



Pfizer Ireland Pharmaceuticals  
Ringaskiddy Active Pharmaceutical Ingredient Plant  
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## **Pfizer Ireland Pharmaceuticals**

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

**20-Feb-23**

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

**Re: For Agency Approval: Update to site inventory of materials: ARV-471 [PF-07850327]**

Dear Sir/Madam,

We wish to notify the Agency that it's planned to introduce the following new materials for the manufacture of ARV-471, PF-07850327, an oncology drug.

There are a number of processing steps required to manufacture the final Active Pharmaceutical Ingredient, ARV-471. Step 1 and 2 intermediates are manufactured off-site. The final 4 steps of this process will be manufactured on site commencing with Step 3. The Step 2 intermediate, manufactured off-site will be supplied as PF-07841770 (PF-07850327 regulatory intermediate) which is the regulatory starting material for the first step to be manufactured on site, step 3.

The following steps will be manufactured on site

- PF-07850327 Step 3
- PF-07850327 Step 4/5
- PF-07850327 Step 6/7
- PF-07850327 Step 7R [R-recrystallisation]

This notification requests Agency approval to manufacture PF-07850327 Step 3 only. Request for approval to manufacture the remaining steps will be in a separate notification.

We request Agency approval to introduce the following new materials for the manufacture of PF-07850327 Step 3

- (1S)-(+)-10-Camphorsulfonic Acid [R enantiomer used previously on site]
- PF-07841770 (PF-07850327 regulatory intermediate, ARV-471 2a)
- PF-07868399-BW [PF-07850327 Step 3 intermediate]

We confirm that Acetonitrile and sulfolane are the solvents that will be used in the process. These materials were previously approved by the Agency and are in routine use.

The SDS for the above materials are attached in Appendix 1. H [Hazard] Phrases for the new materials are identified in the SDS attached in appendix 1. We confirm that no new H Phrases are being added to the Site Inventory of Materials. The associated H-Phrases identified in appendix 1 are routinely used on site.

The manufacture of the above step 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 ARV-471 are no different to manufacturing any of our existing products. Minimal engineering changes are required to expedite the manufacture of this product.

It's planned that the manufacture of ARV- 471 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 ARV-471 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 or 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 are acetonitrile and sulfolane, both previously approved by the Agency and routinely used on site. Acetonitrile is volatile and will be routed to the headspace but sulfolane is non-volatile so will not enter the headspace of any vessel, hence will have no impact on air emissions. The existing air emissions abatement systems servicing all manufacturing buildings are capable of handling the emissions from these materials explained as follows.

PF-07850327 Step 3 will be initially manufactured in OSP4 so air emissions from this process 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 the OSP3 or OSP1 manufacturing facilities, air emissions from this process and all processes in either OSP3 or OSP1 manufacturing facilities are managed by the existing OSP3 or OSP1 VOC Absorption systems which are the main VOC emission abatement systems for OSP3 and OSP1 respectively. Treated emissions from the OSP3 / OSP1 abatement systems 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. Vessels in OSP4 are manifolded to a contained common header, which is then routed 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 ARV-471 product 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 m<sup>3</sup>/hour for OSP3 and 3,000m<sup>3</sup>/hr for OSP1. The operational volumetric flow range is variable and currently typically in the range 300-1,200 m<sup>3</sup>/hour (approx. 30% of design). All 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 ARV- 471 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 / OSP1] respectively. The abatement system in OSP4 is governed by a Total Organic Carbon emission limit and OSP3 / 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 <sup>3</sup> )	Ringaskiddy average mg/m <sup>3</sup> [2022]	Ringaskiddy average mg/m <sup>3</sup> [2021]
Volatile organic compounds (excluding Particulate matter) expressed as total organic carbon	20mg/m <sup>3</sup> [30 min mean] 10mg/m <sup>3</sup> [24hr mean]	0.47mg/m <sup>3</sup>	0.42 mg/m <sup>3</sup>

Table 2: A2-4 [V5]: ELV's for licensed emission point from OSP3 Production

Solvent	1997 TA Luft Class	Emission Limit Value [ELV]	Ringaskiddy average kg/hr [2022]	Ringaskiddy average kg/hr [2021]
Acetonitrile	TA Luft Organics Class II	100mg/m <sup>3</sup> (at mass flows >2.0 kg/hr)	0.00041 kg/hr	0.0004 kg/hr

