





# SAFETY DATA SHEET

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SECTION 1 – IDENTIFICATION			
<b>PRODUCT IDENTIFIER:</b>	ALFAXAN® MULTIDOSE Alfaxalone Injection 10 mg/ml		
<b>OTHER MEANS OF IDENTIFICATION:</b>	JUROX Product Codes 520415 (10 mL), 520425 (20 mL) HEALTH Canada registration No. DIN #: 02468670		
<b>PRODUCT SIZE:</b>	10 ml or 20 ml multi-dose glass vial		
<b>RECOMMENDED USE:</b>	Veterinary anaesthetic agent used: 1. As an induction agent prior to inhalation anaesthesia in dogs and cats. 2. As a sole anaesthetic agent for the induction and maintenance of anaesthesia for the performance of examination or surgical procedures in dogs and cats.		
<b>RESTRICTIONS ON USE:</b>	For veterinary use only.		
SUPPLIER / MANUFACTURER INFORMATION:			
<b>CANADIAN SUPPLIER'S NAME:</b>	CENTRAL SALES LIMITED	<b>MANUFACTURER'S NAME:</b>	JUROX PTY LIMITED
<b>STREET ADDRESS:</b>	114 REGAN ROAD	<b>STREET ADDRESS:</b>	85 GARDINER STREET
<b>CITY AND PROVINCE:</b>	BRAMPTON, ONTARIO	<b>CITY AND PROVINCE:</b>	RUTHERFORD, NEW SOUTH WALES, AUSTRALIA
<b>POSTAL CODE:</b>	L7A 1B9	<b>POSTAL CODE:</b>	2320
<b>TELEPHONE #</b>	1-800-387-2522	<b>TELEPHONE #</b>	+61 2 4931 8200
EMERGENCY RESPONSE INFORMATION:			
<b>EMERGENCY CONTACT:</b>	CHEMTREC International CHEMTREC	<b>TELEPHONE #</b>	1-800-424-9300 (24 hours) +1-703-527-3887 (24 hours)

SECTION 2 – HAZARD IDENTIFICATION	
<b>PHYSICAL HAZARDS:</b>	Flammable Liquid Category 3.
<b>HEALTH HAZARDS:</b>	Eye Irritant Category 2A.
<b>ENVIRONMENTAL HAZARDS:</b>	Not classified as an environmental hazard using GHS criteria
<b>LABEL ELEMENTS*:</b>	 



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<b>SIGNAL WORD*:</b>	WARNING
<b>HAZARD STATEMENT(S)*:</b>	H226 Flammable liquid and vapor. H319 Causes serious eye irritation
<b>PRECAUTIONARY STATEMENT(S)*:</b>	
<b>Prevention:</b>	P210 Keep away from heat / sparks / open flames / hot surfaces – No smoking. P233 Keep container tightly closed. P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static charge. P264 Wash hands thoroughly after handling P280 Wear protective gloves / protective clothing / eye protection / face protection
<b>Response:</b>	P370 + P378 In case of fire: Use water spray / fog for extinction. P303 + P361 + P353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention
<b>Storage:</b>	P403 + P235 Store in a well-ventilated place. Keep cool.
<b>Disposal:</b>	P 501 Dispose of contents / container in accordance with local regulations.
<b>OTHER HAZARDS WHICH DO NOT RESULT IN CLASSIFICATION:</b>	None known.
<b>SUPPLEMENTAL INFORMATION:</b>	Anesthetic agent: May cause central nervous system and cardiovascular system effects. May cause drowsiness, dizziness, respiratory depression and unconsciousness.

\* Exempt on labelling as product is not classified as a "hazardous product" under WHMIS 2015 (Cosmetics, devices, drugs or foods as defined in the Food and Drugs Act are excluded products under WHMIS 2015).

