MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Lasofoxifene Film-Coated Tablets 0.25 and 0.5 mg

Trade Name: Not determined
Chemical Family: Not determined
Intended Use: osteoporosis

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Silicon dioxide, NF	7631-86-9	231-545-4	*
Opadry orange	NOT ASSIGNED	Not listed	*
Croscarmellose sodium	74811-65-7	Not listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*
Lasofoxifene; CP-336,156-CB	190791-29-8	Not listed	<1.0

Ingredient	CAS Number	EU EINECS List	%
Lactose NF, anhydrous	63-42-3	200-559-2	*
Opadry clear	NOT ASSIGNED	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Triangular or standard round convex, peach film-coated tablets
Signal Word: Not applicable

Statement of Hazard: Not applicable
Eye Contact: Dust may cause irritation (based on components).
Skin Contact: Not a skin irritant (based on animal data). Not a skin sensitizer (based on animal data).
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
Known Clinical Effects: The most common adverse effects reported with the clinical use of this drug include headache, dizziness, vasodilation, leg cramps, and leukorrhea.

Potential Health Effects:	Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use. Adverse reproductive effects seen in repeat-dose animal studies are consistent with the pharmacologic action of this drug and are expected to be relevant to humans.
EU Indication of danger:	Substance toxic to reproduction: Category 2 Dangerous for the Environment
EU Hazard Symbols:	
	R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R60 - May impair fertility.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use water, carbon dioxide, foam or dry chemical extinguishers.
Hazardous Combustion Products:	No data available
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust.
Additional Information:	Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store out of direct sunlight in a cool, well ventilated, dry area.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	15 mg/m³ total dust 5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Lasofoxifene; CP-336,156-CB

Pfizer OEL TWA-8 Hr:	0.3 ug/m^3

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Lasofoxifene: CAM-KAS-98-05; CAM-KAS-98-17; STP C 187.21 (contact Pfizer for additional details)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands:	Rubber gloves
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	**Color:**	Peach
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: None known

Hazardous Decomposition Products: None known
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient. The primary hazard of this material is associated with its pharmacological action as an estrogen agonist/antagonist.

Carcinogenicity: Not listed as a carcinogen by IARC, NTP or US OSHA.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Silicon dioxide, NF
Rat Oral LD50 10 g/kg

Lasofoxifene; CP-336,156-CB
Rat Oral LDmin. > 2000 mg/kg
Mouse Oral LDmin. 1000 mg/kg
Rat IV LDmin. > 100 mg/kg
Mouse IV LDmin. 300 mg/kg

Inhalation Acute Toxicity No data available
Ingestion Acute Toxicity See Acute toxicity table.

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Lasofoxifene; CP-336,156-CB
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild
Skin Sensitization - GPMT Guinea Pig Negative

Lasofoxifene; CP-336,156-CB
3 Month(s) Rat Oral 1 mg/kg/day LOAEL Male reproductive system, Female reproductive system, Liver
3 Month(s) Monkey Oral 1 mg/kg/day LOAEL Cardiovascular system, Central Nervous System
12 Month(s) Rat Oral 1 mg/kg/day LOAEL Female reproductive system, Cardiovascular system, Liver
12 Month(s) Monkey Oral 1 mg/kg/day LOAEL Female reproductive system, Cardiovascular system, Liver

Subchronic Effects Repeated oral administration of doses up to 15 mg/kg/day to rats and monkeys for up to one year produced reproductive tract (ovaries, uterus) effects consistent with pharmacologic activity at all doses tested. In addition, treatment-related changes were noted in the neuromuscular (tremors) and cardiovascular systems (decreased heart rate and blood pressure, prolonged EKG QT interval) in monkeys, and slight liver enzyme elevation was seen in rats. The NOAEL for these effects was 1 mg/kg/day.

Chronic Effects/Carcinogenicity Two-year studies in rats and mice demonstrated increased tumor incidence in ovaries, adrenal glands, testes, and the kidneys, as well as decreased incidence in mammary glands and the pituitary. These effects were attributed to rodent-specific hormonal mechanisms.

Lasofoxifene; CP-336,156-CB

Fertility & Early Embryonic Development - Males Rat Oral 10 mg/kg/day LOAEL Fertility
Fertility & Early Embryonic Development-Females Rat Oral 0.1 mg/kg/day LOAEL Fertility
Fertility & Early Embryonic Development-Females Rat Oral 0.01 mg/kg/day LOAEL Fertility
Embryo / Fetal Development Rat Oral 1 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rat Oral 0.1 mg/kg/day LOAEL Maternal Toxicity

Reproductive Effects Effects consistent with pharmacological action (altered estrous cycle in females, decreased epididymal, prostate and seminal vesicle weights in males) were seen at doses of 0.1 mg/kg and above. On mating, corresponding decreases in implantations and live fetuses were also observed.

Teratogenicity Not teratogenic in rats or rabbits up to maternally toxic doses. Reproductive system Cardiovascular system Eyes

Lasofoxifene; CP-336,156-CB
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
In Vivo Micronucleus Mouse Negative
In Vitro Micronucleus Human Lymphocytes Negative

Mutagenicity Although at very high concentrations, some clastogenic activity was seen in vitro, overall in vitro and in vivo results were negative.

Lasofoxifene; CP-336,156-CB
2 Year(s) Mouse Oral 2 mg/kg/day LOAEL Tumors, Reproductive System, Adrenal gland
2 Year(s) Rat Oral 1 mg/kg/day LOAEL Tumors, Reproductive System, Kidneys

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Silicon dioxide, NF
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to moderately partition to soils and sediments and slowly biodegrade. While no reproductive ecotoxicity data have been developed, it is anticipated to have effects consistent with its pharmacological action. Harmful to aquatic organisms

Mobility, Persistence and Degradability: The active ingredient in this formulation is expected to partition between soil, sediment and water compartments and to have low-moderate mobility. It is anticipated that it will slowly degrade via biodegradation and photolysis mechanisms.

Bioaccumulation and Toxicity: This substance is not expected to bioaccumulate in the environment. While no reproductive ecotoxicity data have been developed, it is anticipated to have effects consistent with its pharmacological action. Acute toxicity to aquatic organisms could occur. See aquatic toxicity data, below.

Lasofoxifene; CP-336,156-CB
Daphnia magna LC50/48h 2.92 mg/L
Mysid Shrimp LC50/48h 0.79 mg/L
Sheepshead Minnow LC50/48h 1.9 mg/L
Red Algae LC50/7 day 0.15 mg/L
Polytox MIC 2.3 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Substance toxic to reproduction: Category 2 Dangerous for the Environment

EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 - May impair fertility.

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
Not applicable
Not applicable

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Silicon dioxide, NF

EU EINECS List	231-545-4
Inventory - United States TSCA - Sect. 8(b)	Listed

Lactose NF, anhydrous

EU EINECS List	200-559-2
Inventory - United States TSCA - Sect. 8(b)	Listed

Microcrystalline cellulose

EU EINECS List	232-674-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet