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.

29-Sep-2024

Ref. IE Licence Register Number P0013-06 (Pfizer Ringaskiddy)

Re: For Agency Approval: Update to site inventory of materials: Atirmociclib Step 1-2, sidechain 1 and sidechain 2

Dear Sir/Madam,

In accordance with Condition 1.4, we request Agency approval to use the following new materials for the manufacture of Atirmociclib Steps 1-2, Sidechain 1 and Sidechain 2:

- Potassium Pivalate
- PF-07845900-06
- CDX-92 (ATA-518) Lyophilized Enzyme Powder
- (R)-(+)-1-Phenylethylamine
- PF-07817173-09

It's intended that these steps will be initially manufactured in the OSP4 production facility.

There will be ***no environmental impact*** resulting from the use of these materials. Table 1 provides an overview of the environmental assessment. Additional detail of the environmental assessment is documented in later sections of this letter.

Table 1: Environmental impact overview

Environmental Impact	***Environmental Impact [Yes/No]***	***Comment***
Impact on emissions to Air	*No***	All new materials are either solids or non-volatile liquids. The solvents used in these manufacturing processes are already approved and routinely used on site.
Impact on emissions to Sewer	*No***	No process waste streams that can have an environmental impact will be routed to the on-site wastewater treatment plant
Impact on emissions to Surface water	*No***	All drains within the manufacturing / storage / waste facilities are process drains and routed to the on-site waste-water treatment plant.
Impact on Storage Facilities	*No***	Sufficient dedicated storage areas available for the storage of solids and liquids including waste materials.
Impact on Fire water retention Capacity	*No***	No impact on fire water retention capacity. Fire water retention capacity available and site is constructing an additional 7,000m^3 capacity.

*** There is no environmental impact from the introduction of the new materials for use in OSP4 or any of the production facilities on site.*

The SDS for the new materials are attached in Appendix 1. PF-078459900-06 and PF-07817173-09 are not classified as hazardous according to Regulation (EC) 1272/2008. Potassium Pivalate is assigned the hazard phrases H302, H315, H319 and H335. CDX-92 (ATA Lyophilized Enzyme Powder) is assigned the hazard phrase H334 and (R)-(+)-1-Phenylethylamine is assigned the hazard phrases H302, H312 and H314. These hazard phrases are assigned to materials which are routinely used so no new hazard phrases are being added to the inventory of materials.

To manufacture the above steps other materials/solvents are used and these include: PF-07227325, Bis(neopentyl Glycolato)Biboron, sodium chloride, Bis(Triphenylphosphine)(Pallaidum(II) Dichloride, 2,4,5-trichlorophyrimidine, PF-07229478, potassium carbonate, Pyridoxal Phosphate Hydrate (PLP), Arbocel, Phosphoric acid, potassium hydroxide and 5% Palladium on carbon. Solvents used are 2-methyltetrahydrofuran, isopropanol, n-Butanol and acetic acid. All of these materials are pre-approved for use and are in routine use.

The manufacture of the above steps is scheduled for OSP4. 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 across the production plants. Therefore, manufacturing plan and batch size will vary during the course of a products lifetime depending on equipment availability and market demand. Equipment trains

are regularly change over and configured to the next scheduled production based on detailed production plans which forecast market demand over extended time periods. The unit operations to manufacture these products are no different to manufacturing any of our existing products.

Irrespective of the manufacturing plant and volume, there will be no environmental impact resulting from the manufacture of these steps explained as follows:

Impact on air emissions:

There will be no new emissions to air resulting from this process. Only solvents / volatile materials used in the process may be routed to the vessel headspace and onto the vent header and abatement system within each manufacturing plant. Depending on their volatility, vapours may be routed to the headspace. We confirm that the solvents used in Atirmociclib Step 1-2 (2-methyltetrahydrofuran, isopropanol), Sidechain 1 (n-butanol, 2-propanol) and Sidechain 2 (2-propanol, acetic acid) are previously approved by the Agency and routinely used on site. These solvents are volatile and vapours will be routed to the vent header and VOC abatement system in OSP4. The existing air emissions abatement systems servicing all manufacturing buildings are capable of handling the emissions from these materials explained as follows.

These steps will be initially manufactured in OSP4. Air emissions from this process and all processes in the OSP4 manufacturing facility are managed by the existing Thermal Oxidiser in 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 OSP1, OSP3, OSP4 or OSP5 manufacturing facilities, air emissions will be managed by the existing OSP1, OSP3, OSP4 or OSP5 abatement systems. OSP3 VOC Absorption System is the main VOC emission abatement systems for OSP3 and OSP5, and the OSP1 VOC Absorption system is the main abatement system for OSP1 and RCMF. The Thermal Oxidiser is the main abatement system for OSP4. Treated emissions from the OSP1/ RCMF, OSP3 / OSP5 and OSP4 abatement systems are directed to atmosphere via the licensed emission points A2-2 [V3], A2-4 [V5] and A2-5 [V13] respectively which are continuously monitored.

In the case of the VOC Absorption Plants serving OSP3 / OSP5 and OSP1/RCMF, 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). 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 these steps 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.

In the case of OSP4, abatement is provided by a flameless thermal oxidiser. Similar to OSP1 and OSP3, all reaction vessels are fitted with condensers to minimise the carry-over of solvent into the header. 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 these steps 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.

The manufacture of these steps can therefore take place fully within the existing design envelope of the VOC Absorption Plants and the flameless thermal oxidiser, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

Tables 2, 3 and 4 identify the solvents / volatile materials used in the processes and their associated ELV's for A2-2 [V3], licensed emissions point for OSP1 and RCMF, A2-4 [V5] licensed emissions point for OSP3 and OSP5 and A2-5 [V13] licensed emissions point for OSP4 respectively. The abatement system in OSP1 / OSP3 are governed by the TA Luft standard and OSP4 is governed by a Total Organic Carbon emission limit.