SECTION 3– COMPOSITION / INFORMATION ON INGREDIENTS			
CHEMICALNAME	COMMON NAME AND SYNONYMS	CAS NUMBER (and any unique identifiers)	CONCENTRATION
Ethanol	Alcohol	64-17-5	< 24 %
Alfaxalone	Alfaxalone	23930-19-0	1 %
4-chloro-m-cresol	Chlorocresol	59-50-7	< 1 %
Ingredients non-hazardous			> 60 %



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SECTION 4 – FIRST AID MEASURES	
<b>Inhalation:</b>	If fumes, aerosols or combustion products are inhaled move victim to fresh air. Other measures are usually unnecessary.
<b>Skin:</b>	Wash affected area thoroughly with soap and water. If irritation occurs and continues, seek medical attention.
<b>Eye:</b>	Rinse eyes thoroughly with water for 20 minutes, holding eyelids apart with fingers. If irritation occurs and continues, seek medical attention.
<b>Ingestion:</b>	DO NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head down position if possible) to maintain open airway and prevent aspiration. Seek medical advice.
<b>Injection</b>	If accidentally injected, seek medical attention immediately.
<b>Most important symptoms / effects, acute and delayed</b>	Sedation, anesthesia, respiratory depression, CNS effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Following recent ingestion or overdose of anxiolytic sedatives, hypnotics and neuroleptics, the stomach may be emptied by gastric lavage and aspiration. Patients should be managed with intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of oxygenation, respiratory, cardiovascular and renal functions. Electrolyte balance should also be maintained.

SECTION 5 – FIRE FIGHTING MEASURES
<b>SUITABLE EXTINGUISHING MEDIA:</b> Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (Large fires only).
<b>UNSUITABLE EXTINGUISHING MEDIA:</b> Avoid contamination with oxidizing agents (e.g. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc) as ignition may result.
<b>SPECIFIC HAZARDS ARISING FROM THE HAZARDOUS PRODUCT (e.g. hazardous combustion products):</b> Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.
<b>SPECIFIC PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIRE-FIGHTERS:</b> For bulk product: Wear breathing apparatus plus protective gloves. Bulk product may be violently or explosively reactive. If safe, switch off electrical equipment until vapor fire hazard removed. Liquid and vapor are flammable. Moderate fire hazard when exposed to heat or flame. Vapor forms an explosive mixture with air. Moderate explosion hazard when exposed to heat or flame. Vapor may travel a considerable distance to source of ignition. Heating may cause expansion or decomposition leading to violent rupture of containers.



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## SECTION 6 – ACCIDENTAL RELEASE MEASURES

### PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

For bulk product: Safety glasses with side shields / chemical goggles. Chemical protective gloves e.g. PVC. Safety footwear or safety gumboots e.g. rubber. Overalls / PVC apron – PVC protective suit may be required if exposure severe. Respiratory protection – Type A filter of sufficient capacity. Eyewash unit. Ready access to a safety shower.

### METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

For small spills (i.e. those associated with normal use of the product), wipe up spill with paper towels or other suitable materials. Rinse area with water. For large spills, contain the spill using booms, dikes, or absorbent material to prevent releases onto land or into waterways. Collect spilled material for future disposal.

## SECTION 7 – HANDLING AND STORAGE

### PRECAUTIONS FOR SAFE HANDLING:

For bulk product: Avoid all personal contact, including inhalation. Wear protective gloves when risk of overexposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid smoking, naked lights or ignition sources.

### CONDITIONS FOR SAFE STORAGE (including incompatible materials):

For individual marketed packs: Store at controlled room temperature (15°C to 30°C). Shelf life after first opening: 28 days.

For bulk product: Store in original containers in approved flammable liquid storage area. Store away from incompatible materials in a cool dry, well-ventilated area. DO NOT store in pits, depressions, basements or areas where vapours may be trapped. No smoking, naked lights, heat or ignition sources. Store according to applicable regulations for flammable materials.

## SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

**CONTROL PARAMETERS** (including occupational exposure limits or biological exposure limits and the source of those values):

### OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT NAME	TWA		STEL	
	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm
Alfaxalone	NE	NE	NE	NE
Ethanol	1880 – 1900	1000	1900	1000 - 1250
4-chloro-m-cresol	NE	NE	NE	NE

\*TWA and STEL values sourced from the Regulatory Lists noted in Section 15

### BIOLOGICAL LIMIT VALUES

Not available

### APPROPRIATE ENGINEERING CONTROLS:

Handle in a well-ventilated area. Local exhaust ventilation may be required in specific circumstances.

### INDIVIDUAL PROTECTION MEASURES (e.g. personal protective equipment):

<b>RESPIRATORY PROTECTION:</b>	Respiratory protection is not considered necessary for normal use of this product. For the bulk product, respiratory protection is likely to be required - Type AB-P filter of sufficient capacity is recommended.
<b>PROTECTIVE GLOVES:</b>	PVC gloves are recommended.