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

Solvent	1997 TA Luft Class	Emission Limit Value [ELV]	Ringaskiddy average kg/hr [2022]	Ringaskiddy average kg/hr [2021]
Acetonitrile,	TA Luft Organics Class II	100mg/m <sup>3</sup> (at mass flows >2.0 kg/hr)	0.00016 kg/hr	0.00015 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 and A2-2 [V3] from 2021 and 2022 and all emissions from the OSP4, OSP3 and OSP1 air emissions abatement systems 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.

**Impact on emissions to sewer:**

The introduction of this new product will not impact on emissions to sewer. We confirm that no waste stream from this process step 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 moved 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 Step 3.

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

# Appendix 1:

# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH)

Version 3.1 Issue date: 15/02/2022

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## Section 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

<b>Product name</b>	<b>2-oxobornane-10-sulphonic acid</b>
<b>CAS</b>	3144-16-9
<b>EC</b>	221-554-1
<b>Index Number</b>	N/A
<b>Reach Registration No</b>	N/A
<b>Other means of identification</b>	D(+)-Camphor Sulphonic Acid D-10-Camphorsulfonic acid.

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

<b>Identified uses</b>	Laboratory chemicals, manufacture of substances. For industrial and professional use only.
<b>Uses advised against</b>	Any other purpose.

### 1.3 Details of the supplier of the safety data sheet

<b>Supplier</b>	Camida Limited New Quay Clonmel Co. Tipperary E91 YV66 Ireland Tel: +353 52 6125455 info@camida.com
<b>Contact person</b>	

### 1.4 Emergency telephone number

<b>Emergency telephone</b>	00 44 (0) 1865 407333 (Carechem24)
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## Section 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification according to regulation EC No. 1272/2008	
Physical and Chemical hazards	Not classified
Human health	Skin Corr. 1B - H314
Environment	Not classified

### 2.2 Label elements

Label in accordance with EC No.  
1272/2008



**Signal word**

Danger

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<b>Hazard statements</b>	H314 Causes severe skin burns and eye damage.
<b>Precautionary statements</b>	<b>Prevention</b> P260 Do not breathe dust/fume/ gas/mist/vapours/spray. P280 Wear protective gloves/ protective clothing/eye protection/face protection. <b>Response</b> P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/ shower. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/physician. <b>Disposal</b> P501 Dispose of contents/ container to a licensed hazardous waste disposal facility in accordance with all applicable regulations.

## 2.3 Other hazards

None known.

## Section 3: Composition/information on ingredients

### 3.1 Substance

Name	Product identifier	Regulation (EC) No 1272/2008	%
2-oxobornane-10-sulphonic acid	CAS-No.: 3144-16-9 EC No.: 221-554-1	Skin Corr. 1B - H314	99%

The full text for all hazard statements are displayed in section 16.

**Composition comments** The data shown are in accordance with the latest EC Directives.

### 3.2 Mixtures

Not applicable.

## Section 4: First aid measures

### 4.1 Description of first aid measures

<b>General information</b>	Provide general first aid, rest, warmth and fresh air. As a general rule, in case of doubt or if symptoms persist, always call a doctor. Seek medical attention for all burns and eye injuries, regardless how minor they may seem. First aid personnel must be aware of own risk during rescue. Show this safety data sheet or product label to medical personnel.
<b>Inhalation</b>	Remove to fresh air. If the exposed person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion</b>	Rinse mouth thoroughly. DO NOT induce vomiting. If vomiting occurs spontaneously, keep head low and/or keep airway clear. Never give anything by mouth to an unconscious person. Get medical attention immediately.
<b>Skin contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. Seek medical attention immediately. Continue to rinse for at least 15 minutes. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Avoid contaminating unaffected eye. Remove contact lenses if present and easy to do so. Immediately flush eyes with plenty of water for at least 15 minutes,

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lifting lower and upper eyelids occasionally. Get medical attention immediately.

