

1. Product and company identification

Product identifier

Trade name: 636K9 - Fast Curing Putty-Akemi

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

General use: Filling compound 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
 Dept. responsible for information:
 Quality Department,
 Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time), Email:
 USRegulatory@ottobock.com

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: Form: liquid, viscous; viscous liquid
 Color: light yellow
 Odor: characteristic
 Classification: Flammable Liquid - Category 3; Skin Irritation - Category 2; Eye Irritation - Category 2A; Reproductive toxicant - Category 2; Specific Target Organ Toxicity (Repeated Exposure) - Category 1; Aquatic toxicity - chronic - Category 3;

Hazard symbols:



Signal word:

Danger

Hazard statements:

Flammable liquid and vapor.
 Causes skin irritation.
 Causes serious eye irritation.
 Suspected of damaging the unborn child.
 Causes damage to organs through prolonged or repeated exposure.
 Harmful to aquatic life with long lasting effects.

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Precautionary statements:

Obtain special instructions before use.
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Store in a well-ventilated place. Keep container tightly closed.

Regulatory status

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

Hazards not otherwise classified

May be harmful if inhaled. Inhaling can lead to irritations of the respiratory tract and mucous membrane.
 The vapors are heavier than air and can accumulate in high concentrations on the ground, in cavities, channels and cellars. Potentially explosive mixtures may form if adequate ventilation is not provided.
 see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Filling compound on the basis of unsaturated polyester resins dissolved in styrene. Without hardener component.

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 100-42-5	Styrene	12.5 - 25 %	Flammable Liquid - Category 3. Acute Toxicity - inhalative - Category 4. Skin Irritation - Category 2. Eye Irritation - Category 2A. Reproductive toxicant - Category 2. Specific Target Organ Toxicity (Repeated Exposure) - Category 1.
CAS 7779-90-0	Zinc phosphate	1 - 5 %	Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.
CAS 1314-13-2	Zinc oxide	< 1 %	Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.

4. First aid measures

General information: Take off immediately all contaminated clothing.
 If victim is at risk of losing consciousness, position and transport on their side.

In case of inhalation: Move victim to fresh air, provide oxygen as needed.
 In case of irregular breathing or respiratory arrest provide artificial respiration.
 Do not allow victim to become chilled. Keep victim warm. Keep airway open. Consult physician.

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- Following skin contact: Immediately clean with water and soap and, if available, apply a generous amount of polyethylene glycol 400.
Seek medical treatment in case of troubles.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult physician.
- After swallowing: Do not induce vomiting. Rinse mouth with water. Immediately get medical attention.
Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

Irritant. Causes damage to organs through prolonged or repeated exposure.
Suspected of damaging the unborn child.
In case of inhalation/After resorption: central nervous system depression.
Symptoms: shortage of breath, drowsiness, headache, dizziness, fatigue, unconsciousness.
Reaction time and coordination may be impaired.
If higher concentrations occur: Pulmonary edema is possible.
Other symptoms: nausea, Sweating, Mucous membrane irritation, cough, vomiting.
Symptoms may occur with delay.

Information to physician

In case of swallowing, gastric irrigation with activated carbon as an additive.
Symptoms of poisoning can only emerge after several hours; medical supervision is therefore essential for at least 48 hours.
Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

89.6 °F

Auto-ignition temperature: not self-igniting

Suitable extinguishing media:

Water fog, alcohol resistant foam, dry chemical powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

High power water jet

Specific hazards arising from the chemical

Flammable liquid and vapor. The vapors are heavier than air and can accumulate in high concentrations on the ground, in cavities, channels and cellars. Potentially explosive vapor/air mixtures may form. Toxic gases may form.
In case of fire may be liberated: phosphorus compounds, Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information:

Do not expose to high temperature. Danger of bursting and explosion. Cool exposed containers with water spray.
Move undamaged containers from immediate hazard area if it can be done safely.
In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.
Do not allow fire water to penetrate into surface or ground water.
Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

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6. Accidental release measures

- Personal precautions:** Eliminate all ignition sources if safe to do so. Provide adequate ventilation. Do not breathe vapors. Use a breathing protection against vapors/aerosol. Avoid contact with the substance. Wear protective equipment. Keep unprotected people away. Use a breathing protection against vapors/aerosol.
- Environmental precautions:** Do not allow to enter drains, surface waters, basements or pits. Danger of explosion! Prevent environmental discharge consistent with regulatory requirements.
- Methods for clean-up:** Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13).
Beware of reignition. Thoroughly clean surrounding area.
In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).
- Additional information:** Take precautionary measures against static discharges. Use only non-sparking tools.
Large amounts: Explosion protection required.
Concentrated vapors are heavier than air.

7. Handling and storage**Handling**

- Advices on safe handling:** Provide good ventilation and/or an exhaust system in the work area. Do not breathe vapors. Avoid contact with skin and eyes.
Wear protective equipment. When using do not eat, drink or smoke. Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.
- Precautions against fire and explosion:**
Keep away from sources of ignition. - No smoking.
Take precautionary measures against static discharges.
The vapors are heavier than air and can accumulate in high concentrations on the ground, in cavities, channels and cellars.
Use only non-sparking tools.
In partially filled containers explosive mixtures may form.

Storage

- Requirements for storerooms and containers:**
Keep only in the original container. Keep in a cool, well-ventilated place. Keep container tightly closed and dry.
Do not drop, drag or bang the container. Store containers in upright position. Do not allow the product to enter the ground.
Protect from heat and direct sunlight. Protect from frost.
- Hints on joint storage:** Do not store together with combustible or self-igniting materials or any highly flammable solids.
Do not store together with alkalis or acids.
keep away from oxidizing agents.
Do not store together with organic peroxides.
Avoid contact with radical former.
Keep away from food and drinks.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
100-42-5	Styrene	OSHA: Ceiling	200 ppm
		USA: ACGIH: STEL	170 mg/m ³ ; 40 ppm
		USA: ACGIH: TWA	85 mg/m ³ ; 20 ppm
		USA: NIOSH: STEL	425 mg/m ³ ; 100 ppm
		USA: NIOSH: TWA	215 mg/m ³ ; 50 ppm
		USA: OSHA: TWA	100 ppm
1314-13-2	Zinc oxide	NIOSH: Ceiling	15 mg/m ³
		USA: ACGIH: STEL	10 mg/m ³
		USA: ACGIH: TWA	2 mg/m ³
		USA: NIOSH: STEL	10 mg/m ³
		USA: NIOSH: TWA	5 mg/m ³
		USA: OSHA: TWA	15 mg/m ³
		USA: OSHA: TWA	5 mg/m ³

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
100-42-5	Styrene	USA: ACGIH-BE1, blood	0.2 mg/L	Styrene in venous blood	end of exposure or end of shift
		USA: ACGIH-BE1, urine	400 mg/g creatinine	Mandelic acid + Phenylglyoxylic acid	end of exposure or end of shift

Engineering controls

Provide good ventilation and/or an exhaust system in the work area.

Keep away from sources of ignition. - No smoking.

Take precautionary measures against static discharges.

Large amounts: Explosion protection required.

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 according to.
- Skin protection: Flame retardant, antistatic and chemical resistant protective clothing.
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: Fluororubber (Viton)
Breakthrough time: >480 min.
Unsuitable materials: nitrile rubber, neoprene.
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.
identification color brown.

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General hygiene considerations:

Use only non-sparking tools. Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Do not breathe vapors. Avoid contact with skin, eyes, and clothing. When using do not eat, drink or smoke. Take off immediately all contaminated clothing. Wash hands before breaks and after work. Safety shower and eye wash station should be easily accessible to the work area. Keep away from food, drink and animal feedingstuffs. When using do not eat, drink or smoke.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid, viscous; viscous liquid Color: light yellow
Odor:	characteristic
Odor threshold:	no data available
pH value:	not determined
Melting point/freezing point:	not determined
Initial boiling point and boiling range:	293 °F
Flash point/flash point range:	89.6 °F
Evaporation rate:	no data available
Flammability:	Flammable liquid and vapor.
Explosion limits:	LEL (Lower Explosion Limit): 1.20 Vol-% UEL (Upper Explosive Limit): 8.90 Vol-%
Vapor pressure:	at 68 °F: 6 hPa
Vapor density:	no data available
Density:	at 68 °F: 1.84 g/mL
Water solubility:	insoluble/slightly miscible
Partition coefficient: n-octanol/water:	not determined
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	Decomposition temperature: not determined
Viscosity, dynamic:	not determined
Viscosity, kinematic:	not determined
Explosive properties:	Product is not explosive. Potentially explosive vapor/air mixtures may form.
Ignition temperature:	896 °F
Solvent content:	14 %
Additional information:	Vapor density: not determined

10. Stability and reactivity

Reactivity:	Flammable liquid and vapor.
Chemical stability:	Stable under recommended storage conditions.

Possibility of hazardous reactions

Do not expose to high temperature. Danger of bursting and explosion.
 Potentially explosive vapor/air mixtures may form.
 Polymerization along with heat production.

Conditions to avoid:

Keep away from heat sources, sparks and open flames.
 Protect against direct sunlight.