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<b>EYE PROTECTION:</b>	For the bulk product, safety glasses with side shields or chemical goggles are recommended.
<b>OTHER:</b>	For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES		
<b>APPEARANCE (physical state, color etc):</b> Clear, colourless liquid	<b>ODOUR:</b> Not available	<b>ODOUR THRESHOLD (ppm):</b> Not available
<b>pH (100%):</b> Approx. 7	<b>MELTING POINT / FREEZING POINT (DEG. C):</b> Not available	<b>INITIAL BOILING POINT / BOILING RANGE (DEG.C):</b> Not available
<b>FLASH POINT (°C):</b> 43.5	<b>EVAPORATION RATE:</b> Not available	<b>FLAMMABILITY (solid; gas):</b> Flammable vapor
<b>LOWER FLAMMABLE / EXPLOSIVE LIMIT:</b> Not available	<b>UPPER FLAMMABLE / EXPLOSIVE LIMIT:</b> Not available	<b>VAPOR PRESSURE (mmHg):</b> Not available
<b>VAPOR DENSITY:</b> Not available	<b>RELATIVE DENSITY:</b> Not available	<b>SOLUBILITY:</b> Miscible in water
<b>PARTITION COEFFICIENT (n-octanol / water):</b> Not available	<b>AUTO-IGNITION TEMPERATURE (°C):</b> Not available	<b>DECOMPOSITION TEMPERATURE:</b> Not available
<b>VISCOSITY:</b> Not available		

SECTION 10 – STABILITY AND REACTIVITY
<b>REACTIVITY:</b> May react with oxidizing agents.
<b>CHEMICAL STABILITY:</b> Unstable in the presence of incompatible material, otherwise stable. Hazardous polymerization will not occur.
<b>POSSIBILITY OF HAZARDOUS REACTIONS:</b> Likely in the presence of excessive heat or oxidizing agents.
<b>CONDITIONS TO AVOID:</b> Avoid exposure to excessive heat.
<b>MATERIALS AND SUBSTANCES TO AVOID (INCOMPATIBILITY):</b> Avoid reaction with oxidizing agents.
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b> This product may release toxic vapors when subjected to fire conditions (see Section 5).



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**SECTION 11 – TOXICOLOGICAL INFORMATION****ACUTE DATA:****INHALATION:**

Not classified as acutely toxic by inhalation by GHS criteria.

**Ethanol:** Inhalation (rat) LC50: 1247 mg/L/4h

**INGESTION:**

Not classified as acutely toxic by ingestion by GHS criteria.

**Ethanol:** Oral (rat) LD<sub>50</sub>: 1501 mg/kg

**Alfaxalone:** Oral (rat) LD<sub>50</sub>: 297 mg/kg

**4-chloro-m-cresol:** Oral (rat) LD<sub>50</sub>: 600 mg/kg

**INJECTION:**

Alfaxalone is an anesthetic. Avoid needle stick injury. The product will cause drowsiness, dizziness or anesthesia.

**Ethanol:** Intravenous LD50 (rat): 1440 mg/kg; Intraperitoneal LD50 (rat): 3.6 mg/kg; Subcutaneous LD50 (mouse): 8285 mg/kg

**Alfaxalone:** Intravenous LD50 (rat): 19.4 mg/kg; Intraperitoneal LD50 (rat): 116 mg/kg; Subcutaneous LD50 (rat): 2200 mg/kg.

**4-chloro-m-cresol:** Intravenous LD50 (mouse): 70 mg/kg; Subcutaneous LD50 (mouse): 360 mg/kg.

**EYES:**

The product is considered to be an **Eye Irritant Category 2A** and may cause eye irritation in some persons.

**Ethanol:** Eye (rabbit): 500 mg - Severe irritation, 100 mg / 24 hr - Moderate irritation.

**SKIN:**

Not classified as acutely toxic by the dermal route by GHS criteria

**Ethanol:** Dermal (rat): LD50: 17100 mg/kg

**Alfaxalone:** Dermal (rat) LD50: > 2,200 mg/kg

**4-chloro-m-cresol:** Dermal (rat) LD50: > 500 mg/kg

Not classified as a skin irritant by GHS criteria.

**Ethanol:** Skin (rabbit): 20 mg / 24 hr - Moderate irritation, 400 mg (open) – mild irritation

**TARGET ORGAN EFFECTS DATA (SUBCHRONIC/CHRONIC):**

Not classified as a specific organ toxicant by GHS criteria. Prolonged exposure to ethanol may cause damage to the liver.

