



SAFETY DATA SHEET

1. Identification

Product identifier	Forteo®	
Other means of identification		
Item Code	AM0355, VL7591, MS9513, VL7590, MS8972, MS8971, VL7641, B02464, MS8400, CT8400, MS9678	
Recommended use	Pharmaceutical	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	Eli Lilly and Company	
Address	Lilly Corporate Center Indianapolis, IN 46285 United States	
Telephone	Phone:	+1-317-276-2000
E-mail	lilly_msds@lilly.com	
Emergency phone number	CHEMTREC:	+1-800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	
H361	Suspected of damaging the unborn child.
Precautionary statement	
Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P281	Use personal protective equipment as required.
Response	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
Storage	Not assigned.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Teriparatide	Phenylalanine,L-seryl-L-valyl-L-seryl-L-alpha-glutamyl-L-isoleucyl-L-glutamyl-L-leucyl-L-methionyl-L-histidyl-L-asparagyl-L-leucylglycyl-L-lysyl-L-histidyl-L-leucyl-L-asparagyl-L-seryl-L-methionyl-L-alphaglutamyl-L-arginyl-L-valyl-L-alpha-glutamyl-L-tryptophyl-L-leucyl-L-arginyl-L-lysyl-L-lysyl-Lleucyl-L-glutamyl-L-alpha-aspartyl-L-valyl-L-histidyl-L-asparagyl-LY333334 PTH(1-34) PARATHYROID HORMONE(1-34) Polypeptide hormone	52232-67-4	0.025 - 0.05
Composition comments	Product contains 0.3% m-cresol. Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.		
4. First-aid measures			
Inhalation	Call a physician if symptoms develop or persist.		
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.		
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.		
Ingestion	Get medical attention if symptoms occur.		
Most important symptoms/effects, acute and delayed	Headache. Dizziness. May cause reproductive effects. Effects of exposure may include: Hyperparathyroidism, malignancy associated with hypercalcemia, vitamin D intoxication. Lowered blood pressure.		
Indication of immediate medical attention and special treatment needed	There is no specific antidote for teriparatide. Treatment of suspected overdose should include discontinuation of teriparatide, monitoring of serum calcium and phosphorus, and implementation of appropriate supportive measures such as hydration.		
5. Fire-fighting measures			
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.		
Unsuitable extinguishing media	None known.		
Specific hazards arising from the chemical	This product is an aqueous mixture which will not burn.		
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.		
6. Accidental release measures			
Personal precautions, protective equipment and emergency procedures	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.		
Methods and materials for containment and cleaning up	Prevent runoff from entering drains, sewers, or streams. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum. See Section 8 of the SDS for Personal Protective Equipment.		
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.		
7. Handling and storage			
Precautions for safe handling	Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. Avoid release to the environment.		
Conditions for safe storage, including any incompatibilities	Keep refrigerated. Storage temperature: between 2 and 8 C. Do not allow material to freeze.		
8. Exposure controls/personal protection			
Occupational exposure limits			
Lilly (LEG) Components	Type	Value	Form
Teriparatide (CAS 52232-67-4)	STEG (15min)	50 ug/m3	(Respirable dust)
	TWA (12hrs)	9 ug/m3	(Respirable dust)

Lilly (LEG) Components	Type	Value	Form
	TWA (8hrs)	9 ug/m3	(Respirable dust)
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Exposure guidelines			
US - Tennessee OELs: Skin designation			
m-Cresol (CAS 108-39-4)	Can be absorbed through the skin.		
Appropriate engineering controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Wear goggles/face shield.		
Skin protection			
Hand protection	Chemical resistant gloves.		
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.		
Respiratory protection	Use an approved respirator. Select respirator with appropriate protection factor. Select appropriate respirator for physical characteristics of material.		
Thermal hazards	Not available.		
General hygiene considerations	Teriparatide is an active pharmaceutical ingredient with a therapeutic dose in humans at or below 1 mg/day.		

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Color	Colorless
Odor	Phenolic.
Odor threshold	No data available.
pH	3.5 - 4.5
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.

Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive.
Oxidizing properties	No oxidizing properties.
Percent volatile	No data available.
VOC (Weight %)	No data available.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None under normal conditions.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity	Not expected to be active orally.
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Components	Species	Test Results
Teriparatide (CAS 52232-67-4)		
<u>Acute</u>		
Inhalation		
LC	Monkey	> 32 mg/m ³ , 15 min (No mortality)
Other		
LD	Rat	> 1000 µg/m ³ ,Subcutaneous > 300 µg/m ³ Intravenous

Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Monkey: No irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.

Germ cell mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Negative Based on available data, the classification criteria are not met.
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Carcinogenicity	In a carcinogenicity study in rats, an increased incidence of osteosarcoma (malignant bone tumor) was observed in animals given daily subcutaneous injections of 5, 30, or 75 micrograms/kg/day. The relevance of these findings to humans is uncertain. Did not produce bone tumors in ovariectomized monkeys treated daily for 18 months. Based on available data, the classification criteria are not met.
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IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity	No effect on fertility in male or female rats at subcutaneous doses up to 300 micrograms/kg. No teratogenic effects in rats, mice or rabbits, and no important adverse embryo/fetal development effects seen in rats or mice administered subcutaneous doses up to 1000 micrograms/kg. In rabbits, decreased embryo/fetal survival was reported at doses greater than or equal to 3 micrograms/kg. Mild growth retardation was reported in the offspring of rats administered 225 micrograms/kg.
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Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Blood effects (increased serum calcium, decreased white blood cell counts), circulatory effects (decreased blood pressure, vasodilation in extremities), kidney effects (tissue changes, mineralization), bone effects (increased bone formation).
Aspiration hazard	Not applicable.
Further information	Highly potent based on therapeutic dose which can be achieved by inhalation exposure. Effects of overexposure may include headaches, dizziness, decreased blood pressure, decreased fetal survival, leg cramps, changes in clinical chemistry including increases in blood levels of calcium, decreased serum phosphorous, and increased urinary calcium and phosphorus.

12. Ecological information

Ecotoxicity	Due to lack of data the classification is not possible.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available on bioaccumulation.
Mobility in soil	No data available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations.
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14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

m-Cresol (CAS 108-39-4) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

m-Cresol (CAS 108-39-4)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

m-Cresol (CAS 108-39-4)

US. Massachusetts RTK - Substance List

m-Cresol (CAS 108-39-4)

US. New Jersey Worker and Community Right-to-Know Act

m-Cresol (CAS 108-39-4)

US. Pennsylvania Worker and Community Right-to-Know Law

m-Cresol (CAS 108-39-4)

US. Rhode Island RTK

m-Cresol (CAS 108-39-4)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer. (Teriparatide)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 11-21-2014**Revision date** 09-14-2015**Version #** 06**Lilly Lab Code** Health: 0
Fire: 0
Reactivity: 0**List of abbreviations**LEG: Lilly Exposure Guideline
STEG: Short Term Exposure Guideline
TWA: Time Weighted Average**Disclaimer**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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Revision Information Physical & Chemical Properties: Multiple Properties