SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Tofacitinib Film-Coated Tablets

Trade Name: Xeljanz; Jaqinus
Chemical Family: Janus kinase 3 (JAK3) inhibitor

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 2
Toxic to Reproduction: Category 3

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R62 - Possible risk of impaired fertility.

Label Elements

Signal Word: Danger
Hazard Statements: H360Df - May damage the unborn child. Suspected of damaging fertility

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Tofacitinib citrate (CP-690,550-10)	540737-29-9	Not Listed	Xn;R22 Repr.Cat2;R61 Repr.Cat.3;R62	Acute Tox.4 (H302) Repr.1B (H360Df)	4
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Opadry II Blue	Not Asssigned	Not Listed	Not Listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Opadry II white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
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.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Tofacitinib citrate (CP-690,550-10)

Pfizer OEL TWA-8 Hr:	15 µg/m^3, Skin

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Russia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	10 mg/m^3 5 mg/m^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	**Color:**	White or Blue
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Tofacitinib citrate (CP-690,550-10)
Predicted 7.4 Log D -2.56
Lactose Monohydrate
No data available
Croscarmellose sodium
No data available
Magnesium stearate
No data available
Opadry II white
No data available
Microcrystalline cellulose
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Active ingredient may be harmful if swallowed.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on lymphatic system, blood and blood forming organs
Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: nausea, headache, immune-mediated disorders, and hematological effects

11. TOXICOLOGICAL INFORMATION

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

Tofacitinib citrate (CP-690,550-10)
Rat Oral Minimum Lethal Dose 500 mg/kg
Non-human Primate Oral Maximum Asymptomatic Dose 40mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Tofacitinib citrate (CP-690,550-10)
Skin Sensitization - LLNA Mouse Negative
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Tofacitinib citrate (CP-690,550-10)
6 Week(s) Rat Oral 1 mg/kg/day NOAEL Erythroid cells, Lymphatic system
1 Month(s) Monkey Oral 10 mg/kg/day NOAEL Lymphatic system, Immune system, Erythroid cells
39 Week(s) Monkey Oral 10 mg/kg/day NOAEL Bone Marrow, Erythroid cells, Lymphatic system
6 Month(s) Rat Oral 1 mg/kg/day NOAEL Lymphatic system, Erythroid cells
39 Week(s) Monkey Oral 2 mg/kg/day NOAEL Blood, Blood forming organs, Spleen, Thymus
1 Month(s) Mini Pig Dermal 10 mg/cm2/day NOAEL None identified
3 Month(s) Mini Pig Dermal 10 mg/cm2/day NOAEL Spleen

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

Tofacitinib citrate (CP-690,550-10)
Embryo / Fetal Development Rat Oral30 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 100 mg/kg/day NOAEL
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Developmental toxicity
Fertility & Embryonic Development (Male/Female) Rat Oral 10 mg/kg/day NOAEL Maternal Toxicity
Fertility & Embryonic Development-Females Rat Oral 1.0 mg/kg/day NOAEL Fertility

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

11. TOXICOLOGICAL INFORMATION

Tofacitinib citrate (CP-690,550-10)
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Cytogenetics Human Lymphocytes Positive with activation
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Rat Bone Marrow Negative
In Vivo Unscheduled DNA Synthesis Rat Hepatocyte Negative

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tofacitinib citrate (CP-690,550-10)
2 Year(s) Rat Female Oral 10 mg/kg/day NOAEL Benign tumors
2 Year(s) Rat Male Oral 10 mg/kg/day LOAEL Benign tumors
6 Month(s) Mouse Oral 200 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Tofacitinib citrate (CP-690,550-10)
Activated sludge OECD EC50 3 Hours 592.9 mg/L
Mysidopsis bahia (Mysid Shrimp) OECD LC50 96 Hours > 1.0 mg/L
Cyprinodon variegatus (Sheepshead Minnow) OECD LC50 96 Hours > 1.0 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Tofacitinib citrate (CP-690,550-10)
Predicted 7.4 Log D -2.56

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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 waste water 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.

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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
D2a very toxic materials

Tofacitinib citrate (CP-690,550-10)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Opadry II Blue

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Lactose Monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present

15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

Magnesium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Opadry II white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.1B; H360Df - May damage the unborn child. Suspected of damaging fertility

Xn - Harmful
Toxic to Reproduction: Category 2
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R62 - Possible risk of impaired fertility.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date: 11-Apr-2015
Product Stewardship Hazard Communication
Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet