

Primecresol
Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC)
1907/2006, Regulation (EC) 1272/2008 and Regulation
(EC) 453/2010)

Date Issued: 11th August 2021

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE
COMPANY/UNDERTAKING**

1.1 Product Identifier:

Trade Name (as labeled): Primecresol

Part/Item Number: 10203

**1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised
Against:**

Recommended Use: Pulp Mummifying solution

Restrictions on Use: For Dental professional use only

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.

Address : Plot No. A-148, Road No. 24, MIDC, Wagle

Industrial Estate, Thane (West)- 400604, Maharashtra,
India

Email : info@prime-dental.in

Web : www.prime-dental.in

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Toxic (T), Corrosive (C), Harmful
(Xn)

EU Risk (R) Phrases: R20, R24/25, R34, R40, R43

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health Environmental Physical

Acute Toxicity Category 3 H311

Acute Toxicity Category 4 H302, H332

Skin Corrosion Category 1B

Eye Damage Category 1

Skin Sensitization Category 1

Carcinogen Category 1A

Aquatic Chronic Category 3 Not hazardous

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements: Contains m-Cresol, p-Cresol, Formaldehyde

Signal Word: Danger!

Hazard Statements Precautionary Statements

H302 Harmful if swallowed

H311 Toxic in contact with skin

H314 Causes severe skin burns and eye damage

H317 May cause an allergic skin reaction



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H332 Harmful if inhaled.
H3350 May cause cancer by inhalation.
H412 Harmful to aquatic life with long lasting effects
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe vapors, mists or spray.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection or face protection.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P310 Immediately call a POISON CENTER or doctor.
P363 Wash contaminated clothing before reuse.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P310 Immediately call a POISON CENTER or doctor.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P330 Rinse mouth.
P310 Immediately call a POISON CENTER or doctor.
P308 + P313 IF exposed or concerned: Get medical attention.
P405 Store locked up.
P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components C.A.S. # EC#

IUPAC Name CLP/GHS / EU

Classification

(1272/2008) (1999/45/EC)

WT %

m-Cresol 108-39-4 / 203-577-9

3-Methylphenol C, T, R24/25, R34

Acute Tox 3 (Oral) H301

Acute Tox 3 (Dermal) H311

Skin Corr. 1B H314

Aquatic Chronic 3 H412 21

p-Cresol 106-44-5 / 203-398-6



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4-Methylphenol C, T, R24/25, R34

Acute Tox 3 (Oral) H301

Acute Tox 3 (Dermal) H311

Skin Corr. 1B H314

Aquatic Chronic 3 H412 14

Formaldehyde 50-00-0 /200-001-8

formaldehyde C ,T, Carc. Cat 3

R23/24/25, R34, R43, R40

Carc. 1A H350

Acute Tox 3 (Oral) H301

Acute Tox 3 (Dermal)

H311

Acute Tox 3 (Inhalation)

H331

Skin Corr. 1B H314

Skin Sens. 1 H317

< 20

Glycerin Proprietary Glycerol Not hazardous < 20

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of

Exposure First Aid Instructions

Eye Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids

apart. Get immediate medical attention.

Skin Immediately remove contaminated clothing and wash exposed skin thoroughly with soap and water

for at least 15 minutes. Get medical attention.

Inhalation Remove from exposure and get medical attention.

Ingestion Give 3 or more glasses of milk or water to drink. Never give anything by mouth to an unconscious

or convulsing person. Get immediate medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Causes eye irritation and burns. May cause severe corneal damage to the eyes.

Ingestion may cause epigastric pain,

vomiting, pallor, sweating, weakness, headache, dizziness, tinnitus, shock, CNS depression, coma, and death. Causes

numbness, then pain on contact with skin. Toxic if absorbed through skin, and lungs.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is required for all routes of exposures.

Note to Physicians (Treatment, Testing, and Monitoring): Skin exposures may be treated with a PEG/EtOH solution

applied liberally to affected area. Allow to remain for 15 to 30 seconds, then wash with water. Continue cycle of



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PEG/EtOH solution application, and washing with water for at least 15 minutes.

PEG/EtOH should consist of 2 parts

polyethylene glycol 400 to 1 part ethanol. (For external use only)

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use carbon dioxide, foam or dry chemical. Use water to cool exposed containers.

5.2 Special Hazards Arising from the Substance or Mixture:

Combustible liquid. Burning generates carbon dioxide, carbon monoxide, and oxides of carbon.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures: Cool fire exposed containers and structures with water.

Precautions for Fire Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full

protective clothing for all fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE SKIN RESPIRATORY THERMAL

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Wear appropriate protective clothing, gloves and eye protection.

Respiratory protection is required. In the United States, refer to OSHA 1910.1048 for specific requirements.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE SKIN RESPIRATORY THERMAL

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. Clean spill area thoroughly.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Prevent contact with the eyes, skin and clothing. Do not breathe vapors, mists or fumes. Wear appropriate

protective clothing and equipment. Use only with adequate ventilation. Wash thoroughly with soap and water

after handling. Keep containers closed when not in use.

Empty containers retain product residue and may be hazardous. Follow all precautions in SDS when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well ventilated area away from incompatible materials.

Protect from physical damage.

7.3 Specific End Use (s): For professional use only.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Note: 29 CFR 1910.1048 is the US OSHA regulation on Occupational Exposure to Formaldehyde. Assure compliance with these regulations.

8.1 Control Parameters:

Occupational Exposure Limits:

m-Cresol United States 5 ppm TWA US OSHA PEL (skin)

20 mg/m³ TWA ACGIH TLV (IFV) (skin)

Germany 0.5 ppm TWA DFG MAK

United Kingdom 5 ppm TWA UK OEL

France 5 ppm TWA INRS VME

Spain 5 ppm TWA VLA-ED

Italy 5 ppm TWA

European Union 5 ppm TWA EU OEL

p-Cresol United States 5 ppm TWA US OSHA PEL (skin)

20 mg/m³ TWA ACGIH TLV (IFV) (skin)

Germany 0.5 ppm TWA DFG MAK

United Kingdom 5 ppm TWA UK OEL

France 5 ppm TWA INRS VME

Spain 5 ppm TWA VLA-ED

Italy 5 ppm TWA

European Union 5 ppm TWA EU OEL

Formaldehyde United States 0.75 ppm TWA, 2 ppm STEL US OSHA PEL (skin)

0.3 ppm CEIL ACGIH TLV (Sensitizer)

Germany 0.3 ppm TWA, 0.6 ppm STEL DFG MAK

United Kingdom 2 ppm TWA, 2 ppm STEL UK OEL

France 0.5 ppm TWA, 1 ppm STEL INRS VME

Spain 0.3 ppm STEL VLA-ED

Italy None Established

European Union None Established

Glycerin United States 15 mg/m³ TWA (total dust), 5 mg/m³ TWA (Respirable Fraction)

US OSHA PEL

10 mg/m³ TWA ACGIH TLV (mist)

Germany 50 mg/m³ TWA (inhalable aerosol), 100 mg/m³ STEL (inhalable aerosol)

DFG MAK

United Kingdom 10 mg/m³ TWA UK OEL

France 10 mg/m³ TWA INRS VME

Spain 10 mg/m³ TWA VLA-ED

Italy None Established

European Union None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety goggles recommended.



