



# SAFETY DATA SHEET

Revision date 07-May-2020

Version 2

Page 1 / 13

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

### 1.1. Product identifier

**Product Name** FLECTOR (diclofenac epolamine) Topical System  
**Product Code(s)** PZ02719  
**Trade Name:** FLECTOR  
**Chemical Family:** Not determined

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

**Recommended Use** Non-steroidal, anti-inflammatory drug (NSAID) topical analgesic

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

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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

### 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

**Reproductive toxicity** Category 1B

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H360D - May damage the unborn child

**Precautionary Statements**  
P201 - Obtain special instructions before use  
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

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 2 / 13  
Version 2



## 2.3. Other hazards

### Other hazards

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

#### Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Diclofenac epolamine	Not Listed	119623-66-4	1.3	Acute Tox.3 (H301) Repr.1B (H360D) Aquatic Chronic 4 (H413)	
Titanium dioxide	236-675-5	13463-67-7	*	Not Listed	
Sodium polyacrylate	Not Listed	9003-04-7	*	Not Listed	
Kaolin	310-194-1	1332-58-7	*	Not Listed	

#### NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Tartaric acid	201-766-0	87-69-4	*	Not Listed	
Sorbitol solution	200-061-5	50-70-4	*	Not Listed	
Propylparaben	202-307-7	94-13-3	*	Aquatic Chronic 3 (H412)	
Povidone	Not Listed	9003-39-8	*	Not Listed	
Polysorbate 80	500-019-9	9005-65-6	*	Not Listed	
Methyl-p-hydroxybenzoate	202-785-7	99-76-3	*	Aquatic Chronic 2 (H411)	
Gelatin	232-554-6	9000-70-8	*	Not Listed	
Fragrance	Not Listed	NOT ASSIGNED	*	Not Listed	
Edetate disodium	205-358-3	139-33-3	*	Not Listed	
Dihydroxyaluminum aminoacetate	Not Listed	41354-48-7	*	Not Listed	
Carboxymethylcellulose sodium	Not Listed	9004-32-4	*	Not Listed	
Butylene glycol	203-529-7	107-88-0	*	Not Listed	

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 3 / 13  
Version 2

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

## 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.

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

### 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.

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 4 / 13  
Version 2

## 6.2. Environmental precautions

### Environmental precautions

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

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

### Methods for containment

Prevent further leakage or spillage if safe to do so.

### Methods for cleaning up

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

### Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

### Reference to other sections

See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on safe handling

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

#### Titanium dioxide

ACGIH TLV	10 mg/m <sup>3</sup>
Austria	5 mg/m <sup>3</sup>
	STEL 10 mg/m <sup>3</sup>
Bulgaria	10.0 mg/m <sup>3</sup> 1.0 mg/m <sup>3</sup>
Denmark	6 mg/m <sup>3</sup>
Estonia	5 mg/m <sup>3</sup>
France	10 mg/m <sup>3</sup>
Germany	0.3 mg/m <sup>3</sup> multiplied by the material density; except ultrafine particles
	Ceiling / Peak: 2.4 mg/m <sup>3</sup>
Ireland	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
	STEL: 30 mg/m <sup>3</sup>
	STEL: 12 mg/m <sup>3</sup>
Latvia	10 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 5 / 13  
Version 2

Poland	STEL: 30 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Romania	10 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
Russia	TWA: 10 mg/m <sup>3</sup>
Slovakia	5 mg/m <sup>3</sup>
Spain	10 mg/m <sup>3</sup>
Switzerland	3 mg/m <sup>3</sup>
OSHA PEL	15 mg/m <sup>3</sup> (vacated) TWA: 10 mg/m <sup>3</sup> total dust
United Kingdom	TWA: 10 mg/m <sup>3</sup> TWA: 4 mg/m <sup>3</sup> STEL: 30 mg/m <sup>3</sup> STEL: 12 mg/m <sup>3</sup>
<b>Tartaric acid</b>	
Germany	2 mg/m <sup>3</sup> Ceiling / Peak: 4 mg/m <sup>3</sup>
Germany	2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup> STEL: 4 mg/m <sup>3</sup>
<b>Sorbitol solution</b>	
Russia	MAC: 10 mg/m <sup>3</sup>
<b>Propylparaben</b>	
Russia	MAC: 10 mg/m <sup>3</sup>
<b>Povidone</b>	
Russia	MAC: 10 mg/m <sup>3</sup>
<b>Methyl-p-hydroxybenzoate</b>	
Russia	MAC: 4 mg/m <sup>3</sup>
<b>Kaolin</b>	
ACGIH TLV	2 mg/m <sup>3</sup>
Bulgaria	3.0 mg/m <sup>3</sup> 6.0 mg/m <sup>3</sup>
Denmark	2 mg/m <sup>3</sup>
Finland	2 mg/m <sup>3</sup>
France	10 mg/m <sup>3</sup>
Ireland	2 mg/m <sup>3</sup>
Poland	10.0 mg/m <sup>3</sup>
Spain	2 mg/m <sup>3</sup>
Switzerland	3 mg/m <sup>3</sup>
OSHA PEL	15 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> (vacated) TWA: 10 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction
United Kingdom	TWA: 2 mg/m <sup>3</sup> STEL: 6 mg/m <sup>3</sup>
<b>Gelatin</b>	
Russia	MAC: 10 mg/m <sup>3</sup>
<b>Edetate disodium</b>	
Russia	MAC: 2 mg/m <sup>3</sup>
<b>Carboxymethylcellulose sodium</b>	
Russia	MAC: 10 mg/m <sup>3</sup>

## Pfizer 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.

## Diclofenac epolamine

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 6 / 13  
Version 2

Pfizer Occupational Exposure  
Band (OEB):

OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

## 8.2. 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.

### Environmental exposure controls

No information available.

### Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). 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.

### Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (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

Patch

#### Color

No information available

#### Molecular formula (MF):

Mixture

#### Molecular weight

Mixture

#### Odor

No data available.

#### Odor threshold

No data available

#### Property

#### Values

##### pH

##### Melting point / freezing point

No data available

##### Boiling point / boiling range

No data available

##### Flash point

No data 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

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 7 / 13  
Version 2

Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
<u>Diclofenac Sodium</u>	
Predicted Log P 4.51	
<u>Diclofenac epolamine</u>	
Predicted Log P 4.05	

## 9.2. Other information

Liquid Density	No data available
Bulk density	No data available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity	No data available.
------------	--------------------

### 10.2. Chemical stability

Stability	Stable at 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 toxicological effects

General Information:	The information included in this section describes the potential hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.
Long Term:	Animal studies indicate that this material may cause adverse effects on the the developing fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on blood spleen gastrointestinal system
Known Clinical Effects:	Clinical use has caused effects on the gastrointestinal system, including abdominal pain, nausea, vomiting, diarrhea, constipation, peptic ulcer, acid reflux, and gastrointestinal bleeding. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Clinical use has caused effects on the nervous system, including drowsiness, anxiety, dizziness, visual disturbances. Serious allergic

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 8 / 13  
Version 2

reactions, including anaphylaxis, have been reported. Clinical use of this drug has caused decreased red blood cell count (anemia), effects on blood forming organs. Clinical use has caused effects on the cardiovascular system, including heart attack (myocardial infarction), stroke. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

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

### **Diclofenac Sodium**

Rat Oral LD 50 53-77 mg/kg

### **Diclofenac epolamine**

Rat Oral LD50 55-240 mg/kg

### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

### **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

### **Butylene glycol**

Rat Oral LD50 22,800 mg/kg

Mouse Oral LD50 12,980 mg/kg

Rabbit Dermal LD50 > 20,000 mg/kg

### **Sorbitol solution**

Rat Oral LD50 15,900 mg/kg

Mouse Oral LD50 17,800 mg/kg

### **Povidone**

Rat Oral LD50 100 g/kg

### **Carboxymethylcellulose sodium**

Mouse Oral LD50 > 27,000 mg/kg

Rat Oral LD50 27,000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

### **Methyl-p-hydroxybenzoate**

Mouse Oral LD50 > 8 g/kg

Rat Oral LD 50 2100 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Titanium dioxide	> 10000 mg/kg ( Rat )	-	-
Sorbitol solution	= 15900 mg/kg ( Rat )	-	-
Sodium polyacrylate	> 40 g/kg ( Rat )	-	-
Povidone	= 100 g/kg ( Rat )	-	-
Polysorbate 80	= 34500 µL/kg ( Rat )	-	-
Methyl-p-hydroxybenzoate	= 2100 mg/kg ( Rat )	-	-
Kaolin	> 5000 mg/kg ( Rat )	> 5000 mg/kg ( Rat )	-
Edetate disodium	= 2 g/kg ( Rat )	-	-
Carboxymethylcellulose sodium	= 27000 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
Butylene glycol	= 18610 mg/kg ( Rat )	> 20 g/kg ( Rabbit )	> 60 ppm ( Rat ) 8 h



# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 9 / 13  
Version 2

**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)**

### **Diclofenac Sodium**

Skin Irritation Positive

Eye Irritation Positive

### **Methyl-p-hydroxybenzoate**

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Slight

Skin Sensitization Guinea Pig Negative

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

### **Diclofenac Sodium**

30 Day(s) Rat Oral 14 mg/kg LOEL None identified

5 Week(s) Mouse Oral 9 mg/kg LOEL Lungs, Spleen

26 Week(s) Rat Oral 50 mg/kg LOEL Blood, Gastrointestinal system

### **Carboxymethylcellulose sodium**

13 Week(s) Rat Oral 227 g/kg LOEL Liver, Kidney, Ureter, Bladder

### **Propylparaben**

3 Week(s) Rat Oral 27.1 g/kg LOEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOEL Male reproductive system

### **Methyl-p-hydroxybenzoate**

28 Day(s) Rat Oral 250 mg/kg/day NOEL Gastrointestinal System, Spleen, Thymus

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

### **Diclofenac Sodium**

Embryo / Fetal Development Rat Oral 24 mg/kg LOEL Maternal toxicity, Fetotoxicity

Embryo / Fetal Development Rat 1 mg/kg LOEL Developmental toxicity

Embryo / Fetal Development Rat No route specified 20 mg/kg/day Not Teratogenic

Embryo / Fetal Development Rabbit No route specified 10 mg/kg/day NOEL Not Teratogenic

### **Methyl-p-hydroxybenzoate**

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity

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

### **Diclofenac Sodium**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

### **Methyl-p-hydroxybenzoate**

*In Vivo* Dominant Lethal Assay Rat Negative

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

### **Diclofenac Sodium**

Not specified Rat Oral 2 mg/kg/day NOEL Not carcinogenic

**Carcinogenicity** See below

### **Titanium dioxide**

IARC Group 2B (Possibly Carcinogenic to Humans)

### **Povidone**

IARC Group 3 (Not Classifiable)

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** May have harmful effects on the aquatic environment. Releases to the environment should be avoided.

### **12.1. Toxicity**

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 10 / 13  
Version 2

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

### Diclofenac Sodium

*Oncorhynchus mykiss* (Rainbow Trout) EC-50 96 hours 130.6 mg/l  
*Daphnia magna* (Water Flea) EC50 48 hours 68 mg/L  
*Skeletonema costatum* (Marine Diatom) ErC50 48 hours 42 mg/l  
*Skeletonema costatum* (Marine Diatom) EC-50 72 Hours 100 mg/L

### Methyl-p-hydroxybenzoate

*Oryzias latipes* (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/l  
*Daphnia magna* (Water Flea) ISO EC50 48 hours 11.2 mg/L

## 12.2. Persistence and degradability

### Persistence and degradability

## Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

### Diclofenac Sodium

Ready 55 % After 28 Day(s) Not Ready

### Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) Ready

## 12.3. Bioaccumulative potential

### Bioaccumulation

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

### Diclofenac Sodium

Predicted Log P 4.51

### Diclofenac epolamine

Predicted Log P 4.05

## 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.

Chemical Name	PBT and vPvB assessment
Titanium dioxide	The substance is not PBT / vPvB PBT assessment does not apply
Tartaric acid	The substance is not PBT / vPvB
Propylparaben	The substance is not PBT / vPvB
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Edetate disodium	The substance is not PBT / vPvB
Butylene glycol	The substance is not PBT / vPvB

## 12.6. Other adverse effects

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

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 11 / 13  
Version 2

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.

## 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

Diclofenac epolamine

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

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Titanium dioxide

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
TSCA	Present
EINECS	236-675-5
AICS	Present

Tartaric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-766-0
AICS	Present

Sorbitol solution

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-061-5
AICS	Present

Sodium polyacrylate

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

Propylparaben

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

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 12 / 13  
Version 2

<b>TSCA</b>	Present
<b>EINECS</b>	202-307-7
<b>AICS</b>	Present
Povidone	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Polysorbate 80	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Methyl-p-hydroxybenzoate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-785-7
<b>AICS</b>	Present
Kaolin	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	310-194-1
<b>AICS</b>	Present
Gelatin	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	232-554-6
<b>AICS</b>	Present
Fragrance	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Edetate disodium	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	205-358-3
<b>AICS</b>	Present
Dihydroxyaluminum aminoacetate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Carboxymethylcellulose sodium	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Butylene glycol	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	203-529-7
<b>AICS</b>	Present

## **15.2. Chemical safety assessment**

# SAFETY DATA SHEET

Product Name FLECTOR (diclofenac epolamine) Topical System  
Revision date 07-May-2020

Page 13 / 13  
Version 2

**Chemical Safety Report**

No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under section 3**

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Hazardous to the aquatic environment, chronic toxicity-Cat.4; H413 - May cause long lasting harmful effects to aquatic life H412 -  
Harmful to aquatic life with long lasting effects H411 - Toxic to aquatic life with long lasting effects

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date** 07-May-2020

**Prepared By** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

**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.**