

1. IDENTIFICATION

Product Name
Recommended use of the chemical and restrictions on use
Identified Uses

INBRIJA Capsules (Levodopa

For treatment of Parkinson's Disease. For further information consult drug product information.

Restrictions on Use

Do not swallow capsules. Do not use

Company Identification

Acorda Therapeutics

Customer Information Number

190 Everett Ave.
Chelsea, MA 02150
(617)-660-4110

Emergency Telephone Number

(617)-660-4110

Issue Date

October 29, 2018

Supersedes Date

NA

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2. HAZARD IDENTIFICATION**Hazard Classification**

Toxic to reproduction -
Category 2

Label Elements

Hazard Symbols



Signal Word: Warning

Hazard Statements

Suspected of damaging fertility or the unborn child.

Precautionary Statements**Prevention**

Do not handle until all safety precautions have been read and understood.
Wear protective gloves.

Response

If exposed or concerned: Get medical attention/advice.

Storage

Store locked up.

Disposal

Dispose of contents/container in accordance with local regulation.

2.1 Hazards not otherwise classified (HNOC) or not covered by GHS - None

2. HAZARD IDENTIFICATION

Specific Concentration Limits

The values listed below represent the percentages of ingredients of unknown toxicity.

Acute oral toxicity	1 - 10%
Acute dermal toxicity	85 - 95%
Acute inhalation toxicity	90 - 100%
Acute aquatic toxicity	10 - 20%

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

Component	CAS Number	Concentration
Levodopa	59-92-7	85%
Organic solvent	Proprietary	1 – 4%

4. FIRST- AID MEASURES

Description of necessary first-aid measures**Eyes**

Flush the eye with plenty of water. Obtain medical attention if symptoms persist.

Skin

Wash affected area with plenty of water. Seek medical attention if symptoms persist.

Ingestion

Rinse mouth with plenty of water.

Inhalation

Not an expected route of entry.

Most important symptoms/effects, acute and delayed

Aside from the information found under description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

Indication of immediate medical attention and special treatment needed**Notes to Physicians**

Treat symptomatically.

5. FIRE - FIGHTING MEASURES

Suitable (and unsuitable) Extinguishing Media

Use foam, dry chemical or carbon dioxide. Use water spray for surroundings and containers.

Specific hazards arising from the chemical

None known.

Special Protective Actions for Fire-Fighters

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Wear appropriate protective clothing.

Environmental Precautions

Prevent the material from entering drains or watercourses.

Methods and materials for containment and cleaning up

Sweep up and transfer into suitable containers for recovery or disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Wear appropriate protective equipment when handling. Do not eat or drink while handling this material.

Conditions for safe storage

Store at room temperature (25°C, 77°F). Do not store in excessive heat (above 40°C, 104°F).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limits are listed below, if they exist.

Organic solvent

ACGIH: 1000 ppm 15-min STEL

OSHA PEL: 1000 ppm TWA

OEL: Not Established

Appropriate engineering controls

No specific measures necessary.

Individual protection measures

Respiratory Protection

Respiratory protection not normally required.

Skin Protection

Gloves

Eye/Face Protection

Safety glasses

Body Protection

Normal work wear.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Powder (in capsule)
Color	White to off-white
Odor	None
Odor Threshold	No data available
pH	No data available
Density	No data available
Boiling Range/Point (°C/F)	No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Melting Range/Point (°C/F)	No data available
Flash Point (PMCC) (°C/F)	No data available
Vapor Pressure	No data available
Evaporation Rate (BuAc=1)	No data available
Solubility in Water	No data available
Vapor Density (Air = 1)	No data available
VOC (%)	<2
Partition coefficient (n-octanol/water)	No data available
Viscosity	No data available
Auto-ignition Temperature	No data available
Decomposition Temperature	No data available
Upper explosive limit	No data available
Lower explosive limit	No data available
Flammability (solid, gas)	No data available

10. STABILITY AND REACTIVITY

Reactivity

No known reactivity.

Chemical Stability

Stable under normal conditions.

Possibility of hazardous reactions

Hazardous polymerization will not occur.

Conditions to Avoid

Heat – high temperatures

Incompatible Materials

Strong oxidizing agents

Hazardous Decomposition Products

Toxic fumes of nitrogen oxides

11. TOXICOLOGICAL INFORMATION

Acute ToxicityLevodopa

Oral LD50 (rat) 1780 mg/kg

Organic solvent

Oral LD50 (rat) >5000 mg/kg (95% solution)

Specific Target Organ Toxicity (STOT) – single exposure

No data available.

11. TOXICOLOGICAL INFORMATION

Specific Target Organ Toxicity (STOT) – repeat exposure

INBRIJA: Oronasal inhalation of INBRIJA for 26 weeks was well tolerated with minimal findings limited to piloerection, with no findings in lungs related to INBRIJA. Accordingly, under the conditions of this study, the NOAEL for pulmonary exposure to INBRIJA is considered to be 174 mg/kg/day, corresponding to a Day 180 C_{max} and AUC_{last} of 9000 ng/mL and 19200 ng.h/mL in males and 8990 ng/mL and 33600 ng.h/mL in females.

Serious Eye damage/Irritation

No data available.

Skin Corrosion/Irritation

No data available.

Respiratory or Skin Sensitization

Levodopa: Non-sensitizing (skin) in guinea pig study.

Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

Germ Cell Mutagenicity

No data available.

Reproductive Toxicity

Levodopa: Teratogenicity studies in rabbits have shown that Levodopa causes visceral and skeletal malformations in offspring (HSDB). However, this effect was only observed at high doses, which ranged from 5 to 10 times the maximum recommended human dose of Levodopa. However, Levodopa is not contraindicated in pregnant women and exposures to dose levels used in the teratogenicity studies are unlikely in the occupational environment.

Aspiration Hazard

Available data indicates this product is not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Levodopa

EC50 Daphnia Magna >100 mg/l 48h

Mobility in soil

No relevant studies identified.

Persistence/Degradability

No relevant studies identified.

Bioaccumulative Potential

No relevant studies identified.

Other adverse effects

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

Non DOT, Not Regulated, N/A, None.

15. REGULATORY INFORMATION

United States TSCA Inventory

All components of this product have not been verified for the inventory listing requirements of the US Toxic Substance Control Act (TSCA) Chemical Substance Inventory.

Canada DSL Inventory

All components of this product have not been verified for inclusion on the Domestic Substance List (DSL).

WHMIS Classification

None

This product was classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations and the MSDS contains all the information required by these regulations.

SARA Title III Sect. 311/312 Categorization

None

California Proposition 65

This product contains materials which the State of California has found to cause cancer, birth defects or other reproductive harm: Levodopa

16. OTHER INFORMATION

NFPA Ratings

NFPA Code for Flammability - 0

NFPA Code for Health - 0

NFPA Code for Reactivity - 0

NFPA Code for Special Hazards – None

HMIS Ratings

HMIS Code for Flammability - 0

HMIS Code for Health - 0

HMIS Code for Physical Hazard - 0

HMIS Code for Personal Protection - See Section 8

*Chronic

Legend

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service

HSDB: Hazardous Substances Data Bank

IARC: International Agency for Research on Cancer

N/A: Denotes no applicable information found or available

16. OTHER INFORMATION

NTP: National Toxicology Program
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit
SDS: Safety Data Sheet
STEL: Short Term Exposure Limit
TLV: Threshold Limit Value

For further information email: info@civitastherapeutics.com

Information Source and References

This SDS is prepared by Hazard Communication Specialists based on information provided by internal company references.

Prepared By: EnviroNet LLC.

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Preparation Information

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