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Specific Skin Protection: Wear impervious gloves such as rubber.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable
Recommended Personal Protective Equipment
EYES/FACE SKIN RESPIRATORY THERMAL

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance: Clear, amber liquid Explosive limits: Not applicable
Odor: Formaldehyde, and phenol Vapor pressure: 1
Odor threshold: Not available Vapor density: Not available
pH: 4.05 @ 25°C Relative density: 1.058 @ 25°C
Melting/freezing point: Not available Solubility: Miscible
Initial boiling point and
range: 392°F (200°C) Partition coefficient: noctanol/water: Not available
Flash point: Not available
Auto-ignition temperature: Not available
Evaporation rate: 0.3 Decomposition temperature: Not available
Flammability: Combustible Viscosity: Not available
Explosive Properties: None Oxidizing Properties: None
Percent Volatile 38% v/v

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: None.
10.4 Conditions to Avoid: Avoid ignition sources.
10.5 Incompatible materials: Avoid contact with strong oxidizing agents
10.6 Hazardous Decomposition Products: Burning generates carbon dioxide, carbon monoxide, and oxides of carbon.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Causes burns to eyes with redness, pain and tearing. Eye damage is possible.

Skin: If spilled on skin, numbness is followed promptly by pain and reddening.

Chemical burns are possible. Toxic when absorbed through skin with symptoms similar to ingestion. May cause an allergic skin reaction.

Ingestion: Swallowing causes intense burning of mouth and throat. Cause epigastric pain, muscular weakness, headache, dizziness, nausea, vomiting, collapse, shock, CNS depression, and death. May cause injury to the kidneys, liver, heart, pancreas, and spleen. Symptoms may be delayed.

Inhalation: Inhalation of mists may cause mucous membrane and upper respiratory tract irritation. Toxic when inhaled with symptoms similar to ingestion. May cause an allergic reaction.

Chronic Health Effects: May cause injury to the kidneys, liver, heart, pancreas, lungs, and spleen.



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Carcinogenicity: Formaldehyde is listed by IARC as "Carcinogenic to Humans", (Group 1), by NTP a "Known to be a Human Carcinogen", by ACGIH as a "Suspected Human Carcinogen" (A2), by the European Union as a Carcinogen Category 3. Cresol Isomers- Possible human carcinogen. Based on an increased incidence of skin papillomas in mice in an initiation-promotion study. The three cresol isomers produced positive results in genetic toxicity studies both alone and in combination. None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive.

Mutagenicity: No data available

Medical Conditions Aggravated by Exposure: Employees with pre-existing eye, skin, kidneys, liver, heart, pancreas, lungs, and spleen disorders may be at increased risk from exposure.

Acute Toxicity Data:

Cresol Isomers: Oral rat LD50 242 mg/kg; Skin rabbit LD50 2050 mg/kg;

Inhalation rat LC50 >710 mg/m³/1hr

Formaldehyde: Oral rat LD50 100 mg/kg; Skin rabbit LD50 0.27 mL/kg;

Inhalation rat LC50 203 mg/m³/1hr

Reproductive Toxicity Data: No data available for mixture. In a reproductive study, rats were exposed to 0-40 ppm

formaldehyde for 6 hr/days on days 6-20 of gestation. At 40 ppm, maternal toxicity was observed. Formaldehyde is slightly

fetotoxic at 20 ppm. Neither embryo-lethal nor teratogenic effects were observed following inhalation exposure at levels up to 40 ppm.

Specific Target Organ Toxicity (STOT):

Single Exposure: Exposure to high doses of formaldehyde (>100 ppm) showed salivation, acute dyspnea, vomiting, cramps and death in laboratory animals. Mice treated with formaldehyde on skin developed severe liver damage.

Repeated Exposure: Animal data revealed a qualitative relationship between formaldehyde absorption and hepatotoxicity.

These data indicate that exposure to formaldehyde at 3 ppm or less for periods up to 6 months causes adverse effects upon the liver; higher exposure concentrations for shorter time periods produce similar effects upon the liver

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Cresol Isomers: LC50 Pimephales promelas (Fathead minnow, 29 days old, size 20.8 mm) 12.8 mg/L/96 hr

Formaldehyde: LC50 Oncorhynchus mykiss (Rainbow trout, weight 0.63 g) 118 ppm/96 hr

Glycine: LC50 Goldfish >5000 mg/l/24 hr

12.2 Persistence and Degradability.

Cresol Isomers: Cresols biodegrade quickly in soils with half-lives on the order of a few days. Cresols biodegrade quickly in water with half-lives of several days to a few weeks.



Formaldehyde: Formaldehyde readily biodegrades under both aqueous aerobic and anaerobic conditions.

Glycerin: If released to soil, glycerin is expected to undergo rapid biodegradation under aerobic conditions. If released to water, glycerin is expected to rapidly degrade under aerobic conditions.

12.3 Bio-accumulative Potential:

Cresol Isomers: Bioconcentration in aquatic organisms is low.

Formaldehyde: Formaldehyde is rapidly metabolized with a half-life in the blood of approx 1.5 min. This half-life is based primarily on primate data although available human data are consistent with this observation of a very short half-life. Data from other species suggest that the half-life of formaldehyde is fairly similar in many species.

Glycerin: Bioconcentration of glycerin in fish and aquatic organisms will not be significant.

12.4 Mobility in Soil:

Cresol Isomers: Cresols are expected to have high mobility in soil.

Formaldehyde: Formaldehyde is expected to have very high mobility in soil

Glycerin: Will display very high mobility in soil.

12.5 Other Adverse Effects: None known

12.6 Results of PBT/vPvB Assessment: Not applicable

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None known.

14. TRANSPORT INFORMATION

14.1 UN

Number

14.2 UN Proper Shipping Name 14.3

Hazard

Class(s)

14.4 Packing

Group

14.5 Environmental

Hazards

6.1 (8) PG II No

n.o.s. (cresol, formaldehyde)

6.1 (8) PG II No

IMDG UN2927 Toxic Liquid, Corrosive, Organic,

n.o.s. (cresol, formaldehyde)

6.1 (8) PG II Marine Pollutant-No

IATA/ICAO UN2927 Toxic Liquid, Corrosive, Organic,

n.o.s. (cresol, formaldehyde)

6.1 (8) PG II No

14.6 Special precautions for user: Corrosive liquid

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC

Code: Not applicable – product is



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transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): The RQ for the product, based on the RQ for Cresol (m-Cresol, and p-Cresol) (35% maximum) of 100 lbs, is 285 lbs. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the ingredients in this product are listed on the EPA TSCA Inventory.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Glycerol listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard: Yes Pressure Hazard: No

Delayed Hazard: Yes Reactivity Hazard: No

Fire Hazard: No

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313

(40 CFR 372):

Components C.A.S. # WT %

Formaldehyde 50-00-0 <20

m-Cresol 108-39-4 21

p-Cresol 106-44-5 14

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components C.A.S. # WT %

Formaldehyde 50-00-0 <20

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

C Corrosive

T Toxic

Carc. Cat 3 Carcinogen category 3

R20 Harmful by inhalation

R23/24/25 Toxic by inhalation, contact with skin and if swallowed

R24/25 Toxic in contact with skin and if swallowed

R34 Causes burns

R40 Limited evidence of a carcinogenic effect

R43 May cause sensitization by skin contact.

Carc. 1A Carcinogen Category 1A



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Acute Tox 3 (Oral) Acute Oral Toxicity Category 3
Acute Tox 3 (Dermal) Acute Dermal Toxicity Category 3
Acute Tox 3 (Inhalation) Acute Inhalation Toxicity Category 3
Skin Corr. 1B Skin Corrosion Category 1B
Skin Sens. 1 Skin Sensitizer Category 1
Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3
H301 Toxic if swallowed
H311 Toxic in contact with skin
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled
H350 May cause cancer.

H412 Harmful to aquatic life with long lasting effects

Date of SDS Preparation/Revision: 11th August 2021.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components,
IUCLID Dataset EU Chemical Bureau

ESIS, Country websites for occupational exposure limits.