

SAFETY DATA SHEETS

This SDS packet was issued with item:

078804547

N/A



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Duramune Lyme
Product No.: 102293
GHS Product Identifier: Not applicable
Synonyms: Lymeavax

Molecular Formula: Mixture, not applicable
Molecular Weight: Mixture, not applicable
CAS Number: Mixture, not applicable
Chemical Family: Veterinary Vaccine

Manufacturer:
Boehringer Ingelheim Vetmedica, Inc.
800 5th Street NW
PO Box 518
Fort Dodge, IA 50501
Telephone: (515) 955-4600

Transportation Emergency: For Chemical
Emergency Spill, Leak, Fire, Exposure, or
Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887
(collect calls accepted)

Medical Emergency (24HR): (866) 638-2226
Non-Emergency Telephone: (800) 821-7467

Intended Use: Indicated for vaccination of
healthy dogs in the prevention of disease
caused by *Borrelia burgdorferi*.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Inactivated bacterin in an injectable opaque solution.
Color: Reddish-white
Odor: Odorless



WARNING!
For use in canines only.
Not for human use.
Allergic reactions can occur.

Precautionary Statements:

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature between 2 - 7°C (35-45F).

Do not freeze.

Store out of direct sunlight.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and incinerate.

In case of accident/exposure or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, flush with gently flowing fresh water thoroughly.

Wash skin thoroughly with soap and water after handling.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Skin

OSHA Regulatory Status: Non-hazardous (exempt)

Environment: No data available

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Borrelia burgdorferi bacterin (inactivated)	----	----	proprietary	----	---
Proprietary adjuvant	----	----	trade secret	----	---

Components not listed are not hazardous or are below reportable limits.

The full texts for all R-Phrases are displayed in Section 16, if applicable.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal injection only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7	HANDLING AND STORAGE
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Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Store at 2°-7°C (35°-45°F). Do not freeze. Shake well before using.

8	EXPOSURE CONTROLS / PERSONAL PROTECTION
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Exposure Limits: None Established.

Engineering Controls: Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) 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 to an acceptable level.

Respiratory Protection: Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

9	PHYSICAL AND CHEMICAL PROPERTIES
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Color: Reddish-white

Odor: Odorless

Odor Threshold: No data available

Physical State: Inactivated bacterin in an injectable opaque solution.

pH: 6 - 8

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: No data available

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: Easily soluble in cold water, hot water, methanol, diethyl ether, n-octanol, acetone.

Partition Coefficient (n-Octanol/water): No data available

Autoignition Temperature: Not applicable

Decomposition Temperature: No data available

10	STABILITY AND REACTIVITY
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Stability: Stable

Conditions to Avoid: Temperatures below 2° C (35° F)

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11	TOXICOLOGICAL INFORMATION
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Duramune Lyme is considered non-toxic.

Listed Carcinogens: None

12	ECOLOGICAL INFORMATION
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Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Not applicable

13	DISPOSAL CONSIDERATIONS
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General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

14	TRANSPORT INFORMATION
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15	REGULATORY INFORMATION
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Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Non-controlled

Inventory Status

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed.

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None listed.

Section 311/312 (40 CFR 370): Not Regulated.

Section 313 Toxic Release Inventory (40 CFR 372): None listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: None listed.

Minnesota Hazardous Substances List: None listed.

New Jersey Right-To-Know List: None listed.

Pennsylvania Right-To-Know List: None listed.

Rhode Island Right-To-Know List: None listed.

European Regulations

Austria MAK List (Annex I): None listed.

Denmark (Annex 3.6): None listed.

Germany (Dangerous Substances Ordinance 2004, Annex III): None listed.

Norway (List of Dangerous Substance): None listed.

Sweden (Annex 3): None listed.

Switzerland (Toxins List 1): None listed.

