

Dinoprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.7	28.09.2024	5245404-00010	Date of first issue: 04.11.2019

SECTION 1. IDENTIFICATION

Product identifier : Dinoprost Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

Reproductive toxicity : Category 1A

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

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Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Sodium acetate trihydrate	6131-90-4	Acute Tox. (Oral), 5	≥ 1 -< 5
Dinoprost	551-11-1	Acute Tox. (Oral), 4 Eye Irrit., 2A Repr., 1A STOT SE, (Oral)(Reproductive organs) , 1 STOT RE, (Oral)(Reproductive organs) , 1	$\geq 0,3$ -< 1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)

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Dry chemical

- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

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- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapors or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dinoprost	551-11-1	TWA	0.1 µg/m ³ (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

- Engineering measures** : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
No open handling permitted.
Totally enclosed processes and materials transport systems are required.

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Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Color	:	colorless
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	6,5 - 7,5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

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Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1,0 - 1,02
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

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Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:**Sodium acetate trihydrate:**

Acute oral toxicity : LD50 (Rat): 2.700 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5,6 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg
Remarks: Based on data from similar materials

Dinoprost:

Acute oral toxicity : LD50 (Rat): 1.170 mg/kg
LD50 (Mouse): 1.300 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 106 mg/kg
Application Route: Intravenous

LD50 (Rat): 112 mg/kg
Application Route: Intramuscular

LD50 (Rat): 95 mg/kg
Application Route: Subcutaneous

LD50 (Mouse): 56 mg/kg
Application Route: Intravenous

LD50 (Mouse): 152 mg/kg
Application Route: Intramuscular

LD50 (Mouse): 212 mg/kg
Application Route: Subcutaneous

LD50 (Rabbit): 2,5 mg/kg
Application Route: Intravenous

LD50 (Rabbit): > 10 mg/kg
Application Route: Intramuscular

Skin corrosion/irritation

Not classified based on available information.

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Components:**Sodium acetate trihydrate:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Sodium acetate trihydrate:**

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

Dinoprost:

Species	:	Rabbit
Result	:	Eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**Sodium acetate trihydrate:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Unscheduled DNA synthesis test (UDS) in testicular cells Species: Mouse Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Dinoprost:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Result: negative Test Type: Chromosomal aberration Test system: Chinese hamster fibroblasts
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Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage the unborn child.

Components:**Sodium acetate trihydrate:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Dinoprost:

Effects on fetal development : Test Type: reproductive and developmental toxicity study
Species: Rat
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 12,5 µg/kg
Symptoms: Fetal mortality.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

STOT-single exposure

Not classified based on available information.

Components:**Dinoprost:**

Assessment : May cause damage to organs.

STOT-repeated exposure

Not classified based on available information.

Components:**Dinoprost:**

Assessment : May cause damage to organs through prolonged or repeated exposure.

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Repeated dose toxicity**Components:****Sodium acetate trihydrate:**

Species	: Rat, male
NOAEL	: ≥ 3.600 mg/kg
Application Route	: Ingestion
Exposure time	: 4 Weeks
Remarks	: Based on data from similar materials

Dinoprost:

Species	: Monkey
LOAEL	: 0,5 mg/l
Application Route	: ocular
Exposure time	: 2 Weeks
Target Organs	: Eye

Species	: Monkey
NOAEL	: 8 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: No specific target organs noted

Species	: Rat
LOAEL	: 32 mg/kg
Application Route	: Subcutaneous
Exposure time	: 6 d
Target Organs	: Gastrointestinal tract, Brain
Symptoms	: Diarrhea, mental depression

Species	: Monkey
LOAEL	: 15 mg/kg
Application Route	: Intravenous
Exposure time	: 4 Weeks
Target Organs	: Immune system
Symptoms	: immune system effects

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Dinoprost:**

General Information	: miscarriage Target Organs: Uterus (including cervix) Symptoms: Effects on prenatal and postnatal growth. Target Organs: Gastro-intestinal system Symptoms: Nausea, Vomiting Target Organs: Cardio-vascular system Symptoms: hypertension
Inhalation	: Target Organs: Lungs

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Eye contact	: Symptoms: bronchospasm, bronchoconstriction
	: Target Organs: Eyes
	: Symptoms: Lowered blood pressure

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Sodium acetate trihydrate:**

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 1.000 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: EC50 (Skeletonema costatum (marine diatom)): > 1.000 mg/l Exposure time: 72 h Remarks: Based on data from similar materials NOEC (Skeletonema costatum (marine diatom)): 1.000 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC50 (Pseudomonas putida): 7,2 g/l Exposure time: 16 h Method: DIN 38 412 Part 8 Remarks: Based on data from similar materials

Dinoprost:**Ecotoxicology Assessment**

Acute aquatic toxicity	: Toxic effects cannot be excluded
Chronic aquatic toxicity	: Toxic effects cannot be excluded

Persistence and degradability**Components:****Sodium acetate trihydrate:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 99 % Exposure time: 28 d Remarks: Based on data from similar materials
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Bioaccumulative potential

No data available

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Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
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Brazil. List of chemicals controlled by the Federal Police	:	Not applicable
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The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific

SAFETY DATA SHEET



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context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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