**CARCINOGENIC EFFECTS DATA:**

This product is not known to be carcinogenic.

**MUTAGENIC EFFECTS DATA:**

This product is not known to be mutagenic.

**REPRODUCTIVE/TERATOGENIC EFFECTS DATA:**

This product is not known to have reproductive / teratogenic effects.



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SECTION 12 – ECOLOGICAL INFORMATION	
<b>Ecotoxicity</b>	<p>The product is not classified as ecotoxic by GHS criteria.</p> <p><b>Ethanol:</b>            LC<sub>50</sub> (96 hr) (fish): 11 mg/L            EC<sub>50</sub> (48 hr) (crustacea): 2 mg/L            EC<sub>50</sub> (96 hr) (algae / aquatic plants): 17.921 mg/L            NOEC (2016 hr) (fish): 0.000375 mg/L</p> <p><b>Alfaxalone:</b>            No data available</p> <p><b>4-chloro-m-cresol:</b>            LC<sub>50</sub> (96 hr) (fish): 0.917 mg/L            EC<sub>50</sub> (48 hr) (crustacea): 1.5 mg/L            EC<sub>50</sub> (72 hr) (algae / aquatic plants): 4.2 mg/L            EC<sub>10</sub> (72 hr) (algae / aquatic plants): 1.85 mg/L            NOEC (96 hr) (fish) 0.366 mg/L</p>
<b>Persistence and degradability</b>	<p><b>Persistence: Water/Soil</b></p> <p><b>Ethanol:</b>            LOW (Half-life = 2.17 days)</p> <p><b>Alfaxalone:</b>            No data available</p> <p><b>4-chloro-m-cresol:</b>            LOW (Half-life = 49 days)</p> <p><b>Persistence: Air</b></p> <p><b>Ethanol:</b>            LOW (Half-life = 5.08 days)</p> <p><b>Alfaxalone:</b>            No data available</p> <p><b>4-chloro-m-cresol:</b>            LOW (Half-life = 0.67 days)</p>
<b>Bioaccumulative potential</b>	<p><b>Ethanol:</b>            LOW (logKOW = -0.31)</p> <p><b>Alfaxalone:</b>            No data available</p> <p><b>4-chloro-m-cresol:</b>            LOW (BCF = 13)</p>
<b>Mobility in soil</b>	<p><b>Ethanol:</b>            HIGH (KOC = 1)</p> <p><b>Alfaxalone:</b>            No data available</p> <p><b>4-chloro-m-cresol:</b>            LOW (KOC = 717.6)</p>
<b>Other adverse effects</b>	In aquatic vertebrates, alfaxalone may cause anesthesia and have both central nervous system and cardiovascular system effects.



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## SECTION 13 – DISPOSAL CONSIDERATIONS

Recycle wherever possible in accordance with local/regional/national/international regulations.  
 Otherwise dispose of contents/container in accordance with local/regional/national/international regulations.  
 Since emptied containers may retain product residue, follow label and SDS warnings even after container is emptied.

## SECTION 14 – TRANSPORT INFORMATION

<b>UN Number</b>	Not applicable.
<b>UN proper shipping name</b>	Not applicable.
<b>Transport hazard class(es)</b>	Marine pollutant: NO. Land transport (TDG): Not regulated for transport of dangerous goods. Air transport (ICAO-IATA / DGR) Not regulated for transport of dangerous goods. Sea transport (IMDG-Code / GGVSee): Not regulated for transport of dangerous goods. Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable.
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	Not applicable.
<b>Transport in bulk, if applicable</b>	Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable.
<b>Special precautions</b>	As for aqueous solutions containing not more than 24 per cent alcohol.

## SECTION 15 – REGULATORY INFORMATION

**Canadian regulations** This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

- **Controlled Drugs and Substances Act:** Not regulated.
- **Export Control List (CEPA 1999, Schedule 3):** Not listed.
- **Greenhouse Gases:** Not listed.
- **Precursor Control Regulations:** Not regulated.

### International regulations

- **Stockholm Convention:** Not applicable.
- **Rotterdam Convention:** Not applicable.
- **Kyoto protocol:** Not applicable.
- **Montreal Protocol:** Not applicable.
- **Basel Convention:** Ethanol waste is listed in Annex 2.