Table 2: 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 [2023]	Ringaskiddy average kg/hr [2022]
None	I	20mg/m3 (at mass flows >0.1 kg/hr)	0.00021 kg/hr	0.00022 kg/hr
2-methyl Tetrahydrofuran, acetic acid	II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00023 kg/hr	0.00016 kg/hr
Isopropanol (2-propanol), n-butanol	III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00036 kg/hr	0.00065 kg/hr

Table 3: 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 [2023]	Ringaskiddy average kg/hr [2022]
None	I	20mg/m3 (at mass flows >0.1 kg/hr)	0.00064 kg/hr	0.00041 kg/hr
2-methyl Tetrahydrofuran, acetic acid	II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00102 kg/hr	0.00041 kg/hr

Isopropanol (2-propanol), n-butanol	III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00143 kg/hr	0.00050 kg/hr

Table 4: A2-5 [V13]: ELV for TOC for licensed emission point from OSP4 Operations

Parameter	Emission Limit Value [ELV] 30-minute mean (mg/m^3)	Ringaskiddy average 30-minute mean mg/m^3 [2023]	Ringaskiddy average 30-minute mean mg/m^3 [2022]
Volatile organic compounds *(excluding Particulate matter)* expressed as total organic carbon	20 mg/m^3	0.62 mg/m3	0.47mg/m3

Tables 2, 3 and 4 above provide a summary of the annual emissions data from A2-2 [V3], A2-4 [V5] and A2-5 [V13], from 2022 and 2023 and all emissions from the OSP1, OSP3 and OSP4 air emissions abatement systems comply with the relevant ELV's. The solvents used in this process are routinely used and historical data confirms 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 these new materials will not impact on emissions to sewer. We confirm that no process waste stream that can have an environmental impact will be routed to the wastewater treatment plant, WWTP. All of the production facilities including OSP4 facility have dedicated mother liquor tanks to collect waste streams from the processes. Waste streams will be segregated and sent to Production Services for final processing but no process waste stream that can have an environmental impact will be treated in the WWTP. Aqueous based waste streams that can have an environmental impact will be sent off site for suitable treatment by the approved waste management broker. 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. Identical to other production facilities, OSP4 has a dedicated weak effluent vessel which will collect floor washings etc. and these will be transferred to the WWTP via the effluent system and discharged at SE1 [TE1] in accordance with the requirements of the licence.

Impact on emissions to surface water:

There will be no emissions to surface water resulting from the manufacture of these product steps. 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 UN approved 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, drum laydown area or RCMF 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 these new product steps do not have any impact on fire water retention capacity. The materials in question do not change the profile of materials being introduced, and no new hazard phrases are introduced. The new materials don't change the risk rating of the site.

Conclusion

In summary, we request Agency approval to use the above listed materials on site. There will be no environmental impact resulting from the manufacture of Atirmociclib Step 1-2, Sidechain 1 and Sidechain 2 on-site.

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.

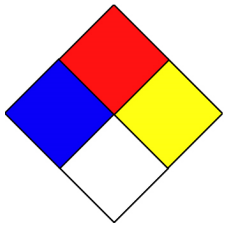
Yours sincerely,

Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant

Geraldine Rooney

Geraldine Rooney
Environment, Health and Safety Department

Appendix 1: SDS of materials



Health
Fire
Reactivity
Personal Protection

An ISO 9001:2015 Company

SAFETY DATA SHEET

Potassium pivalate

Section 1: Chemical Product and Company Identification

ID: P36605

Name: Potassium pivalate

CAS: 19455-23-3

RTECS: Not Available

TSCA: Not TSCA regulated

Alt Name: NA

Chemical Formula: C5H9KO2

Contact Information:

Synthonix, Inc.
2713 Connector Drive
Wake Forest, NC 27587

Ph: 1-919-875-9277

CHEMTREC (24HR EMERGENCY TELEPHONE), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

Section 2: Hazards Identification

GHS Label elements, including precautionary statements:

Signal Word: Warning

Acute toxicity, oral (Category 4) - H302
Skin corrosion/irritation (Category 2) - H315
Serious eye damage/eye irritation (Category 2A) - H319
Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3) - H335

Pictogram

Hazard statement(s)
H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation

Precautionary statement(s)
P261 - Avoid breathing dust/fumes/gas/mist/vapours/spray.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: call a POISON CENTER/doctor/... IF you feel unwell.
P302+P352 - IF ON SKIN: wash with plenty of water.
P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 3: Composition

Composition:

Name:	CAS #	% by Weight
Potassium pivalate	19455-23-3	100%

Section 4: First Aid Measures

Eye Contact:

In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes.

Skin Contact:

In case of contact, immediately wash skin with soap and copious amounts of water.

Serious Skin Contact:

In case of contact, immediately wash skin with soap and copious amounts of water. Seek medical attention immediately.

Inhalation:

If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

Serious Inhalation:

Not available

Ingestion:

If swallowed, wash out mouth with water provided person is conscious. Call a physician. Wash contaminated clothing before reuse.

Serious Ingestion:

Not available

Section 5: Fire and Explosion Data

Flammability of the Product: Not available

Auto-Ignition Temperature: Not available

Flash Point: Not available

Flammable Limit: Not available

Products of Combustion: Not available

Fire Hazards in Presence of Various Substances: Not available

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available

Risks of explosion of the product in presence of static discharge: Not available

Fire Fighting Media and Instructions: N/A

Special Remarks on Fire Hazards:

Not available

Special Remarks on Explosion Hazards:

Not available

Section 6: Accidental Release Measures

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container.

