

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

1.1 Product Identifier:

Trade Name (as labeled):	Purevac® SC
Part/Item Number:	21135, 21132, 21131

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

Recommended Use:	Evacuation system cleaner
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS/CLP Hazard/Danger Classification:

Health	Environmental	Physical
Eye Irritation Category 2	None	Flammable Liquid Category 3

EU Classification: Flammable

EU Risk (R) and Safety (S) Phrases: R10

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

2.2 Labeling Elements:



Signal Word: WARNING

Hazard Statements	Precautionary Statements
H226 Flammable liquid and vapor H319 Causes serious eye irritation.	P210 Keep away from heat, sparks and flames – No smoking. P240 Ground container and receiving equipment. P243 Take precautionary measures against static discharge. P280 Wear eye protection. P303 + P361 + P353 IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P370 + P378 In case of fire, use water spray, carbon dioxide or alcohol-resistant foam for extinction. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P403 + P235 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Water	7732-18-5 / 231-791-2	water	Not Classified as hazardous	40-60
Propylene Glycol	57-55-6 / 200-338-0	propane-1,2-diol	Not Classified as hazardous	25-30
Isopropanol	67-63-0 / 200-661-7	propan-2-ol	F, Xi R11, R36, R67 Flam Liq 2 H225; Eye Irrit 2A H319, STOT SE 3 H336	5-10
Sodium Bicarbonate	144-55-8 / 205-633-8	sodium hydrogen carbonate	Not Classified as hazardous	2-5
1,3-Triazine-2,4,6-(1H, 3H, 5H) – trithione, sodium salt	17766-26-6 / 241-749-5	trisodium 4,6-bis(sulfanylidene)-1H-1,3,5-triazine-2-thiolate	Not Classified as hazardous	2-5

Alcohols, C8-C10, ethoxylated propoxylated	68603-25-8/ Polymer	c8-10, ethoxylatedprop oxylated	Xn R22, R36 Acute Tox 4 H302; Eye Irrit 2A; Aquatic Acute 3 H402	2-5
Fragrance	Mixture	None	Not Classified as hazardous	0-2

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 medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation develops or persists.
Inhalation	If symptoms develop, remove to fresh air and get medical attention.
Ingestion	Do not induce vomiting. Rinse mouth with water and give one glass of water to drink. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

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

Causes eye and skin irritation. Inhalation of vapors or mists may cause upper respiratory tract irritation.

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

If eye irritation occurs, get medical attention. If large amounts are swallowed, get medical attention.

Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use water fog or spray, dry powder, carbon dioxide or alcohol-resistant foam





Fire Fighting Procedures:

Cool fire exposed containers and structures with water.



5.2 Special Hazards Arising from the Substance or Mixture:

Flammable liquid and vapor. Vapors may collect in confined areas presenting a fire and explosion hazard. .

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.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Eliminate all sources of ignition and ventilate the area. Wear appropriate protective clothing; gloves and eye protection. Respiratory protection may be needed for large spills.			
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.

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:
Avoid contact with the eyes, skin and clothing. Avoid breathing mists. Wear appropriate protective clothing and equipment. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:
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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

8.1 Control Parameters:

Occupational Exposure Limits:

Propylene Glycol	10 mg/m ³ TWA AIHA WEEL 150 ppm TWA (vapor and particulates), 10 mg/m ³ (particulates) TWA UK OEL
Isopropyl Alcohol	400 ppm TWA OSHA PEL 200 ppm TWA ACGIH TLV, 400 ppm STEL 200 ppm TWA DFG MAK 400 ppm TWA UK WEL, 500 ppm STEL 400 ppm TWA INRS VLCT 400 ppm TWA VLA-ED, 500 ppm VAL-EC
Sodium Bicarbonate	None Established
1,3-Triazine-2,4,6-(1H, 3H, 5H) – trithione, sodium salt	None Established
Alcohols, C8-C10, ethoxylated propoxylated	None Established
Fragrance	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 should be worn where eye contact is possible.

Specific Skin Protection: Wear impervious gloves such as rubber if needed to avoid prolonged contact.

