Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant
P.O. Box 140, Ringaskiddy, Co. Cork, Ireland
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Website: www.pfizer.ie

Pfizer Ireland Pharmaceuticals

Enforcement Team B,
Office of Environmental Enforcement,
South/South West Region,
Environmental Protection Agency,
Inniscarra,
Co. Cork.

27-Apr-23

Ref. IE Licence Register Number P0013-05 (Pfizer Ringaskiddy)

Re: For Agency Approval: Update to site inventory of materials: Vepdegestrant Steps 4-5, 6-7 and 7R

Dear Sir/Madam,

We refer to EDEN Submission LR073966, submitted on 22-Feb-2023 and subsequent Agency approval on 01-Mar-23 for Step 3 of ARV-471. We confirm that the name of the product has been updated to Vepdegestrant. [PF-07850327], an oncology drug.
There are a number of processing steps required to manufacture the final Active Pharmaceutical Ingredient, Vepdegestrant, PF-07850327. Step 3 was notified in the above referenced submission.

We request Agency approval to manufacture the remaining steps on site

- Vepdegestrant Step 4/5
- Vepdegestrant Step 6/7
- Vepdegestrant Step 7R [R-recrystallisation]

To manufacture the above remaining steps, we request Agency approval to introduce the following new materials:

Vepdegestrant Step 4-5 materials

- PF-07869590 (PF-07850327 Step 5 RSM)
- D-Proline
- PF-07868397-KQ [PF-07850327 Step 5 Seed] / PF-07868397-KQ [PF-07850327 Step 5]

The other materials used in the process are pre-approved for use, these are Tetrahydrofuran, Hydrogen, Isopropanol, palladium on carbon catalyst and water.

Vepdegestrant Step 6-7 materials

- PF-07868397-KQ [PF-07850327 Step 5] *Same material as 3rd material listed for Step 4-5 materials*
- PF-07868399-BW [PF-07850327 Step 3] – *previously approved: reference EDEN Submission LR073966, SDS included in previous submission*
- Trisodium citrate dihydrate
- PF-07850327 Step 7 / PF-07850327 Step 7 (Seed) / PF-07850327 API [Active Pharmaceutical Ingredient]

The other materials used in the process are pre-approved for use, these are Sulphuric acid, Tetrahydrofuran, Butylated hydroxytoluene, N-Methylmorpholine, Ethanol, Sodium Triacetoxy Borohydride (STAB) and Dimethylacetamide (DMAC), water

Vepdegestrant Step 7R

- PF-07850327 Step 7 / PF-07850327 API [same as final material listed under materials for step 6-7]

The other materials used in the process are pre-approved for use, these are dichloromethane [DCM], Butylated hydroxytoluene, methanol, n-butanol and MTBE

The SDS for the new materials are attached in Appendix 1. The SDS list the H [Hazard] Phrases for the new materials. 4 out of 5 of the new materials are non-hazardous. Only one material Vepdegestrant API [PF-07850327] has hazard phrases. We confirm that these hazard phrases are assigned to materials which are in use currently and no new hazard phrases are being added to the Site Inventory of Materials.

The manufacture of the above steps is scheduled for the OSP4 manufacturing plant initially, specifically the Small Equipment Group [SEG] for the launch campaign. The volumes manufactured will be dependent upon patient demand. As noted in previous submissions, Pfizer Ringaskiddy is a multi-product plant with numerous equipment trains to manufacture products. Depending on the product mix at any one time, products may move between equipment trains in the various production plants so manufacturing plant and batch size will vary during the course of a products lifetime depending on equipment availability and market demand. Equipment trains are regularly changed over and configured to the next scheduled product based on detailed production plans which forecast market demand over extended time periods. The unit operations to manufacture Vepdegestrant are no different to manufacturing any of our existing products.
It's planned that the manufacture of Vepdegestrant will commence within the OSP4 manufacturing facility, but it could be moved to other manufacturing areas for the reasons outlined above. Irrespective of the manufacturing plant and volume, there will be no environmental impact resulting from the manufacture of Vepdegestrant explained as follows:

Impact on air emissions:
There will be no new emissions to air resulting from this process.

This process does not involve the introduction of any new solvents / volatile materials. Only solvents / volatile materials used in the process may be routed to the vessel headspace and potentially onto the vent header system within each manufacturing plant. We confirm that the solvents used in the above steps [listed above] are approved for use by the Agency and routinely abated by the on-site air emissions abatement systems in all the manufacturing plants. Depending on their volatility, vapours will be routed to the headspace. From the process steps being notified here, THF, IPA, ethanol, N-methylmorpholine, Dimethylacetamide (DMAC), dichloromethane, methanol, n-butanol and MTBE are volatile and will be routed to the Thermal Oxidiser in OSP4. The existing air emissions abatement systems servicing all manufacturing buildings can abate the emissions from these solvents explained as follows.

PF-07850327 Steps 4-5, 6-7 and 7R will be initially manufactured in OSP4 so air emissions from these process steps and all processes in the OSP4 manufacturing facility are managed by the existing Thermal Oxidiser which is the main VOC emission abatement system for OSP4. Treated emissions from the OSP4 abatement system are directed to atmosphere via the licensed emission point, A2-5 [V13] which is continuously monitored. Should these steps be manufactured in OSP3, OSP1, NPTL and RCMF manufacturing facilities, air emissions from these processes and all processes in either OSP3, OSP1, NPTL and RCMF [Note 1] manufacturing facilities are managed by the existing OSP3 or OSP1 VOC Absorption systems. OSP3 VOC Absorption system is the main VOC emission abatement systems for OSP3 and NPTL and the OSP1 VOC Absorption system is the main abatement system for OSP1 and RCMF. Treated emissions from OSP3 / NPTL and OSP1 /RCMF are directed to atmosphere via the licensed emission points, A2-4 [V5] and A2-2 [V3] respectively which are continuously monitored.

In the case of OSP4, abatement is provided by a flameless thermal oxidiser. All reactor vessels are fitted with condensers to minimise the solvent carryover into the acid / base vent header. Vessels are manifolded to a contained common header, which in turn is routed via the appropriate scrubbers to the oxidation bed. The enthalpy of the header is continuously monitored and the volumetric flowrate is automatically adjusted by header fans such that the total enthalpy within the oxidation bed remains constant and below the flammable limit (flameless thermal oxidation). The supplemental fuel is natural gas and this is simultaneously automatically adjusted by control valves in conjunction with header flow adjustment, to achieve this constant enthalpy. Natural gas provides the majority of the enthalpy and so significant spare capacity is available in the thermal oxidiser. The manufacture of the Vepdegestrant will therefore take place fully within the existing design envelope of the OSP4 thermal oxidiser, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

In the case of the VOC Absorption Plants serving OSP3 and OSP1, the licensed volumetric flowrate of the fans is 2,700 m3/hour for OSP3 and 3,000m3/hr for OSP1. The operational volumetric flow range is variable and currently typically in the range 300-1,200 m3/hour (approx. 30% of design). Similar to OSP4, all reaction vessels are fitted with condensers to minimise the carry-over of solvent into the header. Vessels used in the process are connected to the existing headers, all flowrates are governed by the existing header vacuum pumps and not by the individual vessel unit operations, and therefore there will be no change to these volumetric flowrates. The manufacture of the Vepdegestrant product can therefore take place fully within the existing design envelope of

the VOC Absorption Plants, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

Tables 1, 2 and 3 identify the solvents / volatile materials used in the process and their associated ELV's for A2-5 [V13] [licensed emissions point for OSP4] and A2-4 [V5] / A2-2 [V3] [licensed emissions point for OSP3 & NPTL / OSP1] respectively. The abatement system in OSP4 is governed by a Total Organic Carbon emission limit and OSP3 / NPTL and OSP1 are governed by the TA Luft standard.

Table 1: A2-5 [V13]: ELV for TOC for licensed emission point from OSP4 Production

Parameter	**Emission Limit Value [ELV] 30-minute mean (mg/m^3)**	**Ringaskiddy average mg/m^3 [2022]**	**Ringaskiddy average mg/m^3 [2021]**
Volatile organic compounds *(excluding Particulate matter)* expressed as total organic carbon	20mg/m^3 [30 min mean] 10mg/m3 [24hr mean]	0.47mg/m3	0.42 mg/m3

Table 2: A2-4 [V5],: ELV's for licensed emission point from OSP3 / NPTL Operations

Solvent	**1997 TA Luft Class**	**Emission Limit Value [ELV]**	**Ringaskiddy average kg/hr [2022]**	**Ringaskiddy average kg/hr [2021]**
N-methymorpholine, Dichloromethane	TA Luft Organics Class I	20mg/m3 (at mass flows >0.1 kg/hr)	0.00041 kg/hr	0.00028 kg/hr
Tetrahydrofuran Dimethylacetamide	TA Luft Organics Class II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00041 kg/hr	0.00041 kg/hr
Ethanol, IPA, Methanol, n-butanol, MTBE	TA Luft Organics Class III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00050 kg/hr	0.00071 kg/hr

Table 3: A2-2 [V3]: ELV's for licensed emission point from OSP1 Operations

Solvent	**1997 TA Luft Class**	**Emission Limit Value [ELV]**	**Ringaskiddy average kg/hr [2022]**	**Ringaskiddy average kg/hr [2021]**
N-methymorpholine, Dichloromethane	TA Luft Organics Class I	20mg/m3 (at mass flows >0.1 kg/hr)	0.00022 kg/hr	0.00018 kg/hr
Tetrahydrofuran Dimethylacetamide	TA Luft Organics Class II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00016 kg/hr	0.00015 kg/hr
Ethanol, IPA, Methanol, n-butanol, MTBE	TA Luft Organics Class III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00065 kg/hr	0.00022 kg/hr

Tables 1, 2 and 3 above provide a summary of the annual average emissions data from A2-5 [V13], licensed emission point for OSP4, A2-4 [V5], licensed emission point for OSP3/NPTL and A2-2 [V3] for 2021 and 2022 and all emissions comply with the relevant ELV's. The solvents used in this process are typically used and historical data proves that the on-site VOC emissions abatement systems are capable of abating these materials. The introduction of this process will not result in any impact or change to air emissions from the site.

Step 4-5 involves a hydrogenation process [use of Hydrogen] in the presence of a catalyst which is palladium on carbon catalyst for this process. Hydrogenation reactions occur in vessels dedicated for hydrogen use, these vessels are equipped with condensers to minimise the loss of solvent vapour from the vessels. For process safety purposes, these vessels are vented directly to atmosphere through previously approved minor emission points.

Impact on emissions to sewer:
The introduction of this new product will not impact on emissions to sewer. We confirm that no waste stream containing any of the Vepdegestrant product will be routed to the wastewater treatment plant. Waste streams will be segregated and either sent off site for suitable treatment by the approved waste management broker or recovered on-site. Solvent containing waste streams are either recovered on or off-site or sent to high calorific value waste for off-site treatment, final treatment is typically dependent upon volume, composition, etc.

Impact on emissions to surface water:
There will be no emissions to surface water resulting from the manufacture of this product. All drains within the manufacturing facilities are process drains and depending on the strength of the effluent [weak / strong] are routed to the weak / strong effluent systems. Both weak / strong effluent streams are treated in the on-site waste water treatment plant and discharged at SE1 [TE1] in accordance with the licence requirements. There are no surface water drains in areas where either drums of raw materials or drums of waste are stored.

Impact on storage facilities:
The new materials will be supplied in containers. There is sufficient storage capacity within both the main warehouse and existing drumpad for the storage of these raw materials. Drummed solids are typically stored in the main warehouse. Drummed liquids are stored in the drumpad which is remotely bunded to the WWTP. There are dedicated contained areas within the vicinity of each manufacturing facility to contain both the raw materials and the associated waste drums. Procedures are implemented to ensure all waste drums are labelled at the point of generation. Such waste drums are transferred to dedicated areas within the main warehouse and drum laydown area as appropriate. All waste drums are removed off site by our approved waste management broker which is Indaver Ireland Ltd. Dedicated Indaver resources manage the shipment of waste from site and tracking of materials to final disposal. Disposal of such waste is recorded in the annual environmental report.

