SAFETY DATA SHEET
for
ZORVOLEX® (diclofenac) Capsules (18 mg and 35 mg)

1. Identification

Product Name:	ZORVOLEX® (diclofenac) capsules
Trade Name:	ZORVOLEX®
Synonyms:	None
CAS Number:	See section 3 below.
Chemical Family:	Mixture
Product Use:	Used as a prescription only human therapeutic.[1]
Manufacturer/Supplier:	Egalet US Inc.
Address:	600 Lee Road, Suite 100 Wayne, PA 19087
General Information:	610-833-4200
Emergency Contact Number:	Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 (CCN693919) Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity: Category[2] 4 Skin Corrosion/Irritation: Category 2 Eye Corrosion/Irritation: Category 2 Respiratory Sensitization: Category 1B Skin Sensitization: Category 1 Germ cell mutagenicity: Not classified Carcinogenicity: Not classified Reproductive/Developmental: Category 2 Target Organ Toxicity (Single exposure): Not classified Target Organ Toxicity (Repeated): Category 2	Not available	Not classified

[1] Please refer to the package insert for specific therapeutic indications.

[2] Note: Hazard categories under GHS are not related to potent compound classification schemes used by many pharmaceutical companies. Under GHS, Category 1 is the most toxic and Category 4 is the least toxic.

GHS Label:

Symbols:

Signal word: Danger

Hazard Statements	Precautionary Statements
H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H361: Suspected of damaging fertility or the unborn child (fetal cardiovascular system). H373: May cause damage to organs (cardiovascular, gastrointestinal, renal) through prolonged or repeated exposure.	P261: Avoid breathing dust. P264: Wash hands and forearms after handling. P270: Do not eat, drink, or smoke when using this product. P271: Use only in a well-ventilated area. P280: Wear protective gloves/protective clothing/eye protection/face protection. P285: In case of inadequate ventilation wear respiratory protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P330: Rinse mouth. P304 + P341: IF INHALED: If breathing is difficult, 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. P332 + P313: If skin irritation occurs: Get medical advice/attention. P342 + P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P362: Take off contaminated clothing and wash before reuse. P501: Dispose of contents/container in accordance with local regulations.

3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Diclofenac acid	15307-86-5	12.3
Lactose monohydrate	10039-26-6	68.6
Microcrystalline cellulose	9004-34-6	9.9
Croscarmellose sodium	74811-65-7	6.0
Sodium lauryl sulphate	751-21-3	2.2
All other ingredients (< 1% each)	-	-

4. First Aid Measures

Eye: In case of contact with eyes, rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin: In case of skin contact, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

Inhalation: In the capsule form, not a likely route of exposure. However, in case of inhalation, remove to fresh air at rest. Seek medical attention immediately.

Ingestion: In case of accidental ingestion, wash out mouth with water. Never give anything by mouth to an unconscious person. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media: Use an appropriate media including water spray, dry powder, foam, carbon dioxide.

Firefighting Procedures: Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

Unusual Fire and Explosion Hazards Not applicable

Combustion Products Unknown

6. Accidental Release Measures

Spill Response

Instructions:

The following spill response instructions only apply to bulk quantities of the material and only if capsules are crushed or broken. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Remove all sources of heat and ignition. Avoid creation of dust and use HEPA vacuum for collection of crushed or broken capsules. Collect for disposal. Ventilate the area and clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

7. Handling and Storage

General Handling

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

Storage

Store as directed by product packaging.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	WEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Diclofenac acid	N.E.	N.E.	N.E.	N.E.
Lactose monohydrate	N.E.	N.E.	N.E.	N.E.
Microcrystalline cellulose (respirable)	10 mg/m^3 (5 mg/m^3)	15 mg/m^3 (5 mg/m^3)	10 mg/m^3 (5 mg/m^3)	10 mg/m^3 (5 mg/m^3)
Croscarmellose sodium	N.E.	N.E.	N.E.	N.E.
Sodium lauryl sulphate	N.E.	N.E.	N.E.	N.E.

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. Use explosion-proof ventilation equipment.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear chemical safety goggles, safety glasses or face shield. Have eyewash stations available where eye contact can occur.

Skin Protection: If handling crushed or open capsules, wear gloves to prevent skin contact with dust or powder. Additional protection may be necessary to prevent skin contact including the use of a face shield, boots, or tyvex coveralls. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: N/A
Autoignition Temperature: N/A
Boiling Point: N/A
Melting Point: N/A
Vapor Pressure: N/A
Vapor Density: N/A
% Solubility in Water: N/A
Pour Point: N/A
Molecular Formula: Mixture

Lower Flammability Limit: N/A
Upper Flammability Limit: N/A
Specific Gravity: N/A
% Volatile: N/A
Evaporation Rate (Water=1): N/A
Viscosity: N/A
Octanol/Water Partition Coefficient: N/A
pH: N/A
Molecular Weight: Mixture

Odor/Appearance: blue body/light green capsules (18 mg) and blue body/green capsules (35 mg)

10. Stability and Reactivity

Stability/Incompatibility: The mixture is stable under normal conditions of use.

11. Toxicology Information

Signs and Symptoms of Overexposure: In its capsule form, overexposure is unlikely. May cause slight eye irritation or skin irritation.

Eye Contact: Exposure to dust or powder may cause severe irritation including redness, tearing, swelling and pain. Avoid contact with eyes.

Skin Contact: In a clinical setting, NSAIDs (non-steroidal anti-inflammatory drugs), including Zorvolex, can cause serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Employees should report to their supervisor at the first appearance of skin rash or any other sign of hypersensitivity.

Inhalation: In the capsule form, not a likely route of exposure. However, in a clinical setting, as with other NSAIDs, anaphylactoid reactions may occur in patients without known prior exposure to Zorvolex. Employees with a known aspirin triad (hypersensitivity) should consult their supervisor prior to handling Zorvolex. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs.

Ingestion: May result in gastrointestinal experiences including: abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers (gastric/duodenal) and vomiting.

Target Organ Effects: There are no target organ effects associated with this mixture.

Chronic Effects: No chronic effects have been determined for this mixture.

Acute Toxicity Values:
LD50 (rat oral) = 62.5 mg/kg (for diclofenac acid)
LD50 (rat oral) > 10,000 mg/kg (for lactose monohydrate)
LD50 (rat oral) > 5,050 mg/kg (for croscarmellose sodium)
LD50 (rat oral) > 5,000 mg/kg (for microcrystalline cellulose)
LD50 (rat oral) = 1,288 mg/kg (for sodium lauryl sulfate)

LD50 (rate oral) = 980 mg/kg (for sodium stearyl fumarate)

12. Ecological Information

Ecological impact data has not been determined for this mixture.

13. Disposal Considerations

Disposal Procedure: Must dispose of in accordance with all local, state, and federal regulations.

14. Transportation Information

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

15. Regulatory Information

U. S. Federal Hazardous Waste Regulations
Not regulated.

Toxic Substance Control Act (TSCA): The following ingredients are not included on the TSCA inventory: Diclofenac acid

Clean Water Act (CWA): No ingredients in this mixture are listed in the Clean Water Act.

Clean Air Act (CAA): No ingredients in this mixture are listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: No ingredients in this mixture are listed under SARA.

State Regulations

California: This product does not contain chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm.

Canadian Environmental Protection Act: The following compounds in this mixture are not listed on the Canadian Domestic Substances list (DSL): Diclofenac acid.
Canadian Workplace Hazardous Materials Information System (WHMIS):
This product in not controlled by the WHMIS.

European Inventory of Existing Chemicals (EINECS): Ten components contained in this product (diclofenac acid, microcrystalline cellulose, sodium stearyl fumarate)

are included on the European Inventory of Existing Commercial Chemical Substances.

EU Classification: Not regulated.
EU Risk (R) and Safety (S) Phrases:
R20 Harmful by inhalation
R21 Harmful in contact with skin
R22 Harmful if swallowed
R61 May cause harm to the unborn child
S1 Keep locked up
S2 Keep out of the reach of children
S20 When using do not eat or drink

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 1	**Flammability: 0**	**Reactivity: 0**	**Other: 0**

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