



SAFETY DATA SHEET

Revision date 30-Jun-2022

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Etrasimod
Product Code(s) PF00383
Synonyms APD334; PF-07915503
Trade Name: Not established
Chemical Family: Not determined

Etrasimod
CAS No 1206123-97-8
REACH Registration Number -

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

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Reproductive toxicity Category 2 - (H361d)
Chronic aquatic toxicity Category 1 - (H410)

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements
H361d - Suspected of damaging the unborn child
H410 - Very toxic to aquatic life with long lasting effects
OSHA - May form combustible dust concentrations in air

Precautionary Statements
P201 - Obtain special instructions before use
P273 - Avoid release to the environment

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P308 + P313 - IF exposed or concerned: Get medical advice/attention
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards

Note:

An Occupational Exposure Value has been established for this substance (see Section 8).

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Etrasimod (CAS #: 1206123-97-8)	100	-	Not Listed	Repro.2 (H361d) Aquatic Chronic 1 (H410)	Not Listed	No data available	1

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

- Not Assigned
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Remove to fresh air. Seek immediate medical attention/advice.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

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Consult a physician.

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

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Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Etrasimod

Pfizer OEL TWA-8 Hr: 2 µg/m³

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels.

Environmental exposure controls No information available.

Personal protective equipment Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Wear impervious disposable protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10)

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or international equivalent.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White to light brown
Odor	No information available.
Odor threshold	No information available
Molecular formula	C ₂₆ H ₂₆ F ₃ NO ₃ · C ₆ H ₁₄ N ₄ O ₂
Molecular weight	631.7

Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	0.00226 mg/L pH 5

0.138 mg/L pH 7
2.59 mg/L pH 9

Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

Etrasimod
Measured 5 Log D > 6.25
Measured 7 Log D 5.11
Measured 9 Log D 3.48

9.2. Other information

pKa: 4.45

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

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Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:

Toxicological properties have not been thoroughly investigated.

Known Clinical Effects:

Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: headache, contact dermatitis, constipation, and diarrhea.

Acute toxicity

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

STOT - single exposure

Based on available data, the classification criteria are not met.

STOT - repeated exposure

Based on available data, the classification criteria are not met.

Reproductive toxicity

Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

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

Etrasimod

Mouse Oral Maximally Tolerated Dose 300 mg/kg

Dog Oral LD50 > 1000 mg/kg

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

Etrasimod

91 Day(s) Mouse Oral 20 mg/kg/day NOAEL Liver, Lungs, Lymphoid tissue

4 Week(s) Rat Oral 150 mg/kg/day NOAEL Liver, Lymphoid tissue, Blood

3 Month(s) Rat Oral 200 mg/kg/day NOAEL Lymphoid tissue, Blood

6 Month(s) Rat Oral 150 mg/kg/day NOAEL Blood, Liver, Lymphoid tissue

4 Week(s) Dog Oral 20 mg/kg/day LOAEL Blood, Lungs, Thymus

3 Month(s) Dog Oral 15 mg/kg/day NOAEL Lungs, Thymus, Liver, Lymphoid tissue

9 Month(s) Dog Oral 15 mg/kg/day NOAEL Heart, Lymphoid tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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Embryo / Fetal Development Rat Oral 4 mg/kg/day NOAEL Maternal toxicity
Embryo / Fetal Development Rat Oral < 1 mg/kg/day NOAEL Developmental toxicity
Embryo / Fetal Development Rabbit Oral 20 mg/kg/day NOAEL Maternal Toxicity
Embryo / Fetal Development Rabbit Oral 2 mg/kg/day NOAEL Developmental toxicity
Fertility and Embryonic Development Rat Oral (M) 200 / (F) 4 mg/kg/day NOAEL Reproductive toxicity, No effects at maximum dose

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

Etrasimod

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Rat Bone marrow Negative

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Classification is based on mixture calculation methods based on component data

12.1. Toxicity

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

Etrasimod

Raphidocelis subcapitata (Freshwater alga) OECD NOEC 72 hours 0.089 mg/L

Raphidocelis subcapitata (Freshwater alga) OECD ErC50 72 hours > 0.089 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Etrasimod

Activated sludge OECD EC50 > 1000 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

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Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 0.018 mg/L Survival, Growth

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 > 0.067 mg/L Survival

Daphnia magna (Water Flea) OECD 21 Day(s) LOEC 0.041 mg/L Growth

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 0.016 mg/L Growth, Survival

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) LOEC 0.036 mg/L Survival

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Etrasimod

OECD Activated sludge Ultimate (CO2 Evolution) < 60 % After 28 Day(s) Not Ready

12.3. Bioaccumulative potential

Bioaccumulation

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Partition Coefficient: (Method, pH, Endpoint, Value)

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Measured 5 Log D > 6.25

Measured 7 Log D 5.11

Measured 9 Log D 3.48

12.4. Mobility in soil

Mobility in soil

Sorption:

Etrasimod (1206123-97-8)

<u>Method</u>	<u>Inoculum</u>	<u>End Point</u>	<u>Result</u>
OECD	Activated sludge	Kd (Geometric mean)	3976
OECD	Activated sludge	Koc (Geometric mean)	12,697
OECD	Soil (various)	Kd (Geometric mean)	625
OECD	Soil (various)	Koc (Geometric mean)	54,979

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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 wastewater 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.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (etrasimod)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

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* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Etrasimod

CERCLA/SARA Section 313 de minimus %

Not Listed

California Proposition 65

Not Listed

EINECS

Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child. Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects.

Data Sources:

Pfizer proprietary drug development information.

Reason for revision

New data sheet.

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Prepared By Pfizer Global Environment, Health, and Safety

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