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:	Light green liquid	Explosive limits:	LEL: 2.5% (isopropanol) UEL: 12% (isopropanol)
Odor:	Slightly Citric	Vapor pressure:	45.5 mmHg @ 25°C (isopropanol)
Odor threshold:	Not available	Vapor density:	>1 (air = 1)
pH:	pH at Concentrate: 9 pH at Recommended Dilution: ~7	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	Miscible
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	105°F / 40.6°C	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Flammable liquid	Viscosity:	Not available
Explosive Properties:	Vapors may be explosive in confined areas	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize.
10.2 Chemical Stability: Stable under normal use conditions.
10.3 Possibility of Hazardous Reactions: None known.
10.4 Conditions to Avoid: Avoid heat, sparks, flames and all other sources of ignition.
10.5 Incompatible materials: Avoid strong oxidizing agents, strong bases and strong acids.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides, aldehydes, alcohols, ethers and organic acids.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Causes severe irritation to eyes with redness, pain and tearing.

Skin: May cause skin irritation on prolonged contact.

Ingestion: Swallowing may cause gastrointestinal irritation.

Inhalation: Inhalation of mists may cause mucous membrane and upper respiratory tract irritation. Inhalation of high concentrations of isopropanol vapors may cause headache and dizziness.

Chronic Health Effects: None known.

Carcinogenicity: None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive. There is inadequate evidence of carcinogenicity of isopropyl alcohol in human and animals. Propylene Glycol: The carcinogenic potential of propylene glycol has been investigated in two long term feeding studies. No increase in tumors was recorded in rats receiving the equivalent of 1,700 (males) or 2,100 (females) mg/kg bw/day over two years. Tumor incidences were also unchanged in male and female Beagle dogs ingesting 20% propylene glycol in diet (equivalent to 5,000 mg/kg bw/day), again over two years.

Mutagenicity: Isopropyl Alcohol: In an in-vivo study, isopropanol did not induce micronuclei in bone marrow of mice. ... Studies conducted in mammalian cells in-vitro, it did not induce sister chromatic exchanges or gene mutations. Propylene Glycol: Negative results were observed in bacterial assays, in-vitro mammalian cell gene mutation test, in-vitro mammalian chromosome aberration test, mammalian erythrocyte micronucleus test, and a dominant lethal assay.

Medical Conditions Aggravated by Exposure: Employees with pre-existing eye and skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Propylene Glycol: Oral rat LD50 21,000 mg/kg, Skin rabbit LD50 20,800 mg/kg

Isopropyl Alcohol: Oral rat LD50 5,045 mg/kg, Skin rabbit LD50 12,800 mg/kg

1,3-Triazine-2,4,6-(1H, 3H, 5H) –trithione, sodium salt: LD50 skin rabbit >2,000 mg/kg

Sodium Bicarbonate: LD50 oral rat 4,220 mg/kg

Alcohols, C8-C10, ethoxylated propoxylated: Oral rat LD50 616 mg/kg, Skin rabbit 5,660 mg/kg, Inhalation rat LC50 >8 mg/L/1 hr

Reproductive Toxicity Data: Propylene Glycol: Effects on fetal development have been investigated in pregnant rats, mice, hamsters and rabbits. Orally administered propylene glycol (gavage) was well tolerated with no adverse effect on pregnancy parameters or maternal or fetal survival at any treatment level. There was no evidence of teratogenicity at any dose level. Isopropanol: In a rat developmental study, female Sprague-Dawley rats were dosed by oral gavage with either 0, 400, 800, or 1,200 mg/kg isopropanol during gestation days 6 to 15. Mortality was observed in the mid- (4%) and high-dose (8%) animals and reduced maternal gestational weight gain on gestational days 0 to 20 associated with significantly reduced gravid uterine weights were noted in the high-dose animals. Fetal body weights were reduced at 800 and 1,200 mg/kg. No adverse maternal or developmental effects at 400 mg/kg. No teratogenic effects were noted at any dose tested.

