



SAFETY DATA SHEET

IMVIXA Premix

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : IMVIXA Premix
Product code : 124000000380
Product description : Not available.
Other means of identification : A-20209 A; AH2178; AH-2178 10% Premix; IMVIXA Premix; Lufenuron Premix 10%

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

Identified uses : Veterinary product.
Uses advised against : None known.

1.3 Details of the supplier of the safety data sheet

Elanco Spain, S.L.
Avda. de Bruselas
Nº 13, Edificio América, Polígono Arroyo de La Vega
Alcobendas 28108, Madrid
Telephone number : Not Available
e-mail address of person responsible for this SDS : elanco_sds@elancoah.com

1.4 Emergency telephone number

Supplier or Manufacturer

Transportation : CHEMTREC: 900-868538 (free-phone)
Emergency telephone number : CHEMTREC: 34-931768545 (local)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Aquatic Acute 1, H400
Aquatic Chronic 1, H410

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity : 10 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 - Very toxic to aquatic life with long lasting effects.

SECTION 2: Hazards identification

Precautionary statements

- Prevention** : P273 - Avoid release to the environment.
- Response** : P391 - Collect spillage.
- Storage** : Not applicable.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements : Contains lufenuron (ISO). May produce an allergic reaction.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

- Containers to be fitted with child-resistant fastenings** : Not applicable.
- Tactile warning of danger** : Not applicable.

2.3 Other hazards

- Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII** : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
- Other hazards which do not result in classification** : May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
lufenuron (ISO)	EC: 410-690-9 CAS: 103055-07-8 Index: 616-050-00-7	≥10 - ≤25	Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 See Section 16 for the full text of the H statements declared above.	M [Acute] = 100 M [Chronic] = 100	[1] [2]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

SECTION 4: First aid measures

- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use dry chemical powder.
- Unsuitable extinguishing media** : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : May form explosible dust-air mixture if dispersed. This material is very toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous combustion products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds
metal oxide/oxides

5.3 Advice for firefighters

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

- : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

6.3 Methods and material for containment and cleaning up

- Small spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid release to the environment. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Seveso Directive - Reporting thresholds

SECTION 7: Handling and storage

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
E1	100 tonne	200 tonne

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Iufenuron (ISO)	Elanco OEL (ELANCO). TWA: 0.15 mg/m ³ 8 hours.

Biological exposure indices

None known.

Recommended monitoring procedures : Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

SECTION 8: Exposure controls/personal protection

Hand protection	: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
Body protection	: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Environmental exposure controls	: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state	: Solid. [Powder.]
Colour	: White to yellowish.
Odour	: Not available.
Odour threshold	: Not available.
Melting point/freezing point	: Not available.
Initial boiling point and boiling range	: Not available.
Flammability	: Not available.
Lower and upper explosion limit	: Not applicable.
Flash point	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
pH	: Not available.
Viscosity	: Not applicable.
Solubility(ies)	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/ water	: Not applicable.
Vapour pressure	: Not available.
Evaporation rate	: Not available.
Relative density	: Not available.
Vapour density	: Not applicable.
Explosive properties	: Not available.
Oxidising properties	: No oxidising ingredients present.
<u>Particle characteristics</u>	
Median particle size	: Not available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability** : The product is stable.
- 10.3 Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid** : Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Prevent dust accumulation.
- 10.5 Incompatible materials** : Reactive or incompatible with the following materials:
oxidising materials
- 10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
lufenuron (ISO)	LD50 Dermal	Rat	>2000 mg/kg	-
	LD50 Oral	Rat	>2000 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

N/A

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitisation

Product/ingredient name	Route of exposure	Species	Result
lufenuron (ISO)	skin	Guinea pig	Sensitising

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

SECTION 11: Toxicological information

Information on likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

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

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

Not available.

- Conclusion/Summary** : Not available.
- General** : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Reproductive toxicity** : No known significant effects or critical hazards.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
lufenuron (ISO)	EC50 0.0011 to 0.0013 mg/l	Daphnia	48 hours
	NOEC 0.000026 mg/l	Daphnia	21 days
	NOEC 0.02 mg/l	Fish - Pimephales promelas	(Full life cycle)
	Acute LC50 0.58 mg/l Fresh water	Fish - Colossoma macropomum - Juvenile (Fledgling, Hatchling, Weanling)	96 hours
	Chronic NOEC 1 µg/l Fresh water	Crustaceans - Isopoda	21 days

SECTION 12: Ecological information

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
lufenuron (ISO)	5.12	-	high

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Not available.

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number or ID number	UN3077	UN3077	UN3077	UN3077
14.2 UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Lufenuron)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Lufenuron)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Lufenuron)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Lufenuron)
14.3 Transport hazard class(es)	9  	9  	9  	9  

SECTION 14: Transport information

14.4 Packing group	III	III	III	III
14.5 Environmental hazards	Yes.	Yes.	Yes.	Yes.

Additional information

- ADR/RID** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
Tunnel code (-)
- ADN** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
- IMDG** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
- IATA** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

- 14.6 Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

- 14.7 Maritime transport in bulk according to IMO instruments** : Not available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

- Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

Other EU regulations

- Industrial emissions (integrated pollution prevention and control) - Air** : Not listed

- Industrial emissions (integrated pollution prevention and control) - Water** : Not listed

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

SECTION 15: Regulatory information

Not listed.

Seveso Directive

This product is controlled under the Seveso Directive.

Danger criteria

Category
E1

15.2 Chemical safety assessment

: This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Calculation method Calculation method

Full text of abbreviated H statements

H317 H400 H410	May cause an allergic skin reaction. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
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Full text of classifications [CLP/GHS]

Aquatic Acute 1 Aquatic Chronic 1 Skin Sens. 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 SKIN SENSITISATION - Category 1
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Notice to reader

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.

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