

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Effective date 31-Oct-2025

Revision Number 1

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

1.1. Product identifier

Product Code(s) SDS-00009

Product Name Optitrol Pediatric M Controls

PR No

Product description	Product Code(s)
Optitrol Measles M	SR15045, SR15047, SR15048
Optitrol Parvo M	SR15055, SR15057, SR15058
Optitrol Mumps M	SR15065, SR15067, SR15068
Optitrol VZV M	SR15075, SR15077, SR15078
Optitrol Paediatric M	SR15003, SR15005

Form Not applicable

Pure substance/mixture Mixture

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

Recommended use In Vitro Diagnostic Use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

LGC Clinical Diagnostics, Inc
37 Birch Street
Milford, MA 01757
Phone #: (508) 244-6400
US Toll Free: (800) 676-1881
Fax #: (508) 634-3394
www.seracare.com

For further information, please contact

E-mail address CDx-CustomerService@LGCGroup.com

1.4. Emergency telephone number

Emergency Telephone For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)
Account number: CCN12505

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation	Category 1 - (H317)
--------------------	---------------------

2.2. Label elements

Contains 2-Methyl-4-isothiazolin-3-one(MI)

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls



Signal word
Warning

Hazard statements

H317 - May cause an allergic skin reaction.

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust, fume, gas, mist, vapors and spray

P280 - Wear protective gloves

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P362 + P364 - Take off contaminated clothing and wash it before reuse

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

No information available.

PBT & vPvB

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Sodium azide	-	-
2-Methyl-4-isothiazolin-3-one(MI)	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Chemical nature Biological standards.

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)	Notes
Sodium azide 26628-22-8	<0.1	-	247-852-1 (011-004-00-7)	Acute Tox. 1 (H310) Acute Tox. 2 (H300) Acute Tox. 2 (H330) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH032)	-	-	-	-
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	<0.1	-	220-239-6 (613-326-00-9)	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Skin Sens. 1A :: C>=0.0015%	10	1	-

- Substances contained in this mixture with No registration number are under the REACH threshold in Article 6(1) and not subject to the registration requirements according to REACH Title II

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium azide 26628-22-8	27	20	No data available	No data available	No data available
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	232 120	200	No data available	No data available	No data available

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information
BSL2

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	Itching. Rashes. Hives.
Effects of Exposure	No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically.
-----------------	--

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Product is or contains a sensitiser. May cause sensitisation by skin contact.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place.

TRGS510 Storage of hazardous substances in portable containers

Storage class (TRGS 510)

LGK 6.2.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	-	TWA: 0.05 mg/m ³ Sh+	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ Sk* Ceiling: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk* S+	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.2 mg/m ³	TWA: 0.2 mg/m ³ Peak: 0.4 mg/m ³	TWA: 0.1 ppm TWA: 0.3 mg/m ³ STEL: 0.1 ppm STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	-	-	TWA: 0.2 mg/m ³ Peak: 0.4 mg/m ³ skin sensitizer	-	-

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk* Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ Ceiling: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
Chemical name	Sweden		Switzerland	United Kingdom	
Sodium azide 26628-22-8	NGV: 0.1 mg/m ³ Bindande KGV: 0.3 mg/m ³		TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	-		TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³ S+	-	

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Sodium azide 26628-22-8	-	46.7 µg/kg bw/day [4] [6]	0.164 mg/m ³ [4] [6]
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	-	-	0.021 mg/m ³ [5] [6] 0.043 mg/m ³ [5] [7]

Notes

[4] Systemic health effects.
[5] Local health effects.
[6] Long term.
[7] Short term.

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Sodium azide 26628-22-8	16.7 µg/kg bw/day [4] [6]	-	29 µg/m ³ [4] [6]
2-Methyl-4-isothiazolin-3-one(MI)	0.027 mg/kg bw/day [4] [6]	-	0.021 mg/m ³ [5] [6]

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Chemical name	Oral	Dermal	Inhalation
2682-20-4	0.053 mg/kg bw/day [4] [7]		0.043 mg/m ³ [5] [7]

Notes

[4]	Systemic health effects.
[5]	Local health effects.
[6]	Long term.
[7]	Short term.

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Sodium azide 26628-22-8	0.35 µg/L	3.5 µg/L	15 ng/L	150 ng/L	-
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	3.39 µg/L	3.39 µg/L	3.39 µg/L	3.39 µg/L	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Sodium azide 26628-22-8	16.7 µg/kg sediment dw	0.72 µg/kg sediment dw	30 µg/L	-	-
2-Methyl-4-isothiazolin-3-one(MI) 2682-20-4	-	-	0.23 mg/L	0.0471 mg/kg soil dw	-

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Latex gloves.

Skin and body protection Wear suitable protective clothing.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Physical state	Liquid
Colour	No information available
Odour	No information available
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
SADT (°C)	No data available	None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

9.2.1. Information with regards to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	No information available.
------------	---------------------------

10.2. Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
------------------------------------	-------------------------------

10.4. Conditions to avoid

Conditions to avoid	None known based on information supplied.
---------------------	---

10.5. Incompatible materials

Incompatible materials	None known based on information supplied.
------------------------	---

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

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

Acute toxicity Based on available data, the classification criteria are not met.

