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

1.1. Product identifier

Nirmatrelvir Film-Coated Tablets **Product Name**

Product Code(s) PF00278

Synonyms PF-07321332 (IR) Film-Coated Tablets; Paxlovid

Trade Name: Not applicable **Chemical Family:** Not determined

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

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Pfizer Inc

Pfizer Ireland Pharmaceuticals **OSG** Building 235 East 42nd Street

New York, New York 10017 Ringaskiddy, Co. Cork.

1-800-879-3477 Ireland

+353 21 4378701

1.4. Emergency telephone number

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

E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

2.2. Label elements

Signal word Not classified

Not classified in accordance with international standards for workplace safety. **Hazard statements**

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

This document has been prepared in accordance with standards for workplace safety, Note:

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

Substances

Not applicable

3.2 Mixtures

NonHazardous

Noninazaradas							
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)
Microcrystalline cellulose 9004-34-6	*		232-674-9	No data available	Not Listed	No data available	No data available
Lactose Monohydrate 89466-76-2	*		Not Listed	No data available	Not Listed	No data available	No data available
Nirmatrelvir 2628280-40-8	15 - 20		Not Listed	No data available	Not Listed	No data available	No data available
Opadry Pink MIXTURE	*		Not Listed	No data available	Not Listed	No data available	No data available
Croscarmellose sodium 74811-65-7	*		Not Listed	No data available	Not Listed	No data available	No data available
Sodium stearyl fumarate 4070-80-8	*		223-781-1	No data available	Not Listed	No data available	No data available
+ Silicon dioxide, NF 7631-86-9	< 1		231-545-4	No data available	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4
			mg/L	Tiodi vapoi ilig/E	nour gas ppin
Microcrystalline cellulose 9004-34-6	5000	2000	5.8	No data available	No data available
+ Silicon dioxide, NF 7631-86-9	7900	5000	58.8	No data available	No data available

Additional information

- + Substance with a Union workplace exposure limit
- Not Assigned

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

SAFFTY DATA SHEFT

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Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

Eve 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.

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do Ingestion

not induce vomiting unless directed by medical personnel. Seek medical attention

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immediately.

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

Most important symptoms and

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

effects

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

None. Note to physicians

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

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

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

nitrogen and products of fluorine.

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

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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.

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Contain the source of the spill or leak. Collect spilled material by a method that controls Methods for cleaning up

dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area

thoroughly.

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

6.4. Reference to other sections

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

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 as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

ACGIH TLV 10 ma/m³ Denmark 1 ma/m³ Estonia 10 mg/m³ 2 mg/m³ 10 mg/m³ France 1 mg/m³ 3 mg/m³ Hungary 10 mg/m³ Ireland STEL: 30 mg/m3 Latvia 2 mg/m³ 6 mg/m³ 3 mg/m^3 Poland

10 mg/m³ Romania TWA: 6 mg/m³ Russia MAC: 10 mg/m³ Spain 10 mg/m³ 3 mg/m³ Switzerland 2 mg/m³

> 15 mg/m³ 5 mg/m³

> > (vacated) TWA: 15 mg/m3 total dust (vacated) TWA: 5 mg/m3 respirable fraction

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(vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³

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United Kingdom

TWA: 10 mg/m

TWA: 4 mg/m³

STEL: 20 mg/m³ STEL: 12 mg/m³

+ Silicon dioxide, NF

Netherlands

United Kingdom

Russia

 Austria
 4 mg/m³

 Bulgaria
 0.1 mg/m³

 Czech Republic
 0.1 mg/m³

 4.0 mg/m³
 2 mg/m³

Estonia 2 mg/m³
European Union TWA: 0.1 mg/m³
Finland 5 mg/m³
0.05 mg/m³

0.05 mg/m³ 0.5 mg/m³

Germany 0.5 mg/m³
Ceiling / Peak: 4 mg/m³

Germany 4 mg/m³
Ireland 6 mg/m³

6 mg/m³ 2.4 mg/m³ STEL: 18 mg/m³ STEL: 7.2 mg/m³ 0.1 mg/m³

 Italy
 0.1 mg/m³

 Latvia
 1 mg/m³

 0.1 mg/m³
 0.1 mg/m³

0.1 mg/m³ 0.75 mg/m³ TWA: 1 mg/m³ TWA: 2 mg/m³ TWA: 4 mg/m³ MAC: 3 mg/m³

 $\begin{array}{ccc} MAC: 3 \text{ mg/m}^3 \\ MAC: 6 \text{ mg/m}^3 \\ Switzerland & 4 \text{ mg/m}^3 \\ OSHA PEL & 50 \text{ \mug/m}^3 \\ \end{array}$

(vacated) TWA: 6 mg/m³ <1% Crystalline silica

20 mppcf TWA: 6 mg/m³ TWA: 2.4 mg/m³ TWA: 0.1 mg/m³

STEL: 18 mg/m³ STEL: 7.2 mg/m³

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.

