



PTC Therapeutics, Inc.

100 Corporate Court
South Plainfield, NJ 07080
908.222.7000
www.ptcbio.com

Safety Data Sheet

Product Name: Emflaza™ (deflazacort) Tablets

Section 1: Identification

Product identifier

Product Name • **Emflaza™ (deflazacort) Tablets**

- EMFLAZA is available in four oral tablet strengths: EMFLAZA 6 mg deflazacort tablet: White, round tablet with “6” debossed on one side; EMFLAZA 18 mg deflazacort tablet: White, round tablet with “18” debossed on one side; EMFLAZA 30 mg deflazacort tablet: White, oval tablet with “30” debossed on one side; and EMFLAZA 36 mg deflazacort tablet: White, oval tablet with “36” debossed on one side.

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

Recommended use • Anti-inflammatory corticosteroid. This product should be used under the care of a doctor, consistent with prescribing instructions

Details of the supplier of the safety data sheet

Manufacturer • PTC Therapeutics, Inc.
100 Corporate Court
South Plainfield, NJ 07080
United States
www.ptcbio.com
SDSinfo@ptcbio.com

Telephone (General) • 908-222-7000

Emergency telephone number

Manufacturer • 800-424-9300 - CHEMTREC - US & Canada
Manufacturer • 703-527-3887 - CHEMTREC - Anywhere in the world
• PTC CHEMTREC ID# CCN655610.

Section 2: Hazard Identification

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Reproductive Toxicity 2
Effects on or via Lactation
Specific Target Organ Toxicity Repeated Exposure 2

Label elements

OSHA HCS 2012

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WARNING



- Hazard statements**
- Suspected of damaging fertility or the unborn child.
 - May cause harm to breast-fed children
 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

- Prevention**
- Obtain special instructions before use.
 - Do not handle until all safety precautions have been read and understood.
 - Do not breathe dust.
 - Avoid contact during pregnancy/while nursing.
 - Wash thoroughly after handling.
 - Do not eat, drink or smoke when using this product.
 - Wear protective gloves/protective clothing/eye protection/face protection.
- Response**
- Get medical advice/attention if you feel unwell.
 - IF exposed or concerned: Get medical advice/attention.

- Storage/Disposal**
- Store in a secure manner in a cool, dry location at 20°C to 25°C (68°F to 77°F).

Other hazards

- OSHA HCS 2012**
- Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance.

Mixtures

Composition				
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive
Deflazacort, micronized	CAS:14484-47-0	4.8%	NDA	OSHA HCS 2012: Repr. 2; Lact.; STOT RE 2; Acute Tox. 4 (Orl)

Each tablet consists of deflazacort and the following inactive ingredients: lactose monohydrate, pre-gelatinized corn starch, colloidal silicon dioxide and magnesium stearate.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Move victim to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is



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not breathing.

- Skin** • In case of contact with substance, immediately flush skin with running water for at least 20 minutes.
- Eye** • In case of contact with substance, immediately flush eyes with running water for at least 20 minutes.
- Ingestion** • If large quantities are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

- Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

- Notes to Physician** • All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media** • LARGE FIRE: Water spray, fog or regular foam.
SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.

- Unsuitable Extinguishing Media** • No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards** • Some may burn but none ignite readily.

- Hazardous Combustion Products** • No data available

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions** • Do not walk through spilled material.

- Emergency Procedures** • Use normal clean up procedures.

Environmental precautions

- Avoid release to the environment.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures** • Carefully shovel or sweep up spilled material and place in suitable container.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling** • Use good safety and industrial hygiene practices. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Conditions for safe storage, including any incompatibilities

- Storage** • Store in well-closed containers and store at 20°C to 25°C (68°F to 77°F)



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Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • No applicable exposure limits available for product or components.

Exposure controls

Engineering Measures/Controls • Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory • In case of insufficient ventilation, wear suitable respiratory equipment.

Eye/Face • Wear safety glasses.

Skin/Body • Wear appropriate gloves.

Environmental Exposure Controls • Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. Follow best practice for site management and disposal of waste.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	White round or oval uncoated tablets.
Color	White	Odor	No data available
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Slightly Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		



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Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- Hazardous polymerization will not occur.

Conditions to avoid

- Excess heat.

Incompatible materials

- Strong oxidizing agents, strong bases.

Hazardous decomposition products

- Nitrogen oxides, carbon monoxide, irritating and toxic fume and gases, carbon dioxide, nitrogen.

Section 11 - Toxicological Information

Information on toxicological effects

		Components
Deflazacort, micronized (4.8%)	14484-47-0	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 5200 mg/kg; Ingestion/Oral-Human TDLo • 0.12 mg/kg; <i>Skin and Appendages:After systemic exposure:Dermatitis, other</i> ; Ingestion/Oral-Woman TDLo • 0.12 mg/kg; <i>Vascular:BP lowering not characterized in autonomic section</i> ; <i>Gastrointestinal:Nausea or vomiting</i> ; <i>Skin and Appendages:After systemic exposure:Dermatitis, allergic</i> ; Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 182 mg/kg 2 Year(s)-Continuous; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria</i> ; <i>Musculoskeletal:Tumors</i>

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012•Data lacking
Skin corrosion/Irritation	OSHA HCS 2012•Data lacking
Serious eye damage/Irritation	OSHA HCS 2012•Data lacking
Skin sensitization	OSHA HCS 2012•Data lacking
Respiratory sensitization	OSHA HCS 2012•Data lacking
Aspiration Hazard	OSHA HCS 2012•Data lacking
Carcinogenicity	OSHA HCS 2012•Data lacking
Germ Cell Mutagenicity	OSHA HCS 2012•Data lacking
Toxicity for Reproduction	OSHA HCS 2012•Additional category for effects on or via lactation; Toxic to Reproduction 2
STOT-SE	OSHA HCS 2012•Data lacking
STOT-RE	OSHA HCS 2012•Specific Target Organ Toxicity Repeated Exposure 2



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Potential Health Effects

Inhalation

Acute (Immediate) • No data available

Chronic (Delayed) • No data available

Skin

Acute (Immediate) • No data available

Chronic (Delayed) • No data available

Eye

Acute (Immediate) • No data available

Chronic (Delayed) • No data available

Ingestion

Acute (Immediate) • No data available

Chronic (Delayed) • No data available

Other

Chronic (Delayed) • Endocrine changes have been found for multiple dose administration. Immunosuppressive effects with inhibition of T cell reactivity has been reported for long time exposure.

Reproductive Effects

• The ability of corticosteroids to cross the placenta varies between individual drugs, however, deflazacort does cross the placenta. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important. As with all drugs, corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. When corticosteroids are essential however, patients with normal pregnancies may be treated as though they were in the non-gravid state.

Key to abbreviations

LD = Lethal Dose

TD = Toxic Dose

Section 12 - Ecological Information

Toxicity



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• Non-mandatory section - information about this substance not compiled for this reason.

Persistence and degradability

• Non-mandatory section - information about this substance not compiled for this reason.

Bioaccumulative potential

• Non-mandatory section - information about this substance not compiled for this reason.

Mobility in Soil

• Non-mandatory section - information about this substance not compiled for this reason.

Other adverse effects

• Non-mandatory section - information about this substance not compiled for this reason.

Section 13 - Disposal Considerations

Waste treatment methods

Product waste • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA

Special precautions for user • None specified.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • Chronic

Inventory		
Component	CAS	TSCA
Deflazacort, micronized	14484-47-0	No

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals



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U.S. - OSHA - Specifically Regulated Chemicals		
•Deflazacort, micronized	14484-47-0	Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Section 313 - Emission Reporting		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing		
•Deflazacort, micronized	14484-47-0	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Deflazacort, micronized	14484-47-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Deflazacort, micronized	14484-47-0	Not Listed

Section 16 - Other Information

Revision Date	• 26/September/2017
Last Revision Date	• 01/June/2016
Preparation Date	• 13/April/2016
Disclaimer/Statement of Liability	• The information herein is given in good faith but no warranty, expressed or implied, is made.

Key to abbreviations

NDA = No Data Available