Ringaskiddy is a multipurpose manufacturer of many products, manufactured on a campaign basis. At any one time, there could be circa 20 process steps being manufactured between all the equipment trains within the manufacturing plants. To ensure production plan requirements are met, drummed raw materials are constantly moving onto site for initial storage, moving to the relevant manufacturing plant for use and the associated waste

materials are then removed from the plants to dedicated storage areas for disposal. We confirm that there is sufficient contained storage on site for the drums that will be used in this process.

Impact on firewater retention capacity:
The introduction of this new product does not have any impact on fire water retention capacity. The materials in question do not change the profile of materials being introduced, no new hazard phrases are introduced. New materials don't change the risk rating of the site.

In summary, there will be no environmental impact resulting from the manufacture of PF-07850327 Steps 4-5, 6-7 and 7R.

In accordance with Agency guidance, the Site Inventory of Materials shall be updated to include the above materials and shall be retained onsite for inspection by the Agency as required.

We trust that this is to the satisfaction of the Agency.

Yours sincerely,

Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant

Geraldine Rooney

Geraldine Rooney
Environment, Health and Safety Department

Note 1: Note that the RCMF is scheduled to commence operation circa Q4 2023

Appendix 1:

Pfizer Ireland Pharmaceuticals
Registered in Ireland – Company Number: 490938 – VAT Number: IE 9767830C
Registered Office: Operations Support Group, Ringaskiddy, Co. Cork
Directors: Colm Higgins, Paul Duffy
Company Secretary: Colm Higgins

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07869590

Product Code(s) PF00296
Synonyms AR5471-6
Trade Name: Not established
Chemical Family: Not determined

PF-07869590
CAS No PROPRIETARY

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

Recommended Use Pharmaceutical process intermediate

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards No data available
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-07869590 PROPRIETARY	100		Not Listed	No data available	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 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 Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a 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.

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, eyes, 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 process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits
No exposure limits established.

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures.

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. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, 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	C37H39NO3
Molecular weight	545.72

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	No data available
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-07869590
Predicted 7.4 Log D 8.441

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
No information available

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 investigated.

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: May persist in the aquatic environment. Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

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-07869590
Predicted 7.4 Log D 8.441

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.

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-07869590

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 New data sheet.

Revision date 21-Feb-2022

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.

SAFETY DATA SHEET of D-Proline

1. Identification of the substance/Mixture and of the company undertaking

1.1 Product identifier: D-Proline

1.2 Recommended use of the chemical and restriction on use: pharmaceutical actives, intermediates, specialized nutritional products, cell culture media, excipients.

1.3 Name and address of the manufacturer and supplier:

CAMIDA
SOURCE • SUPPLY • SOLUTION

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New Quay
Clonmel
Co.Tipperary
Ireland

Tel No: +353 (0)52 6125455 (Office Hrs)
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Information provided is advisory only

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E-mail address: International-Biz@jirongpharm.com

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2. Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous product according to the Directive 67/548/EC or Directive 1999/45/EC
Not a hazardous product according to CLP classification - regulation (EC) no. 1272/2008 .
Not a hazardous substance or mixture according to the GHS.
Harmful by inhalation, in contact with skin, and if swallowed.

2.2 Label elements

In according with the Regulation EC 1272/2008 (CLP) the product does not need to be labeled.
Not a hazardous substance or mixture GHS Label elements, including precautionary statements

2.3 Other hazards: None

3. Composition/ Information on ingredients

Name of substance:	D-Proline
Synonyms:	proline (S)-Pyrrolidine-2-carboxylic acid
Chemical formula:	$C_5H_9NO_2$

CAS No.:	344-25-2
EINECS No.:	206-452-7

No components need to be disclosed according to the applicable regulations

4. First aid measures

4.1 Description of first aid measures

Pay attention to self-protection.

Remove the victims from hazardous area. Immediately remove soiled or soaked clothing and remove it to a safe distance. Keep victims warm, in a stabilized position and covered.

Do not leave victims unattended.

Inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Skin contact:

Immediately wash skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists, seek medical attention.

Eye contact:

Immediately wash skin with copious amounts of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, seek medical attention.

Ingestion:

Remove to fresh air. In severe cases or if symptoms persist, seek medical attention. Ingestion: Wash out mouth with copious amounts of water for at least 15 minutes. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No Damage being expected

4.3 Indication of immediate medical attention and special treatment needed

This substance does not have any noteworthy noxious potential

Damage to health is thus not expected.

5. Fire Fighting measures

5.1 Extinguishing media

CO_2, powder, foam, water.

5.2 Specific hazards arising from the substance or mixture

Development of hazardous combustion gases or vapours possible

in the event of fire: Carbon monoxide, Carbon dioxide, Nitrogen oxides (NO_x)- HCN.

In the event of a fire involving this material, alone or in combination with other materials, use dry

powder or carbon dioxide extinguishers. Protective clothing and self-contained breathing apparatus should be worn.

5.3 Advice for fire-fighters

Wear personal protective equipment.
In the event of fire, wear self-contained breathing apparatus.
Fire residues should be disposed in accordance with the regulations.

6. Accidental Release measures

6.1 Personal precautions, protective equipment and emergency procedures.

Avoid contact. Avoid raising dust, don't inhale dust.
Keep unauthorized persons away.

6.2 Environmental precautions.

Do not allow the production into the following compartments: soil, stretches of water, drainage systems.
In case of pollution, prevent competent authorities.Do not allow to enter drainage.

6.3 Methods and materials for containment and cleaning up.

Pick up mechanically. Collect in a suitable containers.
Waste to be packed like clean product and to be marked. Avoid raising dust.
Ventilate area and wash spill site after material pickup is complete.

6.4 References to other sections

See section 8 to 13

7. Handling and storage

7.1 Precautions for safe handling.

Wear suitable protective clothing
This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet.
Storage: Sealed, room temperature, protected from light, stored in a dry environment.

7.2 Conditions for safe storage, including any incompatibilities

Dry and dark at room temperature in tightly closed containers.

7.3 Specific end of use(s)

Follow usual safety precautions while handling (see section 8)

8. Exposure controls/ Personal protection

8.1 Control parameters, exposure limit for dust general rule

No data information

8.2 Exposure controls

Personal protective equipment:
-Breathing protection equipment:
If dust occurs, dust mask must with P1 partial filter.
-Hand protection: wear gloves
-Eye protection:
protective glasses
If dust occurs, basket-shaped glass.
-Skin and body protection:
wearing of suitable chemical resistant protective clothes.
Or when handling for a prolonged exposure cloth specific for chemical products.
Hygiene measures:
Avoid contact with skin and eyes.
No eating, drinking, smoking or snuffing tobacco at work.
Protective measures:
Handle in accordance with good industrial hygiene and safety practices.
If there is the possibility of skin/eye contact, the indicated hand/eye/body protection should be used.

9. Physical and chemical properties

9.1 information on basic physical and chemical properties

Appearance:	White, crystalline powder
Odor:	nearly odourless
Odor threshold:	Not available
pH:	5.5-7.5
Melting point/freezing point:	214 - 217 °C
Initial boiling point and boiling range:	Not available
Flash point:	Not available
Evaporation rat:	Not available
Flammability (solid, gas):	Not available
Upper/lower flammability or explosive limits:	Not available
Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	Not available
Solubility(ies):	155g in 100ml H_2O (20°C)
Partition coefficient:	Not available
Autoignition temperature:	Not available

9.2 Other information

Not available

10. Stability and reactivity

10.1 Reactivity

No reactivity known to occur with correct handling and storage.

10.2 Chemical stability

Stable at a ambient temperature.

10.3 Possibility of hazardous reactions

Not available

10.4 Conditions to avoid

Avoid moisture, excess heat, strong oxidants

10.5 Incompatible materials

Excess heat, strong oxidants

10.6 Hazardous decomposition products

Carbon monoxide-Carbon dioxide-Nitrogen Oxides (NO_X)-HCN,Sulfur oxides.

11. Toxicological information

11.1 information on the likely routes of exposure

Inhalation, ingestion, skin and eye contact.

11.2 Symptoms related to the physical, chemical and toxicological characteristics;

No data available.

11.3 Delayed and immediate effects and also chronic effects from short- and long-term exposure;

No data available.

11.4 Acute toxicity

Classification relevant LD/LC 50 values: LD_{50} oral (rat): 5 110 mg/kg

12. Ecological information

The substance is chemically identical to the natural amino acid and at proper handling and use no ecological harms are known. Bioaccumulation is not expected (log P(o/w)<1).

12.1 Ecotoxicity

No data available.

12.2 Persistence and degradability

Readily biodegradable BOD5/COD=0.93 (ref. Degussa TVC-W Labor U176E/81 1981-0-30)

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No adverse effect known.

13. Disposal considerations

13.1 waste treatment methods

Disposal according to local authority regulations.
Waste to be packed like clean product and to be marked. Identification label on package not to be removed until recycling
Arrange disposal as special waste, by licensed disposal company, in consultation with local waste disposal authority, in accordance with national and regional regulations.

14. Transport information

Production non dangerous in the meaning of transport regulations.

14.1 UN number	Non applicable
14.2 UN proper shipping name	Non applicable
14.3 Transport Hazard class(es)	Non applicable
14.4 Packing group	Non applicable
14.5 Marine pollutant	Non applicable
14.6 Special precautions for user	Non applicable
14.7 Transport in bulk according to annex II of MARAPOL73/78 and the IBC code	Non applicable

15. Regulatory information

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

The present results for assessment are not applicable for classification by hazard characteristics according to the guideline 67/ 548/ EWG and CLP-regulation no. 1272/2008 and the appropriate national legislation, therefore no hazardous symbol, labelling and R-phrases / H-phrases and S-phrases / P-phrases are necessary .

15.2 Chemical safety assessment

No chemical safety assessment

16. Other information

References: Not available.

Other Special Considerations: Not available.

Created: 15th, Feb. 2006

Last Updated: 12th, March, 2021

The information provided in this Safety Sheet is correct to the best of our knowledge, information and belief at the date of publication. There is no demand of completeness and the user should consider this Safety Data Sheet only as a guide.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07868397-KQ

Product Code(s) PF00291
Synonyms ARV-471-1
Trade Name: Not established
Chemical Family: Not determined

PF-07868397-KQ
CAS No PROPRIETARY

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

Recommended Use Pharmaceutical process intermediate

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards No data available
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-07868397-KQ PROPRIETARY	100		Not Listed	No data available	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 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 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 Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a 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.

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, eyes, 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 process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits
No exposure limits established.

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures.

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. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, 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	C35H44N2O5
Molecular weight	572.75

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	No data available
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

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
No information available

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 investigated.

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: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

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.

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-07868397-KQ

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	New data sheet.
Revision date	09-Mar-2022
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	25.08.2021	100000000010	Date of first issue: 25.08.2021
IE / EN			

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	:	Trisodium Citrate Dihydrate
Substance name	:	Trisodium Citrate Dihydrate
Molecular formula	:	C6H5O7Na3 · 2H2O
Chemical identity	:	Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate
CAS-No.	:	6132-04-3
EC-No.	:	200-675-3
REACH Registration Number	:	01-2119457027-40-0000

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

Use of the Substance/Mixture	:	Food/ feedstuff additives, Cosmetic additive, Medical aids, Industrial use
Recommended restrictions on use	:	None known.

