

Safety Data Sheet

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

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Buckley's Formo Cresol
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	10203
U.N. Number:	UN2927
U.N. Dangerous Goods Classification:	6.1 (8), PGII
Recommended Use:	Sterilization and disinfectant solution
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA 17404-0807
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)
Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States-Call Collect)
Email address:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Toxic (T), Corrosive (C) R24/25, R34

EU Labeling:

 Toxic	 Corrosive	Contains: Cresol, Formaldehyde Carc. Cat 3 R20 Harmful by inhalation 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. S1/2 Keep locked up and out of the reach of children S26 In case of contact with eyes, rinse immediately with plenty of
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	<p>water and seek medical advice. S36/37/39 Wear suitable protective clothing, gloves, and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately. S51 Use only in well ventilated areas.</p>
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US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	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	21
p-Cresol	106-44-5 / 203-398-6	4-Methylphenol	C, T, R24/25, R34 Acute Tox 3 (Oral) H301 Acute Tox 3 (Dermal) H311 Skin Corr. 1B H314	14
Formaldehyde	50-00-0 / 200-001-8	formaldehyde	C, T, R23/24/25, R34, R43, R40 Carc. 2 H351 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	None established	< 20





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

4. 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.
Most important symptoms of exposure	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.
Other	Some individuals may be hypersensitive to this material.
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 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

Suitable Extinguishing Media:	Use carbon dioxide, foam or dry chemical. Use water to cool exposed containers.		
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.		
Specific Hazards Arising from the Chemical:	Combustible liquid. Burning generates carbon dioxide, carbon monoxide, and oxides of carbon.		
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

Personal Precautions, PPE 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.			
Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.			
Methods and Materials for Containment and Clean-up: Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. Clean spill area thoroughly.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

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.

In the United States, refer to OSHA 1910.1048 for requirements for handling and use of formaldehyde solutions. Initial monitoring must be conducted to determine if workers are exposed and if personal protective equipment is required.



Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.

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.

Occupational Exposure Limits:		
m-Cresol	United States	5 ppm TWA US OSHA PEL (skin) 20 mg/m ³ 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
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/m ³ TWA (total dust), 5 mg/m ³ TWA (Respirable Fraction) US OSHA PEL 10 mg/m ³ TWA ACGIH TLV (mist)
Germany		50 mg/m ³ TWA (inhalable aerosol), 100 mg/m ³ STEL (inhalable aerosol) DFG MAK	
United Kingdom		10 mg/m ³ TWA UK OEL	
France		10 mg/m ³ TWA INRS VME	
Spain		10 mg/m ³ TWA VLA-ED	
Italy		None Established	
European Union		None Established	
Biological Exposure Limits: None Established			
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. 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
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Prevent contact with the eyes, skin, and clothing. Wash thoroughly with soap and water after handling. Eye wash facilities should be available in the work area.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling.			

9. 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: n-octanol/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		

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize.

Chemical Stability: Stable

Possibility of Hazardous Reactions: None

Conditions to Avoid: Avoid ignition sources.

Incompatible materials: Avoid contact with strong oxidizing agents.

Hazardous Decomposition Products: Burning generates carbon dioxide, carbon monoxide, and oxides of carbon.

11. TOXICOLOGICAL INFORMATION

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.

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

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

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

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.

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.

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.

Other Adverse Effects: None known.

Results of PBT/vPvB Assessment: Not applicable

13. DISPOSAL CONSIDERATIONS

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

UN Number:	ADR/RID: UN2927	IMDG: UN2927	IATA: UN2927	DOT: UN2927
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UN proper shipping name:	ADR/RID: Toxic Liquid, Corrosive, Organic, nos (cresol, formaldehyde) IMDG: Toxic Liquid, Corrosive, Organic, nos (cresol, formaldehyde) IATA: Toxic Liquid, Corrosive, Organic, nos (cresol, formaldehyde) DOT: Toxic Liquid, Corrosive, Organic, nos (cresol, formaldehyde)
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Transport hazard class(es):	ADR/RID: 6.1 (8)	IMDG: 6.1 (8)	IATA: 6.1 (8)	DOT: 6.1 (8)
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Packaging group:	ADR/RID: PGII	IMDG: PGII	IATA: PGII	DOT: PGII
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Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
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Special precautions for user: Not applicable

15. REGULATORY INFORMATION

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.

OSHA Hazard Classification: Corrosive, toxic, target organ effects, carcinogen.

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.

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

R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed

R34 Causes burns.

R35 Causes severe burns.

Carc. 2 Carcinogen Category 2

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

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

H351 Suspected of causing cancer

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.