Incompatible materials:

Reacts with peroxides and radical former.
 Reacts with acids, alkalis, oxidizing agents.

Hazardous decomposition products:

In case of fire may be liberated: phosphorus compounds, Carbon monoxide and carbon dioxide. Toxic gases may form.

Thermal decomposition:

Decomposition temperature: not determined

11. Toxicological information

Toxicological tests

Acute toxicity:

LD50 Rat, oral (Styrene):	> 5000 mg/kg
LD50 Rat, dermal (Styrene):	> 2000 mg/kg
LC50 Rat, inhalative (Styrene):	11.8 mg/L/ 4h
LC50 Mouse, inhalative (Styrene):	9.5 mg/m ³ /4 h
LD50 Rat, oral (Trizinkbis(orthophosphat):	> 5000 mg/kg
LD50 Rat, oral (Zinc oxide):	> 6000 mg/kg

Toxicological effects:

Acute toxicity (oral): Based on available data, the classification criteria are not met.
 Acute toxicity (dermal): Based on available data, the classification criteria are not met.
 Acute toxicity (inhalative): Based on available data, the classification criteria are not met.
 Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.
 Eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.
 Sensitisation to the respiratory tract: Lack of data.
 Skin sensitisation: Lack of data.
 Germ cell mutagenicity/Genotoxicity: Lack of data.
 Carcinogenicity: Lack of data.
 Reproductive toxicity: Reproductive toxicant -
 Category 2 = Suspected of damaging the unborn child.
 Effects on or via lactation: Lack of data.
 Specific target organ toxicity (single exposure): Lack of data.
 Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) -
 Category 1 = Causes damage to organs through prolonged or repeated exposure.
 Aspiration hazard: Lack of data.

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Other information: The product has not been tested. The statement is derived from the properties of the single components.

Styrene:
 Affects the central nervous system, possible disturbances from: 50 mL/m³.
 DFG 2010 (Germany): Substance with a carcinogenic and genotoxic effect from which there is not to be expected an important contribution to the risk of cancer for persons as far as the AGW-value (German WEL) is observed. Classified according to IARC: 2B (possible for humans).
 Harmful: danger of serious damage to health by prolonged exposure through inhalation. Chronic uptake results in damage of: nervous system, lung.

Symptoms

In case of inhalation: central nervous system depression.
 Symptoms: shortage of breath, drowsiness, headache, dizziness, fatigue, unconsciousness.
 Reaction time and coordination may be impaired.
 If higher concentrations occur: Pulmonary edema is possible.
 Other symptoms: nausea, Sweating, Mucous membrane irritation, cough, vomiting.
 Symptoms may occur with delay.
 In case of ingestion: If swallowed or in the event of vomiting, risk of entering the lungs.

General remarks

Polyester resin: May produce an allergic reaction.

12. Ecological information

Ecotoxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.

Information about Zinc phosphate:
 Algae toxicity:
 EC50 Desmodesmus subspicatus (green algae): 0.14 mg/L/72h.
 Daphnia toxicity:
 EC50 Daphnia magna (Big water flea): 0.04-0.86 mg/L/48h.
 Fish toxicity:
 LC50 Oncorhynchus mykiss: 0.14 - 2.6 mg/L/48h.

Information about Zinc oxide:
 Algae toxicity:
 EC50 Selenastrum capricornutum: 0.14 - 0.17 mg/L/72h.
 Daphnia toxicity:
 EC50 Daphnia magna (Big water flea) : > 1000 mg/L/48h.
 Fish toxicity:
 LC50 Oncorhynchus mykiss: 1.1 mg/L/96h.

Information about Styrene:
 Does not dissolve in water. Floats on water surface.

Mobility in soil

no data available

Persistence and degradability

Analytical method: BSD
 Degree of elimination: Styrene >= 60%
 Evaluation text: Product is highly biodegradable.
 Further details: Information about Styrene:
 Biodegradation: 71 %/ 28 d. Product is readily biodegradable.
 Does not dissolve in water. Floats on water surface.

Additional ecological information

Volatile organic compounds (VOC):
 13.5 % by weight = 248.7 g/L
 General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.
 Do not dispose of with household waste.

Contaminated packaging

Recommendation: Handle empty containers with care. Incineration may cause explosion. Dispose of waste according to applicable legislation.
 Non-contaminated packages may be recycled.

Additional information

Do not empty into drains.