Large Spill:

Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions: For precautions see section 2

Storage: Keep container tightly closed. Keep container in a well-ventilated area at room temperature. Moisture sensitive.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Splash goggles. Synthetic apron. Vapor and dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Vapor and dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:

Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid

Odor: Not available.

Taste: Not available.

Molecular Weight: 140.2229 g/mole

Color:

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not available.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility:

Not available.

Section 10: Stability and Reactivity Data

Stability: Not available.

Instability Temperature: Not available.

Conditions of Instability:
Excess heat, incompatible materials, moisture. May decompose on contact with moist air or water.

Incompatibility with various substances: Not available.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Not available.

Special Remarks on Corrosivity:
Not available.

Polymerization: Not available.

Section 11: Toxicological Information

Routes of Entry: Unknown.

Toxicity to Animals: Not available.

Chronic Effects on Humans:
Not available.

Other Toxic Effects on Humans:
Not available.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:
Not available.

Special Remarks on other Toxic Effects on Humans:
Not available.

Section 12: Ecological Information

Ecotoxicity Not available.

BOD5 and Not available.

Products of Biodegradation:
Unknown

Toxicity of the Products of Biodegradtion: Not available.

Special Remarks on the Products of Biodegradation:
Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not regulated by IATA

Identification:
Not available

Special Provisions for Transport: Not available.

Section 15: Other Regulatory Information

Federal and State Regulations:
Not Available.

Other Regulations: Not Available.

Other Classifications: Not Available.

WHMIS (Canada):
Not Available.

DSCL (EEC):
Not Available.

HMIS (U.S.A.):

Health Hazard:	Not Available
Fire Hazard:	Not Available
Reactivity:	Not Available
Personal Protection:	Not Available

National Fire Protection Association (U.S.A.):

Health:	Not Available
Fire:	Not Available
Reactivity:	Not Available
Specific Hazard:	Not Available

Protective Equipment:
Not Available

Section 16: Other Information

References: N/A

Other Special Considerations: N/A

Created: 12/08/2022 **Last Updated:** 12/8/2022

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Synthonix, Inc. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Synthonix, Inc. has been advised of the possibility of such damages.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07845900-06

Product Code(s) PF00518
Trade Name: Not established
Chemical Family: Not determined

PF-07845900-06
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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning (OSHA)

Hazard statements OSHA - 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-07845900-06 (CAS #: -)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

Additional information - Not Assigned
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 Fine particles (such as dust and mists) may fuel fires/explosions.

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

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

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 active.

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 any 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	C12 H15 K O6 S
Molecular weight	326.40

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	Soluble in water
Solubility(ies)	Partly soluble: Alcohols
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:	Endotherm of 38 J/g at 137 °C. Exotherm of -12 J/g at 209 °C and -89 J/g at 238 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No data available.
10.2. Chemical stability
Stability Hygroscopic.
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.
Acute toxicity Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

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

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

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

Section 15: REGULATORY INFORMATION

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

PF-07845900-06

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	11-Jan-2023
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.

PHARMACEUTICAL SCIENCES	STANDARD OPERATING PROCEDURE FORM/TEMPLATE
Pfizer	TITLE: **Receipt Inspection Form**
	NUMBER AND VERSION: **SOP-MAT-00222-F01 V6.0**
	PAGE: **1 OF 1**

SECTION A:	1. Vehicle transport compartment free of damage, debris, pests and/or contamination? N/A ☐ Yes ☑ No ☐*	2. Date Received: (DD-MMM-YEAR) 01 NOV 2023	3. Time Received: (HHMM) 09:15	4. Site Received: SANDWICH-1

5. Reference or insert Receipt photo(s) if applicable ☑ N/A

6. Material Name (Per Suppliers/ Manufacturers Label): See Photo ☐	7. Part Number(s): See Photo ☐
ATA-518	N/A.

8. Expiration or review date on Label: See Photo ☐	9. Batch Number on Label:	10. Storage Condition on label: See Photo ☐
N/A	PF1352	-20°C

11. Name/Location of Supplier Per Label on Containers	See Photo ☐
	CODEXIS – U.S.A.

12. List all Containers Types, Quantities & the Total Quantity received:

1x Foil Bag of 15kg Net
1x Foil Bag of 5kg Net

TOTAL Net Weight :20kg

Inspection of Container(s), Tamper evidence and documentation	N/A	YES	NO
13. Are material containers sealed and free of damage, debris, pest(s) and/or contamination? Note damage to Shipping Containers in the comments section, take photos if necessary.		☑	☐*
14. Are Tamper Evident Seals intact?	☐	☑	☐*
15. If the Tamper Evident Seals are numbered, do the numbers match shipping documentation?	☑	☐	☐*
16. Does material match supplier shipping docs/purchase order/Item Specification? (Part #, Quantity, Description, batch #)		☑	☐*
17. Required documentation available? E.g. CofA/CofC, packing slip. (If no; contact material requestor for documentation)		☑	☐*
18. Was a temperature monitoring device included in the shipment?		☑	☐
19. Are the serial numbers documented on the shipping documentation? (if No, add the serial numbers to comments section).	☐	☐	☑*
20. Can the Temperature Monitor device be downloaded? (if No, add the return contact information in the comments box)	☐	☑	☐*

21. Shipping Conditions:	22. Temperature-controlled shipping Solution:
☐ Ambient/CRT ☐ Dry Ice ☑ -20°C ☐ 2 to 8°C ☐ Liq Nitrogen ☐ Other *	☑ Passive solution - (non-automated container) ☐ Active solution - (automated container) ☐ N/A (not shipped in a temperature-controlled shipping solution)

23. Comments: (* = enter details here)

☐ N/A -

Temp Tale 924279909
Serial N° MDT6T00090

24. Any issues that require QA notification/guidance? If yes, QA Sign & Date (DD-MMM-YEAR):	No ☑ Yes ☐
25. Name (Print)	26. Signature: Section A is a true & accurate record (Sign & Date (DD-MMM-YEAR))
JOHN DEANE	J. Deane 01 NOV 2023

SECTION B: CAIS receipt (To be completed following data entry into the CAIS)

27. Item ID	28. Inventory system to be received into	29. Batch number:
AR-00787	☑ AXIS 360 ☐ Other	23-AR-01940

30. CAIS receipt and labelled by: (Sign & Date (DD-MMM-YEAR))	J. Deane 01 NOV 2023	31. CAIS data entry, label review and receipt documentation reviewed by: (Sign & Date (DD-MMM-YEAR))	S. Neits 02 NOV23

CODEXIS®

Codexis, Inc.
200 Penobscot Drive
Redwood City, CA 94063
Tel: +1 650.421.8100
Fax: +1 650.421.8102
www.codexis.com

Certificate of Analysis

ATA-518
Lyophilized Enzyme Powder
CAS #: 61461-61-8

Lot Number: PF1352
Date of Manufacture: 22 September 2023
Manufacturer: Lactosan GmbH & Co. KG, Industriestrasse West 5, A-8605 Kapfenberg, Austria, on behalf of Codexis, Inc.
Storage Conditions: -20 °C
Retest Date: N/A

TEST	RESULT
Conversion	55%

Quality Assurance: DocuSigned by: Angel Hook

Signer Name: Angel Hook
Signing Reason: I approve this document
Signing Time: 11-Oct-23 | 4:02:57 PM PDT
AB74187F49E54DC484EC344FCC54DEEF

Date: 11-Oct-23 | 4:03:29 PM PDT

CODEXIS®

Codexis, Inc.
200 Penobscot Drive
Redwood City, CA 94063
Tel: +1 650.421.8100
Fax: +1 650.421.8102
www.codexis.com

TSE/BSE Certificate

Product: ATA-518
Lot Number: PF1352
Date of Manufacture: 22 September 2023

Method of Production: By fermentation of recombinant lab strains of *Escherichia Coli*.

All materials used in the manufacture of this product are stated by the suppliers to be of non-animal origin and non-human origin. Product has not come in contact with material of animal or human origin.

Quality Assurance: DocuSigned by: Angel Hook Date: 11-Oct-23 | 4:03:29 PM PDT

Signer Name: Angel Hook
Signing Reason: I approve this document
Signing Time: 11-Oct-23 | 4:03:03 PM PDT
AB74187F49E54DC484EC344FCC54DEEF

TempTale® Ultra Dry Ice

Serial #: MDT6T00JG0

Alarm Status

OK

Monitor Configuration

Start Up Delay:	30 min	Interval:	5 min

Monitor Read

On :	2023-11-01 9:48:47 AM	By :	TempTale® Ultra Dry Ice
Note:	All Times in GMT		

Recorded Data

First Point:	2023-10-31 6:18:27 AM
Stop Time	2023-11-01 9:39:04 AM
Number of Points:	329
Trip Length:	1 day 3 hr 25 min

Summary Data

Low Extreme:	-80.9 °C @ 2023-10-31 8:33:27 PM
High Extreme:	-64.9 °C @ 2023-10-31 8:43:27 AM
Mean ± Std Deviation:	-76.6 °C ± 1.1 °C
Mean Kinetic Temperature:	-76.3 °C
Activation Energy:	83.144 kJ/mol

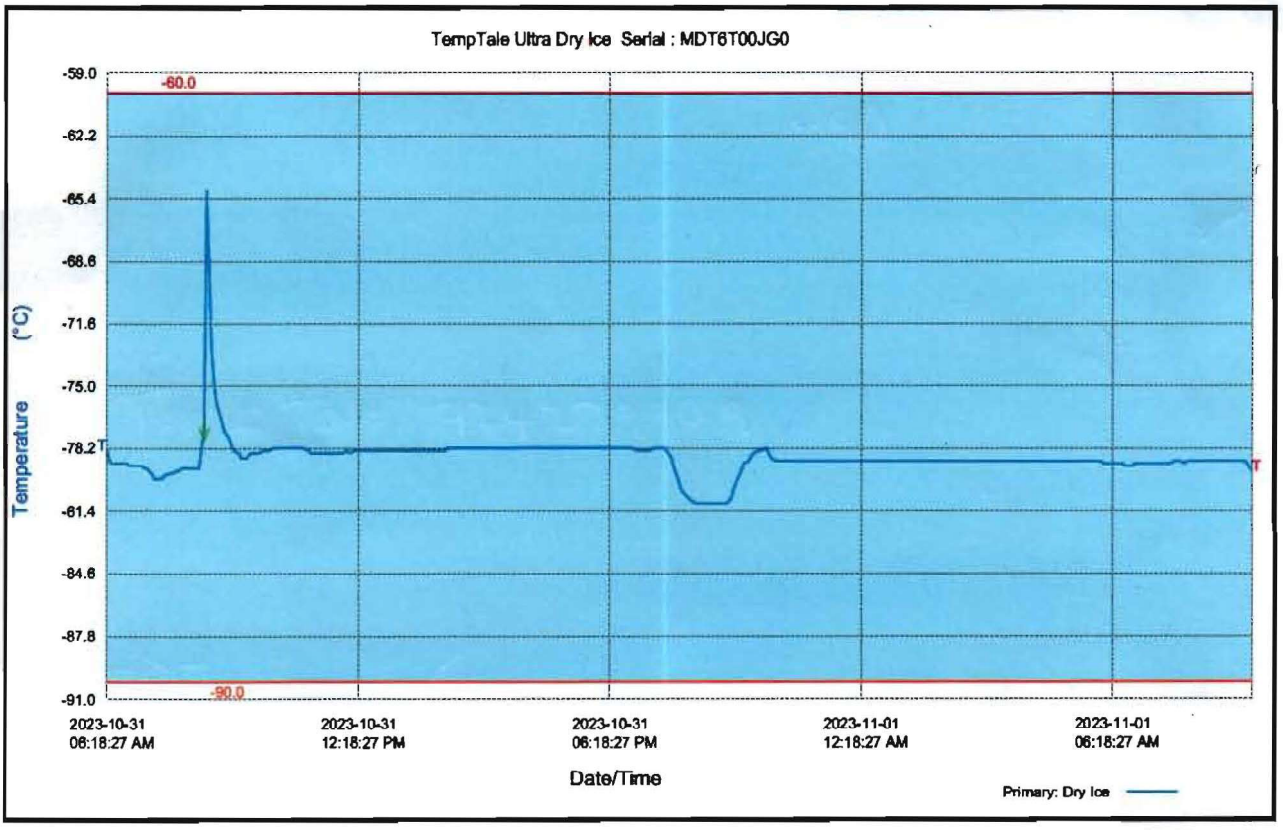
Alarm Summary

Alarm Data

Alarm	Alarms Settings	Degree Minutes	Threshold (Type)	Total Time	Number of Events	Triggered	Status
Ideal range	>=-90.0 °C <=-60.0 °C	–	Unlimited	1 d 3 h 25 m	1	–	–
Alarm 1	Over -60.0 °C	0.0 °C min	0 d 0 h 0 m (S/E)	0 d 0 h 0 m	0	–	OK
Alarm 2	Under -90.0 °C	0.0 °C min	0 d 0 h 0 m (S/E)	0 d 0 h 0 m	0	–	OK

Originator Notes:

HWB 924279909



Time and Temperature Report Created By: TempTale® Ultra Dry Ice

File Created: 2023-11-01 9:48:47 AM

ATA Lyophilized Enzyme Powder

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and OSHA 1910.1200

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product form	:	Mixture
Product	:	ATA Lyophilized Enzyme Powder
EINECS-No.	:	618-523-3
CAS-No.	:	61461-61-8
Type of product	:	Mixture - containing Enzyme
Formula	:	Proprietary
Synonyms	:	Amine Transamiase Enzyme, Amine Transaminase Enzyme, ATA-007, ATA-012, ATA-013, ATA-014, ATA-016, ATA-024, ATA-025, ATA-032, ATA-033, ATA-036, ATA-051, ATA-103, ATA-113, ATA-117, ATA-200, ATA-217, ATA-234, ATA-237, ATA-238, ATA-251, ATA-254, ATA-256, ATA-260, ATA-270, ATA-301, ATA-302, ATA-303, ATA-412, ATA-414, ATA-415, ATA-417, ATA-426, ATA-436, ATA-436-CT-HIS, ATA-436-NT-HIS, ATA-440, ATA-444, ATA-447, ATA-450, ATA-457, ATA-478, ATA-481-CT-HIS, ATA-485, ATA-486, ATA-490, ATA-492, ATA-493, ATA-494, ATA-496, ATA-498, ATA-499, ATA-500, ATA -503, ATA-513, ATA-518, ATA-P1-A01, ATA-P1-A06, ATA-P1-B04, ATA-P1-F03, ATA-P1-G05, ATA-P1-G06, ATA-P2-A01, ATA-P2-A07, ATA-P2-B01, ATA-PLATE1, ATA-PLATE2, ATA-PLATE3, ATASK-200250P, ATASK-201000P, ATASK-200250P-JAPAN.
Product group	:	Enzymes

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

1.2.1. Relevant identified uses

Catalyst enzyme for use in synthetic chemical process:	:	For research and development purposes only.

1.2.2. Uses advised against

Restrictions on use	:	No additional information available.

1.3. Details of the supplier of the safety data sheet

Codexis, Inc.
200 Penobscot Drive
Redwood City, CA 94063
Main: 1-650-421-8100
Fax: 1-650-421-8119
E-mail: SDS@codexis.com

1.4. Emergency telephone number

Emergency number	:	Codexis-Carechem 24 (24-hour availability): +1 (202) 464-2554 (USA and Canada) +44 1865 407333 (International; collect calls accepted) +86 512 8090 3042 (China)

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Respiratory sensitization, Category 1	:	H334

Full text of H- and EUH-statements: see Section 16.

Adverse physicochemical, human health and environmental effects

May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP: Classification, Labelling, Packaging.) :

GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements (CLP) : P261 - Avoid breathing dust.
P285 – In case of inadequate ventilation: Wear respiratory protection.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). This mixture is considered to be a chemical of unknown or variable composition, complex reaction product and biological material ("UVCB"). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

This mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Mixture contains an enzyme/protein that catalyzes reactions important for synthetic chemical processes. In a workplace setting, the likelihood of systemic effects following accidental ingestion or inhalation is low, due to the rapid breakdown of proteins in the digestive tract and the large molecular weight of the particles, respectively. However, proteins, in general, may cause respiratory sensitization and corresponding allergic reactions (e.g., potential to cause anaphylaxis). Allergic reactions have been associated with the clinical administration of recombinant human proteins.

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP] and GHS Classification
ATA Lyophilized Enzyme Powder	CAS-No.:61461-61-8	40–70	Resp. Sens. 1, H334

Comments : Only components with health hazards above the applicable thresholds and/or Exposure Limit values are shown.
The remaining components of the mixture are not hazardous and/or present at amounts below reportable limits.
The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

Full text of H- and EUH-statements: see Section 16.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

First-aid measures general : If exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation : If experiencing respiratory symptoms: Call a poison center or a doctor. Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

First-aid measures after skin contact : Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

First-aid measures after eye contact : If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

First-aid measures after ingestion : If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

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

Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

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

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing media : Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No information identified.

Explosion hazard : No information identified. High concentrations of finely divided organic particles can explode if ignited.

Hazardous decomposition products in case of fire : No information identified. May emit carbon monoxide, carbon dioxide, oxides of oxides of nitrogen, and other nitrogen-containing compounds.

5.3. Advice for firefighters

Firefighting instructions : In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : If Product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

Emergency procedures : Do not breathe dust.

6.1.2. For emergency responders

Protective equipment	: If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Emergency procedures	: Do not breathe dust.

6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Do not empty into drains. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other Sections

See Sections 8 and 13 for more information.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Precautions for safe handling	: Follow recommendations for handling bulk formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe dust.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store at -20 °C in tightly sealed containers. Protect against physical damage.

7.3. Specific end use(s)

Enzyme for use in synthetic chemical processes.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No information available.

8.1.2. Recommended monitoring procedures

No information available.

8.1.3. Air contaminants formed

No information available.

8.1.4. DNEL and PNEC

No information available.

8.1.5. Control banding

No information available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:
Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. EN166.

8.2.2.2. Skin protection

Skin and body protection:
Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. EN374.

8.2.2.3. Respiratory protection

Respiratory protection:
Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly fitted air-purifying respirator with particulate filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with particulate filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known or in any other circumstances where a lower level of respiratory protection may not provide adequate protection. EN 12941. EN143.

8.2.2.4. Thermal hazards

No information available.

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state	:	Powder
Color	:	White to colored
Appearance	:	Lyophilized powder
Odor	:	Not available.
Odor threshold	:	Not available.
Melting point	:	Not available.
Freezing point	:	Not available.
Boiling point	:	Not available.
Flammability	:	Not available.
Explosion limits	:	Not available.
Lower explosive limit (LEL)	:	Not available.

Upper explosive limit (UEL)	: Not available.
Flash point	: Not applicable.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
pH	: Not applicable.
pH solution	: Not available.
Viscosity, kinematic	: Not applicable.
Solubility	: Not available.
Log Kow	: Not available.
Vapor pressure	: Not applicable.
Vapor pressure at 50 °C	: Not applicable.
Molecular Mass	: 36 -50 kDa
Density	: Not available.
Relative density	: Not available.
Relative vapor density at 20 °C	: Not applicable.
Particle size	: Not available.
Particle size distribution	: Not available.
Particle shape	: Not available.
Particle aspect ratio	: Not available.
Particle aggregation state	: Not available.
Particle agglomeration state	: Not available.
Particle specific surface area	: Not available.
Particle dustiness	: Not available.

9.2. Other information

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

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions. Could form asymmetric amine from ketone and amine donor.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see Section 7).

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological Information

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

Acute toxicity (oral) : Not classified (Lack of data).

Acute toxicity (dermal)	: Not classified (Lack of data).
Acute toxicity (inhalation)	: Not classified (Lack of data).
Skin corrosion/irritation	: Not classified (Lack of data).
Serious eye damage/irritation	: Not classified (Lack of data).
Respiratory or skin sensitization	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified (Lack of data).
Carcinogenicity	: Not classified (Lack of data).
Reproductive toxicity	: Not classified (Lack of data).
STOT-single exposure	: Not classified (Lack of data).
STOT-repeated exposure	: Not classified (Lack of data).
Aspiration hazard	: Not classified (Lack of data).

11.2. Information on other hazards

No additional information available.

SECTION 12: Ecological Information

12.1. Toxicity

Ecology - general	: The environmental characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided.
Hazardous to the aquatic environment, short-term (acute)	: Not classified.
Hazardous to the aquatic environment, long-term (chronic)	: Not classified.
Additional information	: No data available.

12.2. Persistence and degradability

ATA Lyophilized Enzyme Powder (61461-61-8)

Persistence and degradability	: Protein, bacterial degradation may be expected.

12.3. Bioaccumulative potential

ATA Lyophilized Enzyme Powder (61461-61-8)

Bioaccumulative potential	: No data available.

12.4. Mobility in soil

No additional information available.

12.5. Results of PBT and vPvB assessment

No evidence that substance is PBT.
No evidence that substance is vPVB.

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties	: None known.

12.7. Other adverse effects

No additional information available.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Waste treatment methods : Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g, appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g, appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14: Transport Information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not regulated.
UN-No. (IMDG) : Not regulated.
UN-No. (IATA) : Not regulated.
UN-No. (ADN) : Not regulated.
UN-No. (RID) : Not regulated.

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated.
Proper Shipping Name (IMDG) : Not regulated.
Proper Shipping Name (IATA) : Not regulated.
Proper Shipping Name (ADN) : Not regulated.
Proper Shipping Name (RID) : Not regulated.

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not regulated.

IMDG
Transport hazard class(es) (IMDG) : Not regulated.

IATA
Transport hazard class(es) (IATA) : Not regulated.

ADN
Transport hazard class(es) (ADN) : Not regulated.

RID
Transport hazard class(es) (RID) : Not regulated.