Nirmatrelvir

Pfizer Occupational Exposure

Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m3 to <

100ug/m³)

8.2. Exposure controls

Engineering controls

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

process containment, local exhaust ventilation, or other engineering controls to maintain

airborne levels to below the OEB range.

Environmental exposure controls No information available.

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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

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selection and use of personal protective equipment (PPE).

Eve/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

Product Name Nirmatrelvir Film-Coated Tablets

Physical state Tablet
Color White to pink

Odor No information available.
Odor threshold No information available

Molecular formulaMixtureMolecular weightMixture

<u>Property</u> <u>Values</u>

pHMelting point / freezing pointNo data availableNo data available

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

No data available Vapor pressure No data available Vapor density No data available Relative density 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

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Particle Size
Particle Size Distribution
Explosive properties

No information available No information available No information available Page 7/11

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

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Predicted 7.4 Log D 1.591

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available. **Sensitivity to Static Discharge** No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

measure, keep away from electrostatic discharge.

10.5. Incompatible materials

Incompatible materialsAs a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information: Toxicological properties have not been thoroughly investigated.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this

compound may include: Inflammation of the nasal passages (nasopharyngitis), dizziness,

headache, diarrhea, nausea, and vomiting.

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

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Rat Oral NOAEL 1000 mg/kg

- 1010 - 1101 -						
	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50		
	Microcrystalline cellulose > 5 g/kg (Rat)		> 2000 mg/kg (Rabbit)	> 5800 mg/m³(Rat)4 h		
	+ Silicon dioxide, NF	= 7900 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	> 58.8 mg/L (Rat) 4 h		

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Safety Pharmacology: PF-07321332: Neurofunction: not significant. Pulmonary: increased respiratory rate,

(1000 mg/kg). In vivo Cardiovascular: decreased heart rate, increase blood pressure,

(150 (75 BID) mg/kg).

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin irritation Rabbit Non-irritating Eye irritation Rabbit Non-irritating

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

Nirmatrelvir

14 Day(s) Rat Oral 1000 mg/kg/day NOAEL None identified

14 Day(s) Monkey Oral 600 (300 BID) mg/kg/day NOAEL None identified

1 Month(s) Rat Oral 1000 mg/kg/day NOAEL None identified

1 Month(s) Monkey Oral 600 (300 BID) mg/kg/day NOAEL None identified

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

Nirmatrelvir

Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Maternal toxicity, Developmental toxicity

Embryo / Fetal Development Rabbit Oral 1000 mg/kg/day NOAEL Maternal Toxicity

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOAEL Developmental toxicity

Reproductive & Fertility Rat Oral M / F 1000 mg/kg/day NOAEL Paternal toxicity, Fertility

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

Nirmatrelvir

Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative

In Vitro Cytogenetics TK6 cells Negative

In Vivo Micronucleus Rat Bone marrow Negative

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

+ Silicon dioxide, NF

IARC Group 3 (Not Classifiable)

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.

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12.3. Bioaccumulative potential

Bioaccumulation

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

Nirmatrelvir

Predicted 7.4 Log D 1.591

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name		PBT and vPvB assessment		
	+ Silicon dioxide, NF	The substance is not PBT / vPvB PBT assessment does		
		not apply		

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.

Section 15: REGULATORY INFORMATION

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

Microcrystalline cellulose

CERCLA/SARA Section 313 de minimus % Not Listed

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California Proposition 65 carcinogen 12/18/2009

TSCA Present EINECS 232-674-9 AICS Present

Lactose Monohydrate

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

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

Opadry Pink

CÉRCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
EINECS Not Listed

Croscarmellose sodium

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed EINECS Not Listed AICS Present

Sodium stearyl fumarate

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed EINECS 223-781-1

+ Silicon dioxide, NF

CERCLA/SARA Section 313 de minimus %

California Proposition 65 carcinogen 10/1/1988 airborne particles of respirable size

Not Listed

TSCA Present
EINECS 231-545-4
AICS Present

France

Occupational Illnesses (R-463-3, France)

Occupational inflocuous (it loss of Franco)		
Chemical name	French RG number	Title
Microcrystalline cellulose 9004-34-6	RG 66	-
+ Silicon dioxide, NF 7631-86-9	RG 25	-

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

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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. Publicly available toxicity information.

Reason for revision Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

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