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

<b>General information</b>	The severity of the symptoms described will vary dependent on the concentration and the length of exposure.
<b>Inhalation</b>	Corrosive and irritating to upper respiratory tract and mucous membranes. May cause cough, shortness of breath, sore throat and labored breathing. Risk of delayed pulmonary oedema.
<b>Ingestion</b>	If ingested, product may cause severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. May cause nausea or vomiting.
<b>Skin contact</b>	Causes severe skin burns.
<b>Eye contact</b>	Causes serious eye damage.

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

<b>Notes to the physician</b>	Immediately call a POISON CENTER or doctor/physician.
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## Section 5: Firefighting measures

### 5.1 Extinguishing media

<b>Extinguishing media</b>	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Unsuitable extinguishing media</b>	High volume water jet.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	When heated, toxic and corrosive vapours/gases may be formed. Combustion products may include and are not limited to: Oxides of carbon. Sulphur oxides (SO <sub>x</sub> ).
<b>Unusual fire &amp; explosion hazards</b>	Dust clouds may be explosive. Avoid generating dust.
<b>Specific hazards</b>	Do not allow run-off from fire fighting to enter drains or water courses. Water used for fire extinguishing, which has been in contact with the product, may be corrosive

### 5.3 Advice for firefighters

<b>Special fire fighting procedures</b>	Keep up-wind to avoid fumes. Avoid breathing fire vapours. Ventilate closed spaces before entering them. Fight advanced or massive fires from safe distance or protected location. Containers close to fire should be removed immediately or cooled with water if safe to do so.
<b>Protective equipment for firefighters</b>	Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents. Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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## Section 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** Wear protective clothing as described in Section 8 of this safety data sheet. Avoid inhalation of dust and contact with skin and eyes. Evacuate and ventilate area. Eliminate all sources of ignition. Do not touch or walk through spilled material. Avoid raising powdered materials into airborne dust. Read and follow manufacturer's recommendations.
- For emergency responders** Follow safe handling advice and personal protective equipment recommendations for normal use of product.

### 6.2 Environmental precautions

- Environmental precautions** Do not discharge into drains, water courses or onto the ground. Spillages or uncontrolled discharges into watercourses must be IMMEDIATELY alerted to the Environmental Agency or other appropriate regulatory body

### 6.3 Methods and material for containment and cleaning up

- Spill clean up methods** Wear appropriate personal protective equipment as specified in Section 8. Ventilate and evacuate the area. Eliminate all ignition sources. Take care not to raise dust.  
Use non-sparking hand tools and explosion proof electrical equipment for clean up. Shovel or sweep up. Ensure that waste and contaminated materials are collected and removed from the work area as soon as possible in a suitably labelled container. Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4 Reference to other sections

- Reference to other sections** See section 1 for emergency contact. For personal protection, see section 8. For waste disposal, see section 13.

## Section 7: Handling and storage

### 7.1 Precautions for safe handling

- Handling** Use proper personal protection when handling (refer to Section 8). Provide good ventilation. Avoid inhalation of dust and contact with skin and eyes. Avoid generation of dust clouds/accumulation of dust in work area. Use process enclosures and local exhaust ventilation when working with the product. Remove contaminated clothing and protective equipment before entering eating areas. Wash hands thoroughly after handling. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

### 7.2 Conditions for safe storage, including any incompatibilities

- Storage precautions** Store in tightly closed original container in a dry, cool and well-ventilated place. Keep away from incompatible materials (see section 10). Protect against static discharge and keep away from sources of ignition. Hygroscopic. Protect from moisture.
- Storage class** Corrosive storage.

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## 7.3 Specific end use(s)

### Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

### Usage description

Use only according to directions. Keep container tightly closed and sealed when not in use.

## Section 8: Exposure controls/Personal protection

### 8.1 Control parameters

#### Ingredient comments

Ireland, Occupational Exposure Limits 2021.

No exposure limits noted for ingredient(s).

Where exposure limits have not been established for specific components of this material, please observe the following non specific limits for particulates or dust: Please note the OELV (TWA, 8 hour) for 'Dusts, non-specific' are - Total inhalable dust: 10 mg/m<sup>3</sup>; Respirable dust: 4 mg/m<sup>3</sup>. [Ireland, Code of Practice for the Chemical Agents Regulations 2021.]

