local exhaust as needed.
Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment.
When using do not eat, drink or smoke. Do not breathe mist/vapors/spray. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Storage

Requirements for storerooms and containers:

Keep container tightly closed. Keep only in the original container.
Protect from frost.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
107-21-1	Ethanediol	USA: ACGIH: STEL	10 mg/m ³ (inhalable fraction Aerosol)
		USA: ACGIH: STEL	50 ppm (vapor)
		USA: ACGIH: TWA	25 ppm (vapor)
1314-13-2	Zinc oxide	USA: ACGIH: STEL	10 mg/m ³ (respirable fraction)
		USA: ACGIH: TWA	2 mg/m ³ (respirable fraction)
		USA: IDLH: TWA	500 mg/m ³
		USA: NIOSH: Ceiling	15 mg/m ³ (Dusts)
		USA: NIOSH: STEL	10 mg/m ³ (Smoke)
		USA: NIOSH: TWA	5 mg/m ³ (Dusts)
		USA: NIOSH: TWA	5 mg/m ³ (Smoke)
		USA: OSHA: TWA	15 mg/m ³ (total dust)
		USA: OSHA: TWA	5 mg/m ³ (respirable fraction or Smoke)
7664-41-7	Ammonia, anhydrous	USA: ACGIH: STEL	24 mg/m ³ ; 35 ppm
		USA: ACGIH: TWA	17 mg/m ³ ; 25 ppm
		USA: NIOSH: STEL	27 mg/m ³ ; 35 ppm
		USA: NIOSH: TWA	18 mg/m ³ ; 25 ppm
		USA: OSHA: TWA	35 mg/m ³ ; 50 ppm

Engineering controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010

Skin protection: Wear suitable protective clothing.

Protective gloves according to OSHA Standard - 29 CFR: 1910.138

Glove material: nitrile rubber, butyl caoutchouc (butyl rubber)-Breakthrough time: > 480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Avoid contact with skin, eyes, and clothing. Take off immediately all contaminated clothing.

Do not breathe vapors. Wear appropriate protective equipment.

Have eye wash bottle or eye rinse ready at work place.

Keep away from food, drink and animal feedingstuffs.

Wash hands before breaks and after work. When using do not eat, drink or smoke.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Color: white milky
Odor:	No data available
Odor threshold:	No data available
pH:	approx. 8.0 (ISO 4316)
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 68 °F: 1.03 g/mL (OECD 109)
Water solubility:	Completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	No data available

Explosive properties: not explosive

Oxidizing characteristics: Not oxidising

10. Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:
No dangerous reactions are known.

Conditions to avoid: heating

Incompatible materials: No data available

Hazardous decomposition products:
No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

11. Toxicological information

Toxicological tests

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met.

ATEmix (calculated): > 2,000 mg/kg

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

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

Contains 2-Methyl-2H-isothiazol-3-one. May produce an allergic reaction.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Other information:

Information about 2-(2-Ethoxyethoxy)ethanol (CAS 111-90-0):

LD50 Rat, oral: 5,540 mg/kg

LD50 Rabbit, dermal: 5,940 mg/kg

LC0 Rat, inhalative (mist): > 5.24 mg/L/8h (OECD 403)

Information about Ethanediol (CAS 107-21-1):

LD50 Rat, oral: 7,712 mg/kg

LD50 Rabbit, dermal: > 2,000 mg/kg

LC50 Rat, inhalative (mist): > 2.5 mg/L/6h (no mortality occurred)

Information about Isotridecanol, ethoxylated (CAS 69011-36-5):

LD50 Rat, oral: 300 - 2,000 mg/kg (OECD 423)

LD50 Rabbit, dermal: > 2,000 mg/kg

Information about Zinc oxide (CAS 1314-13-2):

LD50 Rat, oral: > 5,000 mg/kg

Information about Ammonia, aqueous solution (CAS 1336-21-6):

LD50 Rat, oral: 350 mg/kg

LC50 Rat, inhalative: 7.035 mg/L/0.5 h

Information about 1,2-Benzisothiazol-3(2H)-one (CAS 2634-335):

LD50 Rat, oral: > 2,000 mg/kg

LD50 Rabbit, dermal: > 2,000 mg/kg (OECD 402)

Information about 2-Methyl-2H-isothiazol-3-one (CAS 2682-20-4):

LD50 Rat, oral: 120 mg/kg (OECD 401)

LD50 Rabbit, dermal: 242 mg/kg (OECD 402)

LC50 Rat, inhalative (mist): 0.11 mg/L/4h (OECD 403)

Symptoms

In case of inhalation: Mucous membrane irritation, cough.

In case of ingestion:

After intake of large amounts: nausea, vomiting, Diarrhea, CNS disorders.

After contact with skin: Mild irritant.

Ethylene glycol: Danger of cutaneous absorption.

12. Ecological information

Ecotoxicity

Aquatic toxicity:

Harmful to aquatic life with long lasting effects.

Information about Zinc oxide:

Fish toxicity:

LC50 Oncorhynchus mykiss: 1.1 mg/L/96h

Daphnia toxicity:

NOEC Daphnia magna (Big water flea): 0.4 mg/L/48h

Algae toxicity:

EC50 Desmodesmus subspicatus (green algae): 0.17 mg/L/72h

Information about Ammonia, aqueous solution:

Fish toxicity:

LC50 fish: 0.56 - 2.48 mg/L/96h

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): 1.1 - 22.8 mg/L

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation: Dispose of waste according to applicable legislation.

Package

Recommendation: Incinerate according to applicable local, state and federal regulations.
Non-contaminated packages may be recycled.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

Environmental hazards

Marine pollutant: no

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

No data available

USA: Department of Transportation (DOT)

Proper shipping name: Not restricted

Sea transport (IMDG)

Proper shipping name:: Not restricted

Marine pollutant: no

Air transport (IATA)

Proper shipping name:: Not restricted

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

2-(2-Ethoxyethoxy)ethanol:	<p>TSCA Inventory: listed</p> <p>Clean Air Act:</p> <p>CAA Hazardous Air Pollutants: yes</p> <p>CAA SOCM Chemical: yes</p>
Tris(2-Butoxyethyl) phosphate:	TSCA Inventory: listed
Ethenediol:	<p>TSCA Inventory: listed</p> <p>Clean Air Act:</p> <p>CAA Hazardous Air Pollutants: yes</p> <p>CAA SOCM Chemical: yes</p> <p>Other Environmental Laws:</p> <p>CERCLA: RQ 5000 lbs.</p> <p>SARA Title III - Section 313, Toxic Release: Conc. 1.0% / Threshold Standard</p> <p>NIOSH Recommendations:</p> <p>Occupational Health Guideline: 0272</p>
Isotridecanol, ethoxylated:	TSCA Inventory: listed; UVCB
Zinc oxide:	<p>TSCA Inventory: listed</p> <p>NIOSH Recommendations:</p> <p>Occupational Health Guideline: 0675*</p>
Ammonia, aqueous solution:	<p>TSCA Inventory: listed</p> <p>Clean Water Act:</p> <p>CWA Hazardous Substances: RQ 1000 lbs.</p> <p>Other Environmental Laws:</p> <p>CERCLA: RQ 1000 lbs.</p>
1,2-Benzisothiazol-3(2H)-one:	TSCA Inventory: listed
2-Methyl-2H-isothiazol-3-one:	TSCA Inventory: listed; EPA flags PMN; SP
Ammonia, anhydrous:	<p>TSCA Inventory: listed</p> <p>Clean Air Act:</p> <p>CAA Accidental Release Prevention: Threshold 20000 lbs. / Basis for listing = a,b</p> <p>Clean Water Act:</p> <p>CWA Hazardous Substances: RQ 100 lbs.</p> <p>Other Environmental Laws:</p> <p>CERCLA: RQ 100 lbs.</p> <p>SARA Title III, Section 302, EHS: TPQ 500 lbs. / RQ 100 lbs.</p> <p>SARA Title III - Section 313, Toxic Release: Conc. 1.0% / Threshold Standard</p> <p>NIOSH Recommendations:</p> <p>Occupational Health Guideline: 0028*</p> <p>OSHA Process Safety Management: Threshold 10000 lbs.</p>

National regulations - U.S. State Regulations

Ethanediol: California Proposition 65: developmental

Ammonia, anhydrous: California Proposition 65 code: not listed
 Delaware Air Quality Management List:
 DRQ: 50 - RQ State: State requirement differs from Federal
 Idaho Air Pollutant List:
 Title 585: AAC: 0.9 - EL: 1.2 - OEL: 18 - Title 586: -
 Maine Hazardous Air Pollutants:
 Me 2005: CAP / HAP - Hap Rpt: 2000
 Massachusetts Haz. Substance codes: 2,4,5,6 *E* F6 F8 F9
 Minnesota Haz. Substance:
 Codes: ANOS - Ratings: 9.39 - Status: Title III. TRI.
 New Jersey Extraordinarily Hazardous Substances:
 EPA Threshold: 10000 - NJ Treshold: 5200
 NJ Group: II - NJ Table: I Part A - NJ Basis: Not on List
 New Jersey RTK Hazardous Substance:
 DOT: 1005 - Sub No.: 0084 - TPQ: -- EHS: Yes
 New York List of Hazardous Substances:
 RQ-Air: 100 - RQ-Land: 100 - Note: No Note Associated with this chemical.
 Pennsylvania Haz. Substance code: E
 Washington Air Contaminant:
 TWA: 25 ppm - 18 mg - STEL: 35 ppm - 27 mg

16. Other information

Text for labeling:

Contains 1 - 3 % Ethanediol, < 3 % Isotridecanol, ethoxylated, < 2.5 % Zinc oxide, < 1 % Ammonia, aqueous solution, < 0.005 % 1,2-Benzisothiazol-3(2H)-one, < 0.0015 % 2-Methyl-2H-isothiazol-3-one.

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)
 Fire: 1 (Slight)
 Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)
 Flammability: 1 (Slight)
 Physical Hazard: 0 (Minimal)
 Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 Aquatic toxicity - acute: Hazardous to the aquatic environment - acute
 Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
 AS/NZS: Australian Standards/New Zealand Standards
 ATEmix: Acute Toxicity Estimate of mixture
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 CNS: Central Nervous System
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 EC: European Community
 EC50: Effective Concentration 50%
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 Eye Damage: Eye damage
 Eye Irritation: Eye irritation
 IATA: International Air Transport Association
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
 IMDG Code: International Maritime Dangerous Goods Code
 IMO: International Maritime Organization
 LC0: Lethal concentration 0%
 LC50: Median lethal concentration
 LD50: Lethal dose 50%
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 M-factor: Multiplication factor
 NOEC: No Observed Effect Concentration
 OECD: Organisation for Economic Co-operation and Development
 OEL: Occupational Exposure Limit Value
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Sensitization - skin: Skin sensitisation
 Skin Corrosion: Skin corrosion
 Skin Irritation: Skin irritation
 STOT RE: Specific target organ toxicity - repeated exposure
 STOT SE: Specific target organ toxicity - single exposure
 TLV: Threshold Limit Value
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit

Reason of change: Changes in section 2: Labeling
 Changes in section 3: Composition/information on ingredients
 General revision

Date of first version: 8/25/2011

Department issuing data sheet

Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.