14.4. Packing group

Packing group (ADR) : Not regulated.
Packing group (IMDG) : Not regulated.
Packing group (IATA) : Not regulated.
Packing group (ADN) : Not regulated.
Packing group (RID) : Not regulated.

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available.

14.6. Special precautions for user

Special transport precautions : Avoid release to the environment.

Overland transport
Not regulated.

Transport by sea
Not regulated.

Air transport
Not regulated.

Inland waterway transport
Not regulated.

Rail transport
Not regulated.

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions.
Contains no REACH candidate substance.
Contains no REACH Annex XIV substances.
Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. Safety, health and environmental regulation/legislations specific for the substance or mixture:
This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

15.1.3 WHMIS classification:
RS1: H334. This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.

15.1.4. TSCS status:
Not listed.

15.1.5. SARA Section 313:
Not listed.

15.1.6. California Proposition 65:
Not listed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other Information

Abbreviations and acronyms:	
	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Data sources : Information from published literature and internal company data.

Full text of H- and EUH-phrases:	
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitization, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Document Approval Record

Document Name:	23-AR-01940 Receipt Pack
Document Title:	23-AR-01940 ATA-518 ENZYME

Signed By:	Date(GMT)	Signing Capacity
Deane, John	02-Nov-2023 07:55:03	Author Approval
Long, James	06-Nov-2023 11:36:05	Verification of Electronic Image Completeness and Accuracy

CODEXIS®

Memorandum

From: **Diana Liem, Quality Assurance, Manager**

Subject: **GMO Declaration**

Date: **04 September 2024[A]**

Signed by:
Diana Liem
Signer Name: Diana Liem
Signing Reason: I approve this document
Signing Time: 04-Sep-24 | 3:54:41 PM PDT
07D226C756DF4788BD863DA5B4F79D16

Codexis CDX-092 Lyophilized enzyme powder is produced by fermentation of genetically modified strains of E. coli K12, which has a history of safe use in the manufacture of drugs, food enzymes, specialty chemical and large-scale industrial chemicals.

The production of CDX-092 enzyme powder includes unit operations that deactivate or kill the production organism and separate whole cells and cellular debris from the soluble enzyme. High pressure homogenization is used to disrupt the production organism's cell wall and release the soluble cytosolic enzyme from the cell for further recovery. The disruption of the cell wall effectively kills the organism. It is typical to realize greater than 95% breakage during homogenization.

The protein solution is concentrated by ultrafiltration and passed through a 0.2-micron filter (Filter type: "Sartopore 2XLG_5442507G3 from company "Sartorius") to remove microbial cells and any remaining solids larger than 0.2 microns.

This product is consequently not classified as a genetically modified material under the requirements of Directive 2009/41/EC on the contained use of Genetically Modified Organisms (GMOs).

Footnote A: Memo revised to clarify that solution is 0.2-micron filtered and therefore not classified as a genetically modified material.

200 Penobscot Drive, Redwood City, CA 94063 | Tel: +1 (650) 421-8100 Fax: +1 (650) 421-8102
www.codexis.com

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

1.1. Product identifier

(R)-(+)-1-Phenylethylamine

Further trade names

D-a-Methylbenylamine
Benzenemethanamine, a-methyl-, (aR)-
(R)-(+)-1-Phenylethylamine

REACH Registration Number:	01-2119978251-35-0002
CAS No:	3886-69-9
EC No:	223-423-4

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

Use of the substance/mixture

Identified uses:
Manufacture of fine chemicals.

Uses advised against

No information available.

1.3. Details of the supplier of the safety data sheet

Company name:	Reuter Chemische Apparatebau e.K.
Street:	Engesserstrasse 4b
Place:	D-79108 Freiburg
Telephone:	+49-(0)761-5596460
e-mail:	verwaltung@rca-separations.de
Contact person:	Dr. Karl Reuter

1.4. Emergency telephone number:

Intoxication: Giftnotruf Freiburg +49(0)761/19240
Transport: Consultank: +49(0)178/4337434

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: C - Corrosive, Xn - Harmful
R phrases:
Harmful in contact with skin and if swallowed.
Causes burns.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:
Acute toxicity: Acute Tox. 4
Acute toxicity: Acute Tox. 4
Skin corrosion/irritation: Skin Corr. 1B
Hazard Statements:
Harmful in contact with skin.
Harmful if swallowed.
Causes severe skin burns and eye damage.

2.2. Label elements

Signal word:	Danger
Pictograms:	GHS05-GHS07

Hazard statements

H302+H312	Harmful if swallowed or in contact with skin.
H314	Causes severe skin burns and eye damage.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Sum formula: C8H11N

Molecular weight: 121,18

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	GHS Classification	
REACH No		
223-423-4	(R)-(+)-1-Phenylethylamine	>99 %
3886-69-9	C - Corrosive, Xn - Harmful R21/22-34	
	Acute Tox. 4, Acute Tox. 4, Skin Corr. 1B; H312 H302 H314	
01-2119978251-35-0002		

Full text of R, H and EUH phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air. Seek medical attention if problems persist.

After contact with skin

After contact with skin, wash immediately with: Water. Subsequently wash off with: Polyethylene glykol 400. Remove contaminated, saturated clothing immediately. Medical treatment necessary.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Hazards identification:

Stomach perforation. Call a physician immediately. Do not allow a neutralisation agent to be drunk.

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

Coughing. Lung irritation. shortage of breath. vomiting. Headache. Dizziness.

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

No data available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Carbon dioxide (CO2). Foam. Extinguishing powder.

