MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Maraviroc Film-Coated Tablets

Trade Name:	CELSENTRI; SELZENTRY
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used for Treatment of HIV

2. HAZARDS IDENTIFICATION

Appearance: Blue film-coated tablets
Signal Word: WARNING

Statement of Hazard: May cause damage to cardiovascular system through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: May produce slight eye irritation. if tablets are crushed or broken (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
Known Clinical Effects: Adverse effects most commonly reported in clinical use include diarrhea, headache, nausea, vomiting, dizziness, insomnia and skin rash.
EU Indication of danger: Harmful

EU Hazard Symbols:

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Maraviroc	376348-65-1	Not listed	Xn; R48/22	24

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	*
Sodium starch glycolate	9063-38-1	Not listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not listed	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. Emits toxic fumes of oxides of nitrogen, carbon monoxide, carbon dioxide, and halogen-containing gases.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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: Contain the source of the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation.

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:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Maraviroc

Pfizer OEL TWA-8 Hr:	80µg/m^3

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method: Analytical method available for Maraviroc. Contact Pfizer Inc for further information.
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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:	Film-coated Tablet	**Color:**	Blue
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Maraviroc
Rat Oral LD50 > 2000 mg/kg
Mouse Oral LD50 > 2000 mg/kg

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
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Maraviroc
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Non-irritating
Skin Sensitization - LLNA Mouse Negative

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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Maraviroc
1 Month(s) Dog Oral 5 mg/kg/day NOAEL Cardiovascular system, Eyes, Heart
6 Month(s) Dog Oral 5 mg/kg/day NOAEL Cardiovascular system Heart Eyes
1 Month(s) Rat Oral 300 mg/kg/day NOAEL Liver Gastrointestinal system
6 Month(s) Rat Oral 100 mg/kg/day NOAEL Liver
9 Month(s) Monkey Oral 120 mg/kg/day NOAEL Cardiovascular system Heart

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Maraviroc
Fertility and Embryonic Development Rat Oral 1000 mg/kg/day NOAEL Maternal toxicity, Embryotoxicity
Embryo / Fetal Development Rat Oral 300 (maternal) /1000 (fetal) mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 75 (maternal)/ 200 (fetal) mg/kg/day NOAEL Maternal Toxicity
Peri-/Postnatal Development Rat Oral 300 mg/kg/day NOAEL Maternal Toxicity, Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Maraviroc
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Maraviroc
6 Month(s) Mouse Oral 1500 mg/kg/day NOAEL Not carcinogenic
104 Week(s) Rat Oral 900 mg/kg/day Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected. This material has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. No toxicity to wastewater treatment microorganisms is expected. Releases to the environment should be avoided.

Bioaccumulation and Toxicity: See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

12. ECOLOGICAL INFORMATION

Maraviroc
Daphnia magna (Water Flea) OECD EC50 48 Hours 69 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 73 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours > 115 mg/L
Ceriodaphnia dubia (Daphnids) EPA EC50 7 Days > 92 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Maraviroc
Activated sludge OECD EC50 > 1000 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

EU Safety Phrases:
S36 - Wear suitable protective clothing.
S22 - Do not breathe dust.

OSHA Label:
WARNING
May cause damage to cardiovascular system through prolonged or repeated exposure.

Canada - WHMIS: Classifications

15. REGULATORY INFORMATION

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

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

Calcium phosphate dibasic, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-826-1

Sodium starch glycolate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Full text of S3 R phrases

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information.

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet