

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Name:** Ampyra<sup>®</sup> Extended Release Tablets, 10 mg

**Synonyms:** dalfampridine

#### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical. The therapeutic use is to improve walking in patients with multiple sclerosis (MS). For professional use only.

#### 1.3. Name, Address, and Telephone of the Responsible Party

##### Company

Acorda Therapeutics  
420 Saw Mill River Road  
Ardsley, NY 10502  
914-347-4300

[www.acorda.com](http://www.acorda.com)

#### 1.4. Emergency Telephone Number

**Emergency Number** : 1-800-367-5109

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

##### Classification (GHS-US)

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii).*

#### 2.2. Label Elements

##### GHS-US Labeling

No labeling applicable

#### 2.3. Other Hazards

**Other Hazards Not Contributing to the Classification:** This product is a pharmaceutical. If dust is generated, dust clouds suspended in air can be explosive. Dust may be harmful if inhaled, in contact with skin, or if swallowed.

#### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and the composition does not need to be disclosed.*

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**First-aid Measures After Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**First-aid Measures After Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**First-aid Measures After Ingestion:** If accidental ingestion occurs, flush mouth out with water and get medical attention.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Not flammable. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known.

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### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not flammable.

**Explosion Hazard:** Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Other information:** Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all contact with skin, eyes, or clothing. Avoid generating dust.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Material for Containment and Cleaning Up

**Methods for Cleaning Up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

### 6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection. Concerning disposal elimination after cleaning, see item 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Hygiene Measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Storage Conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

### 7.3. Specific End Use(s)

Pharmaceutical. The therapeutic use is to improve walking in patients with multiple sclerosis (MS). For professional use only.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

Component A		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>
Component C		
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	6 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	3000 mg/m <sup>3</sup>

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

#### Personal Protective Equipment

: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

#### Hand Protection

: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

#### Eye Protection

: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

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- Skin and Body Protection** : In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
- Respiratory Protection** : When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Solid
- Appearance** : Biconvex, oval shaped, non-scored white to off white tablet with flat edge
- Odor** : No data available
- Odor Threshold** : No data available
- pH** : No data available
- Relative Evaporation Rate (butylacetate=1)** : No data available
- Melting/Freezing Point** : No data available
- Boiling Point** : No data available
- Flash Point** : No data available
- Auto-ignition Temperature** : No data available
- Decomposition Temperature** : No data available
- Flammability (solid, gas)** : No data available
- Vapor Pressure** : No data available
- Relative Vapor Density at 20 °C** : No data available
- Relative Density** : No data available
- Solubility** : No data available
- Partition coefficient: n-octanol/water** : No data available
- Viscosity** : No data available

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2 Chemical Stability:** Stable under normal conditions.
- 10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4 Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.
- 10.5 Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6 Hazardous Decomposition Products:** Carbon oxides (CO, CO<sub>2</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

#### Acute Toxicity:

Ampyra® Extended Release Tablets, 10 mg	
ATE (Oral)	100.00 mg/kg body weight
Component B	
ATE (Oral)	5.00 mg/kg body weight
Component A	
LC50 Inhalation Rat	> 5800 mg/m <sup>3</sup> (Exposure time: 4 h)
Component C	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 2.2 mg/l (Exposure time: 1 h)

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

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**Carcinogenicity:** Not classified

<b>Component C</b>	
<b>IARC group</b>	3

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** None expected under normal conditions of use.

**Symptoms/Injuries After Skin Contact:** None expected under normal conditions of use.

**Symptoms/Injuries After Eye Contact:** None expected under normal conditions of use.

**Symptoms/Injuries After Ingestion:** Accidental Pharmaceutical ingestion may be harmful or have adverse effects.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

<b>Component B</b>	
<b>LC50 Fish 1</b>	2.3 - 3.5 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
<b>Component C</b>	
<b>LC50 Fish 1</b>	5000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
<b>EC50 Daphnia 1</b>	7600 mg/l (Exposure time: 48 h - Species: Ceriodaphnia dubia)

**12.2. Persistence and Degradability** No additional information available

**12.3. Bioaccumulative Potential**

<b>Component C</b>	
<b>BCF fish 1</b>	(no bioaccumulation expected)

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects** No additional information available

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer.

**Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

## SECTION 14: TRANSPORT INFORMATION

**14.1 In Accordance with DOT** Not regulated for transport

**14.2 In Accordance with IMDG** Not regulated for transport

**14.3 In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

<b>Component B</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on SARA Section 302 (Specific toxic chemical listings)	
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	≤ 10000
<b>Component A</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Component D</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Component C</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Component E</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

### 15.2 US State Regulations

<b>Component B</b>	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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### Component A

U.S. - Massachusetts - Right To Know List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

### Component C

U.S. - Massachusetts - Right To Know List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision date** : 08/26/2014

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

*Acorda believes 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.*

SDS US (GHS HazCom)