### 8.2 Exposure Controls

#### Protective equipment



#### Engineering measures

Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. Where necessary use lighting and electrical equipment designed for use in atmospheres where dusts are present, and which can direct static electricity by grounding equipment.

#### Respiratory equipment

Where risk assessment shows air-purifying respirators are appropriate a full face respirator conforming to EN143, and suitable respirator cartridges as a backup to engineering controls. Suggested filter type: ABEK-P2 (EN 143). If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respiratory protection as specified by an industrial hygienist or other qualified professional. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).

#### Hand protection

Where hand contact with the product may occur the use of gloves approved to relevant standards (e.g. Europe: EN374) is recommended. (Suggested suitable materials for longer, direct contact or splash contact) Nitrile rubber. Minimum layer thickness: 0.11 mm. Breakthrough time: >480 min. Consult manufacturer for specific advice. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

#### Eye protection

Wear safety glasses with side shields. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

#### Other protection

Protective clothing should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Wear appropriate dustproof clothing to prevent any possibility of skin contact. The selected clothing must satisfy the European norm standard EN 943.

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<b>Hygiene measures</b>	Remove contaminated clothing and protective equipment before entering eating areas. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.
<b>Process conditions</b>	Ensure that eye flushing systems and safety showers are located close by in the work place.

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Powder.
<b>Colour</b>	White or almost white.
<b>Odour</b>	No odour information available.
<b>Odour threshold - lower</b>	No information available as testing has not been completed.
<b>Odour threshold - upper</b>	No information available as testing has not been completed.
<b>pH-Value, Conc. Solution</b>	Not applicable - The product is a solid.
<b>pH-Value, Diluted solution</b>	0.3 at 200 g/l (literature value).
<b>Melting point</b>	192.00 - 202.00 °C
<b>Initial boiling point and boiling range</b>	No information available as testing has not been completed.
<b>Flash point</b>	Not applicable - The product is a solid.
<b>Evaporation rate</b>	No information available as testing has not been completed.
<b>Flammability state</b>	Not classified as flammable.
<b>Flammability limit - lower(%)</b>	No information available as testing has not been completed.
<b>Flammability limit - upper(%)</b>	No information available as testing has not been completed.
<b>Vapour pressure</b>	No information available as testing has not been completed.
<b>Vapour density (air=1)</b>	No information available as testing has not been completed.
<b>Relative density</b>	1.331g/cm <sup>3</sup> @ 20.00 °C (literature value).
<b>Bulk density</b>	No information available as testing has not been completed.
<b>Solubility</b>	Soluble in water.
<b>Decomposition temperature</b>	No information available as testing has not been completed.
<b>Partition coefficient; n-Octanol/Water</b>	No information available as testing has not been completed.
<b>Auto ignition temperature (°C)</b>	No information available as testing has not been completed.
<b>Viscosity</b>	Not applicable - The product is a solid.
<b>Explosive properties</b>	Not classified as explosive.

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**Oxidising properties** The product does not meet the criteria to be classified as oxidising.

## 9.2 Other information

**Molecular weight** 232.30g/mol

**Volatile organic compound** No information available as testing has not been completed.

**Other information** None noted.

## Section 10: Stability and reactivity

### 10.1 Reactivity

**Reactivity** Stable under recommended transport or storage conditions. See section 10.3 for further information.

### 10.2 Chemical stability

**Stability** Stable under normal temperature conditions and recommended use.

### 10.3 Possibility of hazardous reactions

**Hazardous reactions** Dust clouds may be explosive.

**Hazardous polymerisation** None under normal processing.

**Polymerisation description** Not applicable.

### 10.4 Conditions to Avoid

**Conditions to avoid** Avoid heat, flames and static discharge and sparks. Fine powder or dust dispersed in air in a confined space. Avoid exposure to direct sunlight. Protect from moisture. Hygroscopic.

### 10.5 Incompatible materials

**Materials to avoid** Avoid strong oxidising substances and strong bases.

### 10.6 Hazardous decomposition products

**Hazardous decomposition products** Decomposition products can include and are not limited to: Oxides of carbon. Sulfur oxides.

## Section 11: Toxicological information

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

**Toxicological information** Not classified based on available information.

**Acute toxicity (Oral LD50)** No information available as testing has not been completed.

**Acute toxicity (Dermal LD50)** No information available as testing has not been completed.

**Acute toxicity (Inhalation LD50)** No information available as testing has not been completed.

**Serious eye damage/irritation** Causes serious eye damage.

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<b>Skin corrosion/irritation</b>	The product is classified as a skin corrosion/irritation hazard.
<b>Respiratory sensitisation</b>	The product is not classified as a respiratory hazard.
<b>Skin sensitisation</b>	The product is not classified as a skin sensitisation hazard.
<b>Germ cell mutagenicity</b>	The product is not classified as a mutagen.
<b>Carcinogenicity</b>	The product is not classified as a carcinogen hazard.
<b>Specific target organ toxicity - Single exposure:</b>	
<b>STOT - Single exposure</b>	The product is not classified as a single exposure specific target organ toxin.
<b>Specific target organ toxicity - Repeated exposure:</b>	
<b>STOT - Repeated exposure</b>	The product is not classified as a repeat exposure specific target organ toxin.
<b>Inhalation</b>	Corrosive and irritating to upper respiratory tract and mucous membranes. May cause cough, shortness of breath, sore throat and labored breathing. Risk of delayed pulmonary oedema.
<b>Ingestion</b>	If ingested, product may cause severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. May cause nausea or vomiting.
<b>Skin contact</b>	Causes severe skin burns.
<b>Eye contact</b>	Causes serious eye damage.
<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
<b>Routes of entry</b>	Eye and skin contact, ingestion or inhalation.
<b>Target organs</b>	Eyes, skin, digestive system, respiratory system.
<b>Aspiration hazards:</b>	The product is not classified as an aspiration hazard.
<b>Reproductive toxicity:</b>	The product is not classified as a reproductive hazard.

## 11.2 Information on other hazards

**Information on other hazards** None known.

## Section 12: Ecological information

### 12.1 Toxicity

<b>Acute toxicity - Fish</b>	No information available as testing has not been completed.
<b>Acute toxicity - Aquatic invertebrates</b>	No information available as testing has not been completed.
<b>Acute toxicity - Aquatic plants</b>	No information available as testing has not been completed.
<b>Acute toxicity - Microorganisms</b>	No information available as testing has not been completed.
<b>Chronic toxicity - Fish</b>	No information available as testing has not been completed.
<b>Chronic toxicity - Aquatic invertebrates</b>	No information available as testing has not been completed.
<b>Chronic toxicity - Aquatic plants</b>	No information available as testing has not been completed.
<b>Chronic toxicity - Microorganisms</b>	No information available as testing has not been completed.
<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Eco toxicological information</b>	The product may affect the acidity (pH-factor) in water with risk of harmful

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effects to aquatic organisms.

## 12.2 Persistence and degradability

<b>Degradability</b>	No information available as testing has not been completed.
<b>Biological oxygen demand</b>	No information available as testing has not been completed.
<b>Chemical oxygen demand</b>	No information available as testing has not been completed.

## 12.3 Bioaccumulative potential

<b>Bioaccumulative potential</b>	No information available as testing has not been completed.
<b>Bioaccumulation factor</b>	No information available as testing has not been completed.
<b>Partition coefficient; n-Octanol/Water</b>	No information available as testing has not been completed.

## 12.4 Mobility in soil

<b>Mobility</b>	No information available as testing has not been completed.
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## 12.5 Results of PBT and vPvB assessment

<b>Results of PBT and vPvB assessment</b>	The product does not contain any PBT or vPvB substances.
---	--

## 12.6 Endocrine disrupting properties

<b>Endocrine disrupting properties</b>	The product does not contain any substances with endocrine disrupting properties at a concentration above or equal to 0.1%.
--	---

## 12.7 Other adverse effects

<b>Other adverse effects</b>	None known.
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## Section 13: Disposal considerations

<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
-------------------------	--

## 13.1 Waste treatment methods

<b>Disposal methods</b>	Contact a licensed professional waste disposal service. Dispose of waste and residues in accordance with local authority requirements, and in accordance with all local, national and international regulations.
-------------------------	--

## Section 14: Transport information

### 14.1 UN number or ID number

<b>UN no. (ADR)</b>	UN3261
<b>UN no. (IMDG)</b>	UN3261
<b>UN no. (IATA)</b>	UN3261