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## Regulatory lists:

### Ethanol (64-17-5) is found on the following regulatory lists:

- Canada – Northwest Territories Occupational Exposure Limits (English);
- Canada – Alberta Occupational Exposure Limits;
- Canada – British Columbia Occupational Exposure Limits;
- Canada – Nova Scotia Occupational Exposure Limits;
- Canada – Prince Edward Island Occupational Exposure Limits;
- Canada – Prince Edward Island Occupational Exposure Limits – Carcinogens;
- Canada – Quebec Permissible Exposure Values for Airborne Contaminants (French);
- Canada – Saskatchewan Occupational Health and Safety Regulations – Contamination Limits;
- Canada – Yukon Permissible Concentrations for Airborne Contaminant Substances;
- Canada Categorization decisions for all DSL substances;
- Canada Domestic Substances List (DSL);
- Canada Forensic Identification Services Chemical Carcinogenicity Evaluation – Table – Chemicals Considered for Assessment (English).

### Alfaxalone (23930-19-0) is found on the following regulatory lists:

- Not applicable.

### 4-Chloro-m-cresol (59-50-7) is found on the following regulatory lists:

- Canada Categorization decisions for all DSL substances;
- Canada Domestic Substances List (DSL).

## SECTION 16 – OTHER INFORMATION

<b>DATE UPDATED:</b>	11 January 2018	This is the first SDS for this product.
06MAY2020	Amend storage statement, Ethanol content, section 11 toxicological information – state eye irritant Category 2A and review of available data.	

## Abbreviations

BCF: Bromochlorodifluoromethane

CAS No.: A unique number assigned to a chemical by the Chemical Abstracts Service.

CNS: Central nervous system

DGR: Dangerous Goods Regulations

EC<sub>10</sub>: The one tenth maximal effective concentration, being a statistically derived concentration of a substance that induces a response one tenth between the baseline and maximum after a specified exposure time.

EC<sub>50</sub>: The half maximal effective concentration, being a statistically derived concentration of a substance that induces a response halfway between the baseline and maximum after a specified exposure time.

GGVSee: Gefährgut-Verordnung Seeschiffen (Germany, Hazardous freight ordinance for maritime transport)

GHS: The 'Globally Harmonized System of Classification and Labelling of Chemicals, 3<sup>rd</sup> Revised Edition', published by the United Nations.

HPR: Hazardous Products Regulations

IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

IATA: International Air Transport Association

ICAO-IATA: International Civil Aviation Organization



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IMDG-Code: International Maritime Dangerous Goods Code

KOC: Soil Organic Carbon – Water Partitioning Coefficient. A measure of the mobility of a substance in soil. Higher KOC values correlate to less mobile organic chemicals while lower KOC values correlate to more mobile organic chemicals.

LC<sub>50</sub>: The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of organisms.

LD<sub>50</sub>: The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.

logKOW: A relative indicator of the tendency of an organic compound to adsorb to soil and living organisms. LogKOW are generally inversely related to water solubility and directly proportional to the molecular weight of a substance.

MARPOL: Marine Pollution as in Marpol 73/78 which is the International Convention for the Prevention of Pollution from Ships 1073 as modified by the Protocol of 1978

NE: Not Established

NOEC: No Observed Effect Concentration

PVC: Polyvinyl chloride

SDS: Safety Data Sheet

STEL: Short Term Exposure Limit

TDG: Transport Dangerous Goods

TWA: Time Weighted Average

UN: United Nations

UN Number: Number identifying a hazardous substance, assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods

WHMIS: Workplace Hazardous Materials Information System (Canada)

## References

- I. Europe ECHA Registered Substances
- II. Hazardous Products Regulations (<http://laws-lois.justice.gc.ca/eng/regulations/SPOR-2015-17/index.html>)
- III. Register of Toxic Effect of Chemical Substances (RTECS)
- IV. Veterinary Substances Data Base (VSDB) Alphaxalone (online) Available at: <http://sitem.herts.ac.uk/aeru/vsdb/Reports/1759.htm> last updated 3rd June 2019.
- V. ChemIDplus <https://chem.nlm.nih.gov/chemidplus/>

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Information for this material safety data sheet was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond the control of the supplier, it is assumed that user of this material has been fully trained according to the mandatory requirements of WHMIS. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this form. If user requires independent information on ingredients in this or any other material, we recommend contacting supplier.

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