Numerical measures of toxicity

The following ATE values have been calculated for the mixture:

ATEmix (oral) 99,999.00 mg/kg
ATEmix (dermal) 99,999.00 mg/kg
ATEmix (inhalation-gas) 99,999.00 ppm
ATEmix (inhalation-vapour) 99,999.00 mg/l
ATEmix (inhalation-dust/mist) 99,999.0000 mg/l

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	0.054 - 0.52 mg/L (Rat) 4 h
2-Methyl-4-isothiazolin-3-one(MI)	232 - 249 mg/kg (Rat) = 120 mg/kg (Rat)	= 200 mg/kg (Rabbit)	= 0.11 mg/L (Rat) 4 h

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation May cause an allergic skin reaction.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium azide	-	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)	-	400 µg/L(Daphnia Magna, 48h)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Chemical name	Partition coefficient
2-Methyl-4-isothiazolin-3-one(MI)	-0.486

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Sodium azide	The substance is not PBT / vPvB
2-Methyl-4-isothiazolin-3-one(MI)	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

- 14.1 UN number or ID number UN3373
- 14.2 UN proper shipping name Biological substance, Category B
- 14.3 Transport hazard class(es) 6.2
- 14.4 Packing group Not regulated
- Description UN3373, Biological substance, Category B, 6.2
- 14.5 Environmental hazards No
- 14.6 Special precautions for user
- Special Provisions None

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

ERG Code 11L

IMDG

14.1 UN number or ID number UN3373
14.2 UN proper shipping name Biological substance, category B
14.3 Transport hazard class(es) 6.2
14.4 Packing group Not regulated
Description UN3373, Biological substance, category B, 6.2
14.5 Environmental hazards No
14.6 Special precautions for user
Special Provisions 319, 341
EmS-No. F-A, S-T
14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number or ID number UN3373
14.2 UN proper shipping name Biological substance, category B
14.3 Transport hazard class(es) 6.2
14.4 Packing group Not regulated
Description UN3373, Biological substance, category B, 6.2
14.5 Environmental hazards No
14.6 Special precautions for user
Special Provisions 319
Classification code I4

ADR

14.1 UN number or ID number UN3373
14.2 UN proper shipping name Biological substance, category B
14.3 Transport hazard class(es) 6.2
14.4 Packing group Not regulated
Description UN3373, Biological substance, category B, 6.2, (-)
14.5 Environmental hazards No
14.6 Special precautions for user
Special Provisions 319
Classification code I4
Tunnel restriction code (-)

ADN

14.1 UN number or ID number UN3373
14.2 UN proper shipping name Biological substance, category B
14.3 Transport hazard class(es) 6.2
14.4 Packing group Not regulated
Description UN3373, Biological substance, category B, 6.2
14.5 Environmental hazard No
14.6 Special precautions for user
Special Provisions 319

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Classification code I4
Equipment Requirements PP

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)
Chemical Prohibition Ordinance (ChemVerbotsV) Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material SC 10/12
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable
Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
2-Methyl-4-isothiazolin-3-one(MI) - 2682-20-4	75	

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

Not applicable

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

Ozone-depleting substances (ODS) regulation (EC) 2024/590
Not applicable

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
2-Methyl-4-isothiazolin-3-one(MI) - 2682-20-4	Product-type 11: Preservatives for liquid-cooling and processing systems Product-type 12: Slimicides Product-type 13: Working or cutting fluid preservatives Product-type 6: Preservatives for products during storage

International Inventories

TSCA

U.S. INVENTORY (TSCA): Not listed on inventory. For purposes of 40 CFR 720.36, this product is for Research and Development (R&D) Use Only

DSL/NDSL

Contact supplier for inventory compliance status

EINECS/ELINCS

Contact supplier for inventory compliance status

ENCS

Contact supplier for inventory compliance status

IECSC

Contact supplier for inventory compliance status

KECL

Contact supplier for inventory compliance status

PICCS

Contact supplier for inventory compliance status

AIIC

Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

EUH032 - Contact with acids liberates very toxic gas
EUH071 - Corrosive to the respiratory tract
H300 - Fatal if swallowed
H301 - Toxic if swallowed
H310 - Fatal in contact with skin
H311 - Toxic in contact with skin
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
P261 - Avoid breathing dust, fume, gas, mist, vapors and spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves
P302 + P352 - IF ON SKIN: Wash with plenty of water and soap
P321 - Specific treatment (see supplemental first aid instructions on this label)
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

Legend

ACGIH	American Conference of Governmental Industrial Hygienists
AIDII	Italian Association of Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DFG	German Research Foundation
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EC Number	European Community number
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
EWC	European Waste Codes
GHS	Globally Harmonized System

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

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
ICAO	International Civil Aviation Organisation
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organisation for Standardisation
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MAL	Measuring Technical Hygienic Air Needs
MARPOL	International Convention for the Prevention of Pollution from Ships
MDLPS	Ministry of Labour and Social Policy
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
SVHC	Substance of very high concern
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TRGS	Technical Rule for Hazardous Substances
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
Sen+	Sensitiser
Sk*	Skin designation
**	Hazard Designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Chronic aquatic toxicity	Calculation method
Acute aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-May-2025

Revision Number 1

SDS-00009 - Optitrol Pediatric M Controls

New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 19-May-2025

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet