



Safety Data Sheet

Orphenadrine Citrate ER Tabs 100mg

Revision Date: 03/13/2025

Section 1. Identification

Product identifier

Product Identity

Orphenadrine Citrate ER Tabs 100mg

Other means of identification

Not Applicable

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

Treat Muscle Spasm

Details of the supplier of the safety data sheet

Company Name

Lupin Somerset
400 Campus Drive
Somerset, NJ 08873

Emergency

24 hour Emergency Telephone No.

Customer Service:

800-642-5263

Section 2. Hazard(s) identification

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Acute toxicity(oral), category 4;H302

Harmful if swallowed.

Aquatic toxicity (chronic), category 1;H410

Very toxic to aquatic life with long lasting effects.

Label elements



Warning

H302 Harmful if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

[Prevention]

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

[Response]

P301+312 IF SWALLOWED: Call a POISON CENTER, doctor or physician if you feel unwell.

P312 Call a POISON CENTER, doctor or physician if you feel unwell.

P330 Rinse mouth.

P391 Collect spillage.



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[Storage]

No GHS storage statements

[Disposal]

P501 Dispose of contents or container in accordance with local and national regulations.

Other hazards

This product contains no PBT/vPvB/vPvM chemicals.

This product contains no endocrine disrupting chemicals.

Does not contain component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS) per US or Canadian regulations.

Section 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Orphenadrine dihydrogen citrate CAS Number: 4682-36-4 Synonyms: No available information	30 - 60	Acute toxicity(oral), category 4;H302 Aquatic toxicity (chronic), category 1;H410	-----
Cellulose hydroxypropyl methyl ether CAS Number: 9004-65-3 Synonyms: Hydroxypropyl methyl cellulose	30 - 60	Not Classified	-----
Lactose, monohydrate CAS Number: 64044-51-5 Synonyms: No available information	30 - 60	Not Classified	-----
Magnesium stearate CAS Number: 557-04-0 Synonyms: No available information	0.5 - 1.5	Not Classified	-----

The actual concentration or concentration range is withheld as a trade secret.

*PBT/vPvB - PBT, vPvM or vPvB-substance.

The full texts of the phrases are shown in Section 16.

Section 4. First aid measures

Description of first aid measures

General

In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation

Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious, place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin

Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion

If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.



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Most important symptoms and effects, both acute and delayed

Overview	No specific symptom data available. No chronic toxicity or long term toxicity information available. Treat symptomatically. See section 2 for further details.
Ingestion	Harmful if swallowed.

Section 5. Fire-fighting measures

Extinguishing media

Recommended extinguishing media; alcohol resistant foam, CO², powder, water spray.

Unsuitable extinguishing media: Do not use; water jet.

Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

Advice for fire-fighters

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

ERG Guide No. 171

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

Methods and material for containment and cleaning up

Sweep up or pick up.

Section 7. Handling and storage

Precautions for safe handling

Handle containers carefully to prevent damage and spillage.

See section 2 for further details. - [Prevention]

Conditions for safe storage, including any incompatibilities

Incompatible materials: No data available.

See section 2 for further details. - [Storage]



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Specific end use(s)

No data available.

Section 8. Exposure controls / personal protection

Control parameters

Exposure Limits

CAS No.	Ingredient	Source	Value
557-04-0	Magnesium stearate	OSHA	No Established Limit
		ACGIH	10 mg/m ³ (I) Inhalable, 3 mg/m ³ (R)
		NIOSH	No Established Limit
4682-36-4	Orphenadrine dihydrogen citrate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
9004-65-3	Cellulose hydroxypropyl methyl ether	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
64044-51-5	Lactose, monohydrate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit

Exposure controls

Respiratory

If workers are exposed to concentrations above the exposure limit, they must use the appropriate, certified respirators.

Eyes

Protective safety glasses recommended

Skin

Protective gloves recommended.

Engineering Controls

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details.



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Section 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical State	Solid
Color	Tablet
Odor	Not Provided
Melting point / freezing point	Not Available
Initial boiling point and boiling range	Not Available
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Available Upper Explosive Limit: Not Available
Flash Point	Not Available
Auto-ignition temperature	Not Available
Decomposition temperature	Not Available
pH	Not Available
Viscosity (cSt)	Not Available
Solubility in Water	Not Available
Partition coefficient n-octanol/water (Log Kow)	Not Available
Vapor pressure (Pa)	Not Available
Relative Density	Not Available
Vapor Density	Not Available
Evaporation rate (Ether = 1)	Not Available
VOC Content	Not Available

Other information

No other relevant information.

Section 10. Stability and reactivity

Reactivity

Hazardous Polymerization will not occur.

Chemical stability

Stable under normal circumstances.

Possibility of hazardous reactions

No data available.

Conditions to avoid

No data available.

Incompatible materials

No data available.



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Hazardous decomposition products

No hazardous decomposition data available.

Section 11. Toxicological information

Acute toxicity

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Orphenadrine dihydrogen citrate - (4682-36-4)	No data available.	No data available.	No data available.	No data available.	No data available.
Cellulose hydroxypropyl methyl ether - (9004-65-3)	10,000.00, Mammal - Category: NA	No data available.	No data available.	No data available.	No data available.
Lactose, monohydrate - (64044-51-5)	No data available.	No data available.	No data available.	No data available.	No data available.
Magnesium stearate - (557-04-0)	No data available.	No data available.	No data available.	No data available.	No data available.

Carcinogen Data

CAS No.	Ingredient	Source	Value
557-04-0	Magnesium stearate	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
4682-36-4	Orphenadrine dihydrogen citrate	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
9004-65-3	Cellulose hydroxypropyl methyl ether	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
64044-51-5	Lactose, monohydrate	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit

Classification	Category	Hazard Description
Acute toxicity (oral)	4	Harmful if swallowed.
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable



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Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

Possible routes of entry: No available information

Symptoms and effects, both acute and delayed:

No specific symptom data available.

No chronic toxicity or long term toxicity information available. Treat symptomatically.

Ingestion Harmful if swallowed.

Section 12. Ecological information

Toxicity

Very toxic to aquatic life with long lasting effects.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/L	48 hr EC50 crustacea, mg/L	ErC50 algae, mg/L
Orphenadrine dihydrogen citrate - (4682-36-4)	No data available.	No data available.	No data available.
Cellulose hydroxypropyl methyl ether - (9004-65-3)	No data available.	No data available.	No data available.
Lactose, monohydrate - (64044-51-5)	No data available.	No data available.	No data available.
Magnesium stearate - (557-04-0)	No data available.	No data available.	No data available.

Persistence and degradability

There is no data available on the preparation itself.

Bioaccumulative potential

Not Available

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB/vPvM chemicals.

Other adverse effects

No data available.



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Section 13. Disposal considerations

Waste treatment methods

Waste should not be released to sewers. Observe all federal, state, and local regulations when disposing of this substance.

Section 14. Transport information

Not regulated for packages under 5L (1.3 gallons) or 5.0 kg (11 lbs).

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
UN number	UN3077	UN3077	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s., (Orphenadrine dihydrogen citrate)	Environmentally hazardous substances, solid, n.o.s., (Orphenadrine dihydrogen citrate)	Environmentally hazardous substances, solid, n.o.s., (Orphenadrine dihydrogen citrate)
Transport hazard class(es)	Class: 9 Sub Class: Not Applicable	Class: 9 Sub Class: Not Applicable	Class: 9 Sub Class: Not Applicable
Packing group	III	III	III

Environmental hazards

Marine Pollutant: Yes; (Orphenadrine dihydrogen citrate)

Special precautions for user

Not Applicable

Section 15. Regulatory information

Regulatory Overview The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Toxic Substance Control Act (TSCA)

CAS Number	Ingredient	Toxic Substance Control Act (TSCA)	Comments	Status
0009004-65-3	Cellulose hydroxypropyl methyl ether	Yes	XU	ACTIVE
0064044-51-5	Lactose, monohydrate	No		
0000557-04-0	Magnesium stearate	Yes		ACTIVE
0004682-36-4	Orphenadrine dihydrogen citrate	No		



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EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 Label Warning:

This product contains no chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Section 16. Other information

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The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H302 Harmful if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Disclaimer: The information presented herein is supplied as a guide to those who handles or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a determination regarding the adequacy of the safety procedures employed during the use of this product.

Reviewed & Approved by: IES Engineers

Authored by: Quantum SDS

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