5.2. Special hazards arising from the substance or mixture

Vapours may form explosive mixtures with air.
In case of fire may be liberated: Nitrogen oxides (NOx). Carbon dioxide (CO2). Carbon monoxide

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Suppress gases/vapours/mists with water spray jet. Contaminated fire-fighting water must be collected separately. Do not allow to enter into surface water or drains.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Advice on protection against fire and explosion

Provide earthing of containers, equipment, pumps and ventilation facilities.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Storage class (D): 8A

7.3. Specific end use(s)

Manufacture of fine chemicals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. Exposure controls

Occupational exposure controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Protect skin by using skin protective cream. After work, wash hands and face. When using do not eat or drink.

Respiratory protection

If technical exhaust or ventilation measures are not possible or insufficient , respiratory protection must be worn.

Hand protection

Wear suitable gloves.
Thickness of glove material: Suitable gloves type:
Butyl rubber. 0,7 mm
penetration time (maximum wearing period): >420 min

Eye protection

Tightly sealed safety glasses.

Skin protection

Wear suitable protective clothing. Wash hands before breaks and after work.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless - light yellow
Odour:	Amines

		Test method
pH-Value:	No data available	
Changes in the physical state		
Melting point:	-10 °C	
Initial boiling point and boiling range:	188 °C	
Sublimation point:	No data available	
Softening point:	No data available	
Flash point:	70 °C	
Flammability		
Solid:	No data available	
Gas:	No data available	
Explosive properties		
No data available		
Lower explosion limits:	No data available	
Upper explosion limits:	No data available	
Ignition temperature:	355 °C	
Auto-ignition temperature		

Solid:		No data available
Gas:		No data available
Vapour pressure: (at 20 °C)		0,7 hPa
Vapour pressure:		No data available
Density:		0,952 g/cm³
Water solubility: (at 20 °C)		42 g/L
Partition coefficient:	No data available	
Viscosity / dynamic:		No data available
Viscosity / kinematic:		No data available
Flow time:		No data available
Vapour density:		No data available
Evaporation rate:		No data available
Solvent content:		No data available

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Formation of explosive mixtures with: Air.

10.2. Chemical stability

luftempfindlich

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Conditions to avoid: acid. Oxidizing agents, strong. Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

10.5. Incompatible materials

Acid. Acid chlorides, inorganic.Oxidizing agents, strong. Carbon dioxide (CO2).

10.6. Hazardous decomposition products

For decomposition products formed under fire conditions see chapter 5.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicocinetics, metabolism and distribution

No data available

Acute toxicity

Acute toxicity, oral. Acute toxicity, dermal.

CAS No	Chemical name			
	Exposure route	Method Dose	Species	h
3886-69-9	(R)-(+)-1-Phenylethylamine			
	Acute oral toxicity	ATE 500 mg/kg		
	Acute dermal toxicity	ATE 1100 mg/kg		

Specific effects in experiment on an animal

No data available

Irritation and corrosivity

after ingestion: Irritation and etching. Hazards identification: Stomach perforation.

Sensitising effects

No data available

Severe effects after repeated or prolonged exposure

Irritant effect on the respiratory tract: Serious eye damage/eye irritation: Causes skin irritation. Coughing. shortage of breath. Headache.

Carcinogenic/mutagenic/toxic effects for reproduction

No data available

Additional information on tests

The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

Empirical data on effects on humans

No data available

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

Further information

Do not allow to enter into surface water or drains. The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	UN2735
14.2. UN proper shipping name:	AMINES, LIQUID, CORROSIVE, N.O.S. ((R)-1-Phenylethylamin)
14.3. Transport hazard class(es):	8
14.4. Packing group:	II
Hazard label:	8

Classification code:	C7
Special Provisions:	274
Limited quantity:	1 L
Transport category:	2
Hazard No:	80
Tunnel restriction code:	E

Other applicable information (land transport)

E2

Marine transport (IMDG)

14.1. UN number:	2735
14.2. UN proper shipping name:	AMINES, LIQUID, CORROSIVE, N.O.S. ((R)1-Phenylethylamine)
14.3. Transport hazard class(es):	8
14.4. Packing group:	II
Hazard label:	8

Special Provisions:	274
Limited quantity:	1 L
EmS:	F-A, S-B

Other applicable information (marine transport)

E0

Air transport (ICAO-TI/IATA-DGR)

UN/ID number:	UN2735
14.2. UN proper shipping name:	AMINES, LIQUID, CORROSIVE, N.O.S. ((R)1-Phenylethylamine)
14.3. Transport hazard class(es):	8
14.4. Packing group:	II
Hazard label:	8

Special Provisions:	A3 A803
Limited quantity Passenger:	0.5 L
IATA-packing instructions - Passenger:	851
IATA-max. quantity - Passenger:	1 L
IATA-packing instructions - Cargo:	855
IATA-max. quantity - Cargo:	30 L

Other applicable information (air transport)

E2

: Y840

14.6. Special precautions for user

See protective measures under point 7 and 8.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

SECTION 16: Other information

Relevant R phrases (number and full text)

21/22	Harmful in contact with skin and if swallowed.
34	Causes burns.

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H302+H312	Harmful if swallowed or in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07817173-09

Product Code(s) PF00785
Trade Name: Not established
Chemical Family: Not determined

PF-07817173-09
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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word (OSHA) Warning

Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

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

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all

cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07817173-09 (CAS #: -)	0		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

Additional information - Not Assigned
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 Fine particles (such as dust and mists) may fuel fires/explosions.

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

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

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

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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

PF-07817173-09

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

8.2. Exposure controls

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

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

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

Skin and body protection Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C12 H20 N O6 P
Molecular weight	305.26

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

DSC: Endotherm of 121 J/g at 189 °C. Exotherm of -324 J/g at 264 °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.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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 investigated.

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.

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-07817173-09

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.
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Prepared By	Pfizer Global Environment, Health, and Safety

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