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## 14.2 UN proper shipping name

<b>ADR proper shipping name</b>	CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S. (2-oxobornane-10-sulphonic acid)
<b>IMDG proper shipping name</b>	CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S. (2-oxobornane-10-sulphonic acid)
<b>IATA proper shipping name</b>	CORROSIVE SOLID, ACIDIC, ORGANIC N.O.S. (2-oxobornane-10-sulphonic acid)

## 14.3 Transport hazard class(es)

<b>ADR class</b>	8
<b>IMDG class</b>	8
<b>IATA class</b>	8

**Transport labels**



## 14.4 Packing group

<b>ADR/RID/ADN packing group</b>	II
<b>IMDG packing group</b>	II
<b>IATA packing group</b>	II

## 14.5 Environmental hazards

<b>ADR</b>	No
<b>IMDG</b>	No
<b>IATA</b>	No

## 14.6 Special precautions for user

<b>EMS</b>	F-A, S-B
<b>Emergency action code</b>	A3 A803
<b>Hazard no. (ADR)</b>	80
<b>Tunnel restriction code</b>	(E)

## 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

## Section 15: Regulatory information

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

<b>EU legislation</b>	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments. The UN Globally Harmonized System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 2020/878 of 18 June 2020 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
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**Approved code of practice** 2021 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019)

## 15.2 Chemical safety assessment

**Chemical safety assessment** No chemical safety assessment has been carried out.

### International Inventories

EINECS/ELINCS/NLP	2-oxobornane-10-sulphonic acid
DSL/NDSL	2-oxobornane-10-sulphonic acid
TSCA	2-oxobornane-10-sulphonic acid
KECI	2-oxobornane-10-sulphonic acid
IECSC	2-oxobornane-10-sulphonic acid
ENCS	2-oxobornane-10-sulphonic acid
PICCS	Not listed.
AICS	2-oxobornane-10-sulphonic acid

## Section 16: Other information

<b>General information</b>	This Safety Data Sheet is in accordance with REACH Annex II, (EC) No 2020/878.
<b>Revision comments</b>	[1]Information updated. [4]Information updated. [7]information updated. [8]Code of practice updated. [9]Information updated. [10]Information updated. [11]Information updated. [12]Information updated. [15]Information updated. [16]Information updated.
<b>Revision date</b>	15 February 2022
<b>Revision</b>	3.1
<b>Safety data sheet status</b>	Approved.

## Hazard statements in full

**H314** Causes severe skin burns and eye damage.

### Disclaimer

This 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. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use. Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations. The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions. It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations. The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.



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

### 1.1. Product identifier

**Product Name** PF-07841770  
**Product Code(s)** PF00295  
**Synonyms** ARV-471-2a  
**Trade Name:** Not established  
**Chemical Family:** Not determined  
**PF-07841770**  
CAS No -

### 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

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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-07841770 -	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

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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

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**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)

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**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	C <sub>26</sub> H <sub>38</sub> N <sub>4</sub> O <sub>6</sub>
Molecular weight	502.61

#### 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

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## 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)

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Predicted 7.4 Log D 2.074

## 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

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**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

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

**PF-07841770**

Predicted 7.4 Log D 2.074

### 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.

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## 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-07841770

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	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

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**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.**



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

### 1.1. Product identifier

Product Name	PF-07868399-BW
Product Code(s)	PF00293
Synonyms	ARV-471-2
Trade Name:	Not established
Chemical Family:	Not determined
PF-07868399-BW CAS No	PROPRIETARY

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

Recommended Use	Pharmaceutical process intermediate
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### 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

Not classified as hazardous

OSHA Classification Physical Hazard	Combustible Dust
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### 2.2. Label elements

Signal word	Warning
-------------	---------

Hazard statements	May form combustible dust concentrations in air
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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

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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-07868399-BW 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

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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

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**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** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

## 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)

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**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	C27H36N4O7S
Molecular weight	560.67

#### Property

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

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## 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

DSC: Exotherm of -26 J/g at 296 °C.

## 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.

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**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**

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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.

## Section 15: REGULATORY INFORMATION

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

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<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	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

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## **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** 22-Mar-2022

**Prepared By** Pfizer Global Environment, Health, and Safety

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