1.3 Details of the supplier of the safety data sheet

Company	:	Jungbunzlauer Austria AG Werk Pernhofen 2064 Wulzeshofen Austria www.jungbunzlauer.com
Telephone	:	+43 2527 200-0
Telefax	:	+43 2527 200-80
Responsible/issuing person	:	msds@jungbunzlauer.com

CAMIDA
SOURCE • SUPPLY • SOLUTION

Supplier: Camida Ltd.
New Quay
Clonmel
Co. Tipperary
E91 YV66
Ireland

Tel No: +353 (0)52 6125455 (Office Hrs)
Email: info@camida.com
Emergency Tel No: +44 1865 407333
(Carechem24)

Information provided is advisory only

1.4 Emergency telephone number

Telephone	:	National Chemical Emergency Centre (NCEC) +44 1865 407 333

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name	:	Trisodium Citrate Dihydrate
CAS-No.	:	6132-04-3
EC-No.	:	200-675-3
Chemical nature	:	Solid
Remarks	:	No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	Do not leave the victim unattended.
If inhaled	:	If breathed in, move person into fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Wash off immediately with soap and plenty of water.
In case of eye contact	:	Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Carbon dioxide (CO2)
Foam

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Use personal protective equipment.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

In the event of fire and/or explosion do not breathe fumes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Avoid dust formation.
Avoid breathing dust.
Ensure adequate ventilation, especially in confined areas.
Wear personal protective equipment.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.

Sweep up and shovel.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Avoid creating dust. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Hygiene measures	:	General industrial hygiene practice.
Dust explosion class	:	Not applicable

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed in a dry and well-ventilated place.
Advice on common storage	:	No materials to be especially mentioned.
Further information on storage stability	:	Keep in a dry place. No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s)	:	none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Provide adequate ventilation.

Personal protective equipment

Eye protection	:	Safety glasses

Hand protection

Remarks	:	Wear suitable gloves.
Skin and body protection	:	Protective suit
Respiratory protection	:	In the case of dust or aerosol formation use respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	crystalline
Colour	:	white
Odour	:	odourless
Melting point/freezing point	:	> 150 °C Decomposition
Boiling point/boiling range	:	Decomposes below the boiling point.
Flammability	:	does not ignite
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Ignition temperature	:	Not applicable
Decomposition temperature		
Decomposition temperature	:	Decomposes before melting.
pH	:	7,5 - 9,0 (25 °C) Concentration: 5 %
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	400 - 700 g/l (20 - 25 °C)
Partition coefficient: n-octanol/water	:	log Pow: -1,8 - -0,2 Calculation
Vapour pressure	:	Not applicable
Relative density	:	1,86 (20 °C)

Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	0,2 - 1,25 mm

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	No oxidising effect.
Dust explosion class	:	Not applicable
Molecular weight	:	294,1 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid	:	No data available

10.5 Incompatible materials

Materials to avoid	:	Not applicable

10.6 Hazardous decomposition products

Build-up of dangerous/toxic fumes possible in cases of fire/high temperature.
Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Acute oral toxicity	:	LD50 Oral (Mouse): 5.400 mg/kg body weight Method: OECD Test Guideline 401

Test substance: Non neutralised product
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 Dermal (Rat): > 2.000 mg/kg body weight
Test substance: Non neutralised product
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Does not cause skin sensitisation.
Remarks : No human information is available.

Germ cell mutagenicity

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium

Concentration: 0.0 - 10 mg/plate
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
Information given is based on data obtained from similar substances.

Genotoxicity in vivo : Test Type: in vivo assay
Species: Rat
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative
Test substance: Non neutralised product

Germ cell mutagenicity- Assessment : In vitro tests did not show mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

Reproductive toxicity

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Reproductive toxicity - Assessment : No toxicity to reproduction

STOT - single exposure

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

Remarks : No data available

Repeated dose toxicity

Components:

Trisodium Citrate Dihydrate:

Species	:	Rat
NOAEL	:	8.000 mg/kg
LOAEL	:	16.000 mg/kg
Application Route	:	Oral
Exposure time	:	10 d
Dose	:	2, 4, 8, 16 g/kg bw/day

Aspiration toxicity

Not classified based on available information.

