



Safety Data Sheet
PENTAZOCINE-
NALOXONETABS50/0.5MG(FIS)CIV -

Revision Date: 03/13/2025

Section 1. Identification

Product identifier

Product Identity PENTAZOCINE-NALOXONETABS50/0.5MG(FIS)CIV -

Other means of identification Not Applicable

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

Severe Pain Relief

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.
Skin corrosion/irritation category 2;H315	Causes skin irritation.
Serious eye damage / eye irritation, category 2A;H319	Causes serious eye irritation.
Specific target organ toxicity, Single exposure category 3;H335	May cause respiratory irritation.
Specific target organ toxicity, Single exposure category 3;H336	May cause drowsiness or dizziness.
Combustible Dust	May form combustible dust concentrations in air.

Label elements



Warning

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness and dizziness.



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May form combustible dust concentrations in air.

[Prevention]

- P261 Avoid breathing dust, fume, gas, mist, vapors, spray.
- P264 Wash thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves, eye protection, and face protection.

[Response]

- P301+312 IF SWALLOWED: Call a POISON CENTER, doctor or physician if you feel unwell.
- P302+352 IF ON SKIN: Wash with plenty of soap and water.
- P304+340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 Call a POISON CENTER, doctor or physician if you feel unwell.
- P330 Rinse mouth.
- P332+313 If skin irritation occurs: Get medical attention.
- P337+313 If eye irritation persists: Get medical advice or attention.
- P362+364 Take off contaminated clothing and wash it before reuse.

[Storage]

- P403+233 Store in a well ventilated place. Keep container tightly closed.
- P405 Store locked up.

[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.
 May form combustible dust concentrations in air.
 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
Cellulose CAS Number: 9004-34-6 Synonyms: No available information	10 - 30	Combustible Dust	-----
(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc CAS Number: 64024-15-3 Synonyms: No available information	10 - 30	Acute toxicity(oral), category 4;H302 Skin corrosion/irritation category 2;H315 Serious eye damage / eye irritation, category 2;H319 Specific target organ toxicity, Single exposure category 3;H336	-----



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Calcium hydrogen phosphate, dihydrate CAS Number: 7789-77-7 Synonyms: Calcium phosphate	10 - 30	Serious eye damage / eye irritation, category 2;H319 Skin corrosion/irritation category 2;H315 Specific target organ toxicity, Single exposure category 3;H335	-----
Pregelatinized Starch CAS Number: 9005-25-8 Synonyms: Sago starch	10 - 30	Not Classified	-----
Magnesium stearate CAS Number: 557-04-0 Synonyms: No available information	0.5 - 1.5	Not Classified	-----
Silicon dioxide, chemically prepared CAS Number: 112945-52-5 Synonyms: Amorphous fumed silica	0.1 - 1	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.
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.
Inhalation	May cause respiratory irritation. May cause drowsiness or dizziness.
Eyes	Causes serious eye irritation.
Skin	Causes skin irritation.
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.



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Avoid breathing dust, fume, gas, mist, vapors, spray.

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. ---

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]

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
7789-77-7	Calcium hydrogen phosphate, dihydrate	OSHA	No Established Limit



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		ACGIH	No Established Limit
		NIOSH	No Established Limit
9004-34-6	Cellulose	OSHA	15 mg/m ³ (total dust), 5 mg/m ³ (respirable fraction)
		ACGIH	10 mg/m ³
		NIOSH	TWA 10 mg/m ³ (total) TWA 5 mg/m ³ (resp)
9005-25-8	Pregelatinized Starch	OSHA	15 mg/m ³ (total dust), 5 mg/m ³ (respirable fraction)
		ACGIH	10 mg/m ³
		NIOSH	TWA 10 mg/m ³ (total) TWA 5 mg/m ³ (resp)
64024-15-3	(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
112945-52-5	Silicon dioxide, chemically prepared	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.

Section 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical State

Solid

Color

Tablets

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



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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.

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
Cellulose - (9004-34-6)	> 5,000.00, Rat - Category: NA	No data available.	No data available.	No data available.	No data available.
(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc - (64024-15-3)	No data available.	No data available.	No data available.	No data available.	No data available.
Calcium hydrogen phosphate, dihydrate - (7789-77-7)	No data available.	No data available.	No data available.	No data available.	No data available.
Pregelatinized Starch - (9005-25-8)	No data available.	No data available.	No data available.	No data available.	No data available.



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Magnesium stearate - (557-04-0)	No data available.	No data available.	No data available.	No data available.	No data available.
Silicon dioxide, chemically prepared - (112945-52-5)	3,160.00, Rat - Category: 5	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
7789-77-7	Calcium hydrogen phosphate, dihydrate	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
9004-34-6	Cellulose	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
9005-25-8	Pregelatinized Starch	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	A4
64024-15-3	(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc	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
112945-52-5	Silicon dioxide, chemically prepared	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: Yes;
		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	2	Causes skin irritation.
Serious eye damage/irritation	2A	Causes serious eye irritation.
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



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STOT-single exposure	3	May cause respiratory irritation.
STOT-single exposure	3	May cause drowsiness or dizziness.
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.

Inhalation May cause respiratory irritation. May cause drowsiness or dizziness.

Eyes Causes serious eye irritation.

Skin Causes skin irritation.

Ingestion Harmful if swallowed.

Section 12. Ecological information

Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/L	48 hr EC50 crustacea, mg/L	ErC50 algae, mg/L
Cellulose - (9004-34-6)	100.00, Fish (Piscis)	No data available.	No data available.
(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc - (64024-15-3)	No data available.	No data available.	No data available.
Calcium hydrogen phosphate, dihydrate - (7789-77-7)	No data available.	No data available.	No data available.
Pregelatinized Starch - (9005-25-8)	No data available.	No data available.	No data available.
Magnesium stearate - (557-04-0)	No data available.	No data available.	No data available.
Silicon dioxide, chemically prepared - (112945-52-5)	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

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
UN number	Not Regulated	Not Regulated	Not Regulated
UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
Transport hazard class(es)	Class: Not Applicable Sub Class: Not Applicable	Class: Not Applicable Sub Class: Not Applicable	Class: Not Applicable Sub Class: Not Applicable
Packing group	Not Applicable	Not Applicable	Not Applicable
Environmental hazards			
	Marine Pollutant: No;		
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
0064024-15-3	(2.alpha.,6.alpha.,11R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocin-8-ol hydroc	No		
0007789-77-7	Calcium hydrogen phosphate, dihydrate	No		
0009004-34-6	Cellulose	Yes	XU	ACTIVE
0000557-04-0	Magnesium stearate	Yes		ACTIVE
0009005-25-8	Pregelatinized Starch	Yes	XU	ACTIVE
0112945-52-5	Silicon dioxide, chemically prepared	No		

EPCRA 302 Extremely Hazardous:

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



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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.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness and dizziness.

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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