



MATERIAL SAFETY DATA SHEET

Revision date: 22-Sep-2009

Version: 1.4

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Maraviroc Oral Solution

Trade Name: CELSENTRI; SELZENTRY
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of HIV

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: May cause skin irritation. May cause eye irritation (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on cardiovascular system.

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: Not classified

Australian Hazard Classification (NOHSC): Non-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	%
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Maraviroc	376348-65-1	Not listed	Xn; R48/22	2%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium citrate	68-04-2	200-675-3	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sucralose	56038-13-2	259-952-2	Not Listed	*
Flavoring	NOT ASSIGNED	Not listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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:	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:	Fine particles (such as dust and mists) may fuel fires/explosions.

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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 spill if it is safe to do so. Collect spill with absorbent material. 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:	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:	Avoid breathing vapor or mist. 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.
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.

Maraviroc

Pfizer OEL TWA-8 Hr: 80µg/m³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Cyprus OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³
Germany (DFG) - MAK	2 ppm MAK
	3.0 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m ³
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

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:	Liquid	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	3.8 +/-0.2		
Polymerization:	Will not occur		

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

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

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11. TOXICOLOGICAL INFORMATION

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg

Mouse Oral LD50 1600 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.

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

Maraviroc

Eye Irritation Rabbit Minimal

Skin Irritation Rabbit Non-irritating

Skin Sensitization - LLNA Mouse Negative

Citric acid, anhydrous

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Hydrochloric Acid

Skin Irritation Severe

Eye Irritation Severe

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

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver Kidney Blood Ureter Bladder

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

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL 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

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11. TOXICOLOGICAL INFORMATION

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.

Hydrochloric Acid

IARC:

Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

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

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.

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15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-069-1

Sodium citrate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-675-3

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	208-534-8

Sucralose

Australia (AICS):	Listed
EU EINECS/ELINCS List	259-952-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-595-7

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.
R35 - Causes severe burns.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

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