Components:

Trisodium Citrate Dihydrate:

No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Product:

Remarks	:	No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

Trisodium Citrate Dihydrate:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): 440 mg/l Exposure time: 48 h Test Type: static test Test substance: Non neutralised product Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): 1.535 mg/l Exposure time: 24 h Test Type: static test

Test substance: Non neutralised product
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : NOEC (Scenedesmus quadricauda (Green algae)): 425 mg/l
Exposure time: 8 d
Test Type: static test
Test substance: Non neutralised product

Toxicity to microorganisms : TT (Pseudomonas putida): > 10.000 mg/l
Exposure time: 16 h
Test substance: Non neutralised product

12.2 Persistence and degradability

Components:

Trisodium Citrate Dihydrate:

Biodegradability : Biodegradation: 97 %
Method: OECD Test Guideline 301B
Test substance: Non neutralised product
Readily biodegradable.

Biodegradation: 100 %
Method: OECD Test Guideline 301E
Test substance: Non neutralised product
Readily biodegradable.

Physico-chemical removability : Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Trisodium Citrate Dihydrate:

Bioaccumulation : The product is miscible in water and readily biodegradable in both water and soil. Accumulation is not expected.

Partition coefficient: n-octanol/water : log Pow: -1,8 - -0,2

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with local and national regulations.
Where possible recycling is preferred to disposal or incineration.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

The components of this product are reported in the following inventories:

TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	All substances listed as active on the TSCA inventory
AICS	:	On the inventory, or in compliance with the inventory
DSL	:	All components of this product are on the Canadian DSL
ENCS	:	On the inventory, or in compliance with the inventory
ISHL	:	On the inventory, or in compliance with the inventory
KECI	:	

		On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07850327

Product Code(s) PF00279
Synonyms ARV-471; VC-001420681
Trade Name: Not established
Chemical Family: Not determined

PF-07850327
CAS No 2229711-08-2

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 WRD
445 Eastern Point Road
Groton, Connecticut, USA
1-800-879-3477

Pfizer Australia
Level 15-18, 151 Clarence Street
Sydney NSW 2000
Australia
+61 2 9850 3333

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)
Specific target organ toxicity (repeated exposure) Category 2 - (H373)

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements
H361d - Suspected of damaging the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure reproductive system
OSHA - May form combustible dust concentrations in air

Precautionary Statements
P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required

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

Supplemental Hazard 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

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)
PF-07850327 (CAS #: 2229711-08-2)	100		Not Listed	Repr. 2 (H361d) STOT RE.2 (H373)	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
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 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, 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 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.

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 15 to 30 °C in properly labeled containers. Protect from light. 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

PF-07850327
Pfizer OEL TWA-8 Hr: 10 µg/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, 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 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 yellow
Odor	No information available.
Odor threshold	No information available
Molecular formula	C45 H49 N5 O4
Molecular weight	723.9017

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	No data available
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-07850327
Predicted 7.4 Log D 5.795

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
No information available

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: nausea, exhaustion, joint pain, constipation, lack of appetite, hot flashes, vomiting,
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	May cause damage to organs through prolonged or repeated exposure.
Reproductive toxicity	Possible risk of harm to the unborn child.
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.

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

PF-07850327

28 Day(s) Rat Oral 3 mg/kg/day LOAEL Female reproductive system, Heart
28 Day(s) Dog Oral 15 mg/kg/day LOAEL Reproductive system
3 Month(s) Rat Oral 30 mg/kg/day LOAEL Female reproductive system
3 Month(s) Dog Oral 10 mg/kg/day LOAEL Reproductive system

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

PF-07850327

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Maternal toxicity
Embryo / Fetal Development Rat Oral 30 mg/kg/day LOAEL Developmental toxicity

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

PF-07850327

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

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-07850327
Predicted 7.4 Log D 5.795

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, ADG 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-07850327

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 Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information.
Revision date	07-Feb-2023
Prepared By	Pfizer Global Environment, Health, and Safety

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