



# US - OSHA SAFETY DATA SHEET

Issue Date 14-Jul-2023

Revision Date NA

Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Cyanocobalamin Nasal Spray

### Other means of identification

**Product Code** Not available

**Synonyms** None known.

### Recommended use of the chemical and restrictions on use

**Recommended Use** Nasal Spray.

**Uses advised against** Not available.

### Details of the supplier of the safety data sheet

#### Supplier address

Lupin Somerset, LLC  
400 Campus Drive  
Somerset, NJ 08873

### Emergency telephone number

**Company Phone Number** 908-603-6066

**24 Hour Emergency Phone Number** 908-603-6029

## 2. HAZARDS IDENTIFICATION

### Classification

#### **Health Hazards**

Not classified.

#### **Physical Hazards**

Not classified.

### Label elements

#### Emergency Overview

<b>Appearance</b> Nasal Spray	<b>Physical state</b> Liquid	<b>Odor</b> Not available.
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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	Strength
Cyanocobalamin	68-19-9	500 mcg/0.1 mL

\*\*The exact percentage of the component and other components in this product is withheld as a trade secret.

## 4. FIRST AID MEASURES

### Description of first aid measures

**Eye Contact** In case of eye contact, immediately flush your eyes with fresh water for at least 15 minutes

while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

<b>Skin Contact</b>	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
<b>Inhalation</b>	In case of inhalation, remove the fresh air. If not breathing, call 911 and provide artificial respiration. Do not use mouth-to-mouth method; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device if breathing is difficult. Seek emergency medical attention immediately.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

#### **Most important symptoms and effects, both acute and delayed**

**Symptoms** For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

#### **Indication of any immediate medical attention and special treatment needed**

**Note to Physicians** Treat symptomatically.

### **5. FIRE-FIGHTING MEASURES**

#### **Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, carbon dioxide, dry chemical, chemical foam.

**Unsuitable Extinguishing Media** Caution: Use of water spray when fighting fire may be inefficient as the burning material may be spread.

#### **Specific hazards arising from the chemical**

Not available.

#### **Explosion data**

**Sensitivity to Mechanical Impact** None known.

**Sensitivity to Static Discharge** None known.

#### **Protective equipment and precautions for firefighters**

Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

### **6. ACCIDENTAL RELEASE MEASURES**

#### **Personal precautions, protective equipment, and emergency procedures**

**Personal Precautions** Not applicable to consumer use. In an industrial setting, ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8 and follow handling guidance appropriate for the compound (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

#### **Environmental precautions**

**Environmental precautions** See Section 12 for additional ecological information.

#### **Methods and material for containment and cleaning up**

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for Cleaning Up** Pick up and transfer to properly labeled containers. Package all material in appropriate container for disposal.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on Safe Handling** Handle in accordance with good industrial hygiene and safety practice. Take off contaminated clothing and wash it before reuse. Wash hands after handling.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool, and well-ventilated place.

**Incompatible Materials** None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

**Exposure Guidelines** This product, as supplied, contains the following hazardous material(s) with occupational exposure limits established by the region-specific regulatory bodies.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Cyanocobalamin 68-19-9	-	TWA: 5 mg/m <sup>3</sup> (vacated)	TWA: 25 mg/m <sup>3</sup>

### Appropriate engineering controls

**Engineering Controls** None under normal use conditions. The health hazard risks of handling this material are dependent on factors such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

### Individual protection measures, such as personal protective equipment

**Eye/Face Protection** None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and Body Protection** Wear impervious fire-resistant protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

**Respiratory Protection** None required under normal use conditions. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**General Hygiene Considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Physical state	Liquid	Odor	Not available.
Appearance	Nasal spray	Odor Threshold	Not available.
Color	Not available.		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available	
Melting point/freezing point	No information available	
Boiling point/boiling range	No information available	
Flash point	No information available	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	Not available.	
Vapor density	No information available	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	No information available	
Hyphen	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	
<u>Other information</u>		
Softening point	Not available.	
Molecular weight	Not available.	
VOC Content (%)	No information available	
Density	Not available.	
Bulk density	Not available.	

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available

### Chemical stability

Stable under recommended handling and storage conditions.

### Possibility of hazardous reactions

None under normal processing.

### Conditions to Avoid

Cyanocobalamin is light sensitive so avoid extremes of temperature and direct sunlight.

### Incompatible materials

Acids, Strong acids.

### Hazardous decomposition products

None known.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Product Information** Product does not present an acute toxicity hazard based on known or supplied information

#### Acute Toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Cyanocobalamin 68-19-9	> 5,000 mg/kg (mouse)			

### Symptoms related to the physical, chemical, and toxicological characteristics

**Symptoms** Cyanocobalamin is usually nontoxic even in large doses; however, mild transient diarrhea, peripheral vascular thrombosis, itching, transitory exanthema, urticaria, feeling of swelling of the entire body, anaphylaxis, and death have been reported.

### Delayed and immediate effects as well as chronic effects from short- and long-term exposure

**Skin/Eye Irritation** Not available.

**Respiratory or Skin Sensitization** Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals but does not classify the product as such at component concentration (Cyanocobalamin).

**Germ Cell Mutagenicity** Test Type: Ames test  
Test system: Escherichia coli/Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

**Carcinogenicity** Not listed by IARC, NTP or US OSHA as carcinogenic.

**Reproductive Toxicity** Not available.

**STOT - Single Exposure** Not available.

**STOT - Repeated Exposure** Not available.

**Aspiration Hazard** Not available.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Not available.

### Persistence and degradability

Not available.

### Bioaccumulation

Not available.

### Other adverse effects

No information available

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

**Disposal of Wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations.

**Contaminated Packaging** Do not reuse container/vial.

This product does not contain any substance that is listed with the State of California as hazardous waste.

#### 14. TRANSPORT INFORMATION

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>MEX</b>	Not regulated
<b>IATA</b>	Not regulated.
<b>IMDG</b>	Not regulated.

#### 15. REGULATORY INFORMATION

##### International Inventories

<b>TSCA</b>	Does not comply
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply

##### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

##### US Federal Regulations

##### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

##### SARA 311/312 Hazard Categories

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

##### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

##### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

##### US State Regulations

##### California Proposition 65

This product does not contain any Proposition 65 chemical(s).

**U.S. State Right-to-Know Regulations**

This product does not contain the following substance(s) regulated by state right-to-know regulations.

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable.

<b>16. OTHER INFORMATION</b>
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<b>Issue Date</b>	14-Jul-2023
<b>Revision Date</b>	NA
<b>Revision Note</b>	New SDS.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**