14. Transport information

USA: Department of Transportation (DOT)

Identification numbers: UN3269
 Proper shipping name: UN 3269, POLYESTER RESIN KIT
 DOT hazard class or division: 3
 Label codes: 3
 Special provisions: 40, 149
 Packaging - Exceptions: 165
 Packaging - Non-bulk: 165
 Packaging - Bulk: None
 Quantity limitations - Passenger aircraft / rail:
 5 kg
 Quantity limitations - Cargo only: 5 kg
 Vessel stowage - Location: B



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Sea transport (IMDG)

UN number: UN 3269
Proper shipping name: UN 3269, POLYESTER RESIN KIT
IMDG: Class 3, Subrisk -
Packing Group: III
EmS: F-E, S-D
Special provisions: 236, 340
Limited quantities: 5 L
EQ: SP340
Contaminated packaging - Instructions: P302
Contaminated packaging - Provisions: -
IBC - Instructions: -
IBC - Provisions: -
Tank instructions - IMO: -
Tank instructions - UN: -
Tank instructions - Provisions: -
Stowage and handling: Category A.
Properties and observations: Polyester resin kits consists of two components: a base material (flammable liquid, packaging group II) and an activator (organic peroxide), each separately packed in an inner packaging.
Marine pollutant: no
Segregation group: none

Air transport (IATA)

UN/ID number: UN 3269
Proper shipping name: UN 3269, POLYESTER RESIN KIT
ICAO/IATA: Class 3
PG: III
Hazard: Flamm. liquid
EQ: E0
Passenger Ltd.Qty.: Pack.Instr. Y370 - Max. Net Qty/Pkg. 5 kg
Passenger: Pack.Instr. 370 - Max. Net Qty/Pkg. 10 kg
Cargo: Pack.Instr. 370 - Max. Net Qty/Pkg. 10 kg
Special Provisioning: A163
ERG: 3L

15. Regulatory information

National regulations - U.S. Federal Regulations

Styrene: TSCA Inventory: listed
 TSCA HPVC: not listed
 Carcinogen Status:
 IARC Rating: Group 2B
 OSHA Carcinogen: not listed
 NTP Rating: listed
 Clean Air Act:
 Hazardous Air Pollutants: Code XOY
 SOCM Chemical: yes
 Clean Water Act:
 Hazardous Substances: RQ 1000 lbs.
 Other Environmental Laws:
 CERCLA: RQ 1000 lbs.
 RCRA Groundwater Monitoring: Methods 8020, 8240 / PQL 1, 5
 SARA Title III Section 313, Toxic Release: Conc. 0.1% / Threshold Standard
 NIOSH Recommendations:
 Occupational Health Guideline: 0571

Zinc phosphate: TSCA Inventory: listed
 TSCA HPVC: not listed

Zinc oxide: TSCA Inventory: listed
 TSCA HPVC: not listed
 NIOSH Recommendations:
 Occupational Health Guideline: 0675*

National regulations - U.S. State Regulations

Styrene: Delaware Air Quality Management List:
 DRQ: 1000 - RQ State: Federal Regulations Apply
 Idaho Air Pollutant List:
 Title 585 -- AAC: 1 -- EL: 6.67 -- WEL: - Title 586 -
 Maine Hazardous Air Pollutants:
 Me 2005: HAP - Hap Rpt: 2000
 Massachusetts Haz. Substance codes: 1,2,4,5,6,9 *E*C* F7 F8
 Michigan Critical Material:
 Note: 2 - CMR#: 27 - Parameter#: 00100-42-5 -
 Annual Usage Parameter: 100
 Minnesota Haz. Substance:
 Codes: ANO -- Ratings: 9.63 -- Status: Air Pollutant. Carcinogen. Title III.
 TRI.
 New Jersey RTK Hazardous Substance:
 DOT 2055 - Sub No.: 1748 - TPQ: -
 New York List of Hazardous Substances:
 RQ -- Air: 1000 - RQ -- Land: 1 - Note: No Note Associated with this
 chemical.
 Pennsylvania Haz. Substance code: E
 Washington Air Contaminant:
 TWA: 50 ppm / 215 mg -- STEL: 100 ppm / 425 mg

National regulations - Great Britain

Hazchem-Code: •2YE

16. Other information

Text for labeling: Contains 12.5 - 25 % Styrene, 1 - 5 % Zinc phosphate, < 1 % Zinc oxide. Safety data sheet available on request.

Hazard rating systems: NFPA Hazard Rating:
 Health: 2 (Moderate)
 Fire: 2 (Moderate)
 Reactivity: 0 (Minimal)



HMIS Version III Rating:
 Health: 2 (Moderate) - Chronic effects
 Flammability: 2 (Moderate)
 Physical Hazard: 0 (Minimal)
 Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		2
PHYSICAL HAZARD		0
		X

Reason of change: Changes in section 1: Address

Date of first version: 10/26/1994

Department issuing data sheet

Contact person: see section 1: Dept. 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.