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	0	0	N/A

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

References:

1. Duramune Lyme MSDS and Label. Fort Dodge Animal Health.
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

Revision Information: New MSDS

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 06/22/2010

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SAFETY DATA SHEET

1. Identification

Product identifier Duramune Lyme

Other means of identification

Item Code AV6813, AV6810

Recommended use Veterinary Vaccine

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone: Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973

Email: elanco_sds@elanco.com

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<= 0.074
Thimerosal		54-64-8	<= 0.01
Other components below reportable levels			90 - 100

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Material name: Duramune Lyme

6867 Version #: 02 Revision date: 03-11-2019 Issue date: 12-12-2017

SDS US

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Ingestion	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention.
Most important symptoms/effects, acute and delayed	None known.
General information	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	Not available.
Specific hazards arising from the chemical	Not applicable.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Not available.
Methods and materials for containment and cleaning up	Prevent entry into waterways, sewer, basements or confined areas. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in the dark between 35 - 45 °F (2 - 7 °C). Avoid freezing.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines**US - California OELs: Skin designation**

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards Not available.

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 to remove contaminants.

9. Physical and chemical properties**Appearance**

Physical state Liquid.
Form Liquid
Color Opaque Reddish - White

Odor Odorless

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	10500 mg/m ³ , 4 hours
Oral		
LD50	Rat	640 mg/kg
Thimerosal (CAS 54-64-8)		
<u>Acute</u>		
Oral		
LD50	Rat	75 mg/kg

Skin corrosion/irritation	Rabbit: Corrosive. (Formaldehyde) No skin irritation. (0.1% Thimerosal) Based on available data, the classification criteria are not met.
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Serious eye damage/eye irritation	Rabbit: Corrosive. (Formaldehyde) Slight irritation. (0.1% Thimerosal) Based on available data, the classification criteria are not met.
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Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization

Respiratory sensitization

Respiratory sensitization Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate pre-existing asthmatic conditions.
Based on available data, the classification criteria are not met.

Skin sensitization May cause an allergic skin reaction. (Formaldehyde)
Risk of sensitization or allergic reactions among sensitive individuals. (Thimerosal)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Mixed results (Formaldehyde) Result in genetic toxicity assays (in vitro and in vivo): Negative (Thimerosal) Based on available data, the classification criteria are not met.
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Carcinogenicity May cause cancer. (Formaldehyde)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0) Cancer

US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

Reproductive toxicity No effects identified in animal studies. (Formaldehyde)
May damage fertility or the unborn child. (Thimerosal)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure May cause respiratory irritation. (Formaldehyde)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure No significant target organ toxicity reported. (Formaldehyde)
May cause damage to organs through prolonged or repeated exposure. (Thimerosal)
Based on available data, the classification criteria are not met.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Formaldehyde (CAS 50-00-0)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	29 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	24.1 mg/l, 96 hours
Chronic			
Fish	NOEC	Medaka, high-eyes (Oryzias latipes)	> 48 mg/l, 28 days
Thimerosal (CAS 54-64-8)			
Aquatic			
Acute			
Fish	LC50	Bullhead, catfish (Ictalurus sp.)	7.5 mg/l, 24 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Formaldehyde 0.35

Mobility in soil No data available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde (CAS 50-00-0)

SARA 304 Emergency release notification

FORMALDEHYDE (CAS 50-00-0)

100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0)

Cancer
Skin sensitization
Respiratory sensitization
Eye irritation
Skin irritation
Respiratory tract irritation
Acute toxicity
Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Formaldehyde (CAS 50-00-0)

Thimerosal (CAS 54-64-8)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Formaldehyde (CAS 50-00-0)

US state regulations

California Proposition 65

WARNING:



This product can expose you to Formaldehyde, which is known to the State of California to cause cancer, and Thimerosal, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Thimerosal (CAS 54-64-8) Listed: July 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Formaldehyde (CAS 50-00-0)

International Inventories

Country(s) or region

Inventory name

On inventory (yes/no)*

Canada

Domestic Substances List (DSL)

No

Canada

Non-Domestic Substances List (NDSL)

No

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

No

16. Other information, including date of preparation or last revision

Issue date

12-12-2017

Revision date

03-11-2019

Version #

02

List of abbreviations

TWA: Time Weighted Average

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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