SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-06882961-82

Product Code(s) PZ03449
Synonyms Danuglipron
Trade Name: Not established
Chemical Family: Not determined

PF-06882961-82
CAS No PROPRIETARY
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 Research and Development
445 Eastern Point Road
Groton, CT USA
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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Very high sensitivity to ignition. Compound, not fully tested, additional hazards may exist.

2.3. Other hazards

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

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

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)
PF-06882961-82 (CAS #: PROPRIETARY)	100	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

Additional information - Not Assigned
Non-hazardous ingredients provided for completeness. 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. 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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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 Very high sensitivity of a dust cloud to ignition, based on minimum ignition energy. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen

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 if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion potential and very high sensitivity to ignition. 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.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. All conductive elements of the system that contact the dry substance should be properly bonded and grounded and equipped with proper explosion relief or suppression systems. This material should not be flowed through nonconductive ducts or pipes because of the potential for electrostatic discharge ignition. Restricting the use of high resistivity materials, such as plastics, should be considered. 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

Pfizer Occupational Exposure Band (OEB) Statement: The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06882961-82

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

8.2. Exposure controls

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

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). 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.

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

Hand protection Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (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 Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 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
Odor	No information available.
Odor threshold	No information available
Molecular formula	C31 H30 F N5 O4 . C4 H11 N O3
Molecular weight	676.73

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	~1 mg/mL (25 °C)
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)
PF-06882961
Predicted 7.4 Log D 0.999

9.2. Other information
No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics

Formation of explosible dust/air mixtures

Minimum Ignition Energy (mJ)	6
Milled to:	97.06% < 63 µm
As Received:	d10 - 4.349 d50 - 36.423 d90 - 101.338 % < 500 µm - 100.00 % < 200 µm - 100.00 % < 63 µm - 72.36
DSC:	Endotherm of 86.67 J/g at 158 °C, Exotherm of -750.10 J/g at 158

°C. Medium thermal potential.

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 Very high sensitivity to ignition.

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. As a precautionary measure, keep away from heat sources and electrostatic discharge.

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: nausea, vomiting, headache, difficult digestion (dyspepsia), diarrhea, lack of appetite.
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	Based on available data, the classification criteria are not met.
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)
PF-06882961
Non-human Primate Oral Maximally Tolerated Dose 500 mg/kg
Non-human Primate Subcutaneous NOAEL 5 mg/kg

Safety Pharmacology: **PF-06882961:** *In vivo* Cardiovascular increased blood pressure and decreased QT interval (25 mg/kg or greater)

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
PF-06882961-82
1 Month(s) Rat Oral 250 mg/kg/day NOAEL Heart, Gastrointestinal System, Thymus
1 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified
6 Month(s) Rat Oral 250 mg/kg/day NOAEL Eyes
6 Week(s) Monkey Oral 100 mg/kg/day NOAEL None identified

14 Week(s) Monkey Oral 100 mg/kg/day NOAEL Gastrointestinal system
9 Month(s) Monkey Oral 150 mg/kg/day NOAEL None identified
PF-06882961
21 Day(s) Rat Oral 500 mg/kg/day NOAEL None identified
21 Day(s) Monkey Oral 50 (25 BID) mg/kg/day Maximally Tolerated Dose Gastrointestinal system
6 Month(s) Monkey Oral 50 mg/kg/day LOAEL Heart, Kidney
3 Month(s) Rat Oral 150 mg/kg/day NOAEL None identified
Repeated Dose Toxicity Comments: **PF-06882961:** The above repeated dose toxicity studies (21 Day Oral Rat and 21 Day Oral Monkey) are based on preliminary information.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
PF-06882961-82
Embryo / Fetal Development Rat Oral 500 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 250 mg/kg/day NOAEL No effects at maximum dose
Reproductive & Fertility Rat Oral 500 mg/kg/day No effects at maximum dose
PF-06882961
Reproductive & Fertility-Males Rat Oral 500 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
PF-06882961
In Vitro Micronucleus TK6 Cells Positive
In Vivo Micronucleus Rat Bone Marrow Negative
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Genetic Toxicity Comments: **PF-06882961:** The above genetic toxicity study (*In Vitro* Micronucleus) was a preliminary assay.

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-06882961
Predicted 7.4 Log D 0.999

12.4. Mobility in soil

Mobility in soil No information available.

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.

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

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable
Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

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

PF-06882961-82

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

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.
Revision date	22-Aug-2023
Prepared By	Pfizer Global Environment, Health, and Safety

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