Specific Target Organ Toxicity (STOT):

Single Exposure: Propylene Glycol: Clinical signs (loss of balance, marked depression, and analgesia) were reported in the rabbit and guinea pig only at extremely high doses that exceeded the established limit dose (5,000 mg/kg) for an acute oral toxicity study. Similar effects were also evident in one study with mice only at doses that resulted in lethality (LD50 value of 24,800 mg/kg/day). Isopropanol: Inhalation of 400 ppm (1,000 mg/cu m) isopropanol by guinea pigs for 24 hours reduced the ciliary activity in the nasal mucosa, but recovery was complete within two weeks. Higher concentrations produced damage that required longer to repair.

Repeated Exposure: Isopropanol: A 13 week inhalation study with rats found effects of narcosis at 5,000 ppm. These effects were reversible at the cessation of exposure. A 73 week chronic study found male reproductive effects at 2,500 and 5,000 ppm and liver effects at 2,500 ppm. Propylene Glycol: Rats can tolerate a repeated oral daily dose of up to 30 mL/kg bw in the diet over 6 months, while the dog is unaffected by a repeated oral dose of 2g/kg in the diet for 2 years.

12. ECOLOGICAL INFORMATION

<p>12.1 Toxicity: Propylene Glycol: Selenastrum capricornutum (green algae) 18,100 mg/L, 48 hr LC50 Daphnia magna 43,500 mg/L, 96 hr LC50 Pimephales promelas (Fathead minnow) 46,500 mg/L Isopropyl Alcohol: 96 hr LC50 Pimephales promelas (fathead minnow) 6.12 mg/L Alcohols, C8-C10, ethoxylated propoxylated: 96 hr LC50 pimephales promelas (fathead minnow) 13.3 mg/L; 48 hr EC50 daphnia magna 12.3 mg/L; 16 hr IC50 bacteria 220-770 mg/L</p>
<p>12.2 Persistence and Degradability: Isopropyl Alcohol is readily biodegradable (95% after 21 days). Alcohols, C8-C10, ethoxylated propoxylated is readily biodegradable (70% in 28 days). Propylene glycol is readily biodegradable (100% after 9 days).</p>
<p>12.3 Bio-accumulative Potential: No data available.</p>
<p>12.4 Mobility in Soil: No data available</p>
<p>12.5 Other Adverse Effects: None known.</p>
<p>12.6 Results of PBT/vPvB Assessment: Not required</p>

13. DISPOSAL CONSIDERATIONS

<p>13.1 Waste Treatment Methods:</p>
<p>Regulations: Dispose in accordance with local and national environmental regulations</p>
<p>Properties (Physical/Chemical) Affecting Disposal: None known.</p>
<p>Waste Treatment Recommendations: None</p>

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
DOT	UN1993	Flammable Liquid, n.o.s. (Isopropanol)	3	PG III	No

<p>Note: Not regulated for transport in the United States. See aqueous alcohol exemption at 49CFR 173.150 (e)</p>
<p>14.6 Special precautions for user: Flammable Liquid</p>

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is 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): This product is not subject to release reporting under CERCLA. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not 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:	No	Reactivity Hazard:	No
Fire Hazard:	Yes		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

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

Components	C.A.S. #	WT %
1,4-dioxane	123-91-1	<1 ppm
Propylene Oxide	75-56-9	<2 ppm

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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:

F Highly Flammable

Xi Irritant

Xn Harmful

R10 Flammable

R11 Highly Flammable

R22 Harmful if swallowed.

R36 Irritating to eyes and skin.

R67 Vapors may cause drowsiness and dizziness.

S16 Keep away from sources of ignition - No Smoking!

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S51 Use only in well ventilated areas.

Flam. Liq. 2 Flammable liquid category 2

Acute Tox 4 Acute Toxicity Category 4

Eye Irrit 2A Eye irritation category 2A

STOT SE 3 Specific Target Organ Toxicity category 3

Aquatic Acute 3 Hazardous to Aquatic Environment category 3

H225 Highly flammable liquid and vapor.

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

H336 May cause drowsiness and dizziness.

H402 Harmful to aquatic life

Supersedes: : 8 February 2011

Revision Summary: Comprehensive review, new format

Date of SDS Preparation/Revision: 21 May 2014

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