

Safety Data Sheet


Section 1: Identification of the Substance/Mixture and of the Company/Undertaking
1.1 Product identifier
Product Name • Skin Marker with Ink

Product Code • 26-001; 26-001NS; 26-002; 26-002NS; 26-003; 26-003NS; 26-004; 26-004NS; 26-005; 26-005NS; 26-006; 26-006NS; 26-017NS; 26-018NS; 26-019; 26-019NS; 26-020; 26-001PR; 26-003PR; 26-005PR; 26-005PRNS; 26-018PRNS

1.2 Relevant identified uses of the substance or mixture and uses advised against
Relevant identified use(s) • Skin marker is used to make smooth, clear markings on the skin for perioperative or other procedural settings

1.3 Details of the supplier of the safety data sheet
Manufacturer • DeRoyal Industries, Inc.
 200 DeBusk Lane
 Powell, TN 37849
 United States
 www.deroyal.com
 customerservice@deroyal.com

Telephone • 800-251-9864
 (General)

1.4 Emergency telephone number

• 800-251-9864

Section 2: Hazards Identification
EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the substance or mixture
CLP • Serious Eye Damage 1 - H318
 Carcinogenicity 2 - H351
 Hazardous to the aquatic environment Chronic 2 - H411

2.2 Label Elements
CLP
DANGER

Hazard statements • H318 - Causes serious eye damage
 H351 - Suspected of causing cancer
 H411 - Toxic to aquatic life with long lasting effects

Precautionary statements
Prevention • P273 - Avoid release to the environment.
 P280 - Wear protective gloves and eye/face protection.

- Response** • P391 - Collect spillage
 P308+P313 - If exposed or concerned: Get medical advice/attention.

2.3 Other Hazards

- CLP** • According to Regulation (EC) No. 1272/2008 (CLP) this material is considered hazardous.

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2.1 Classification of the substance or mixture

- UN GHS** • Acute Toxicity Oral 5
 Aspiration 2
 Serious Eye Damage 1

2.2 Label elements

UN GHS

DANGER



- Hazard statements** • May be harmful if swallowed
 May be harmful if swallowed and enters airways
 Causes serious eye damage

Precautionary statements

- Prevention** • Wear protective gloves and eye/face protection.

- Response** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Immediately call a POISON CENTER or doctor/physician.
 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
 Do NOT induce vomiting.
 Call a POISON CENTER or doctor/physician if you feel unwell.

2.3 Other hazards

- UN GHS** • According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US) and Canada

According to: OSHA 29 CFR 1910.1200 HCS and WHMIS 2015 GHS

2.1 Classification of the substance or mixture

- Serious Eye Damage 1

2.2 Label elements

DANGER



- Hazard statements** • Causes serious eye damage

Precautionary statements

Prevention • Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Wear protective gloves and eye/face protection.

Response • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Immediately call a POISON CENTER or doctor/physician.

2.3 Other hazards

• Under 29 CFR 1910.1200 and WHMIS 2015, this product is considered hazardous.

Section 3 - Composition/Information on Ingredients**3.1 Substances**

• Material does not meet the criteria of a substance

3.2 Mixtures

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Isopropyl alcohol	CAS:67-63-0 EC Number:200-661-7 EU Index:603-117-00-0	10% TO 20%	Inhalation-Rat LC50 • 16000 ppm 8 Hour(s) Skin-Rabbit LD50 • 12800 mg/kg Ingestion/Oral-Rat LD50 • 5000 mg/kg	UN GHS: Flam. Liq. 2; Acute Tox. 5 (orl); Skin Irrit. 3; Eye Irrit. 2; Muta. 2; Repr. 2; STOT SE 3: Narc.; STOT SE 3: Resp. Irrit.; Asp. Tox. 2; STOT RE 2 EU CLP: Annex VI, Table 3.1: Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3: Narc., H336 OSHA HCS 2012: Flam. Liq. 2; Eye Irrit. 2; Muta. 2; Repr. 2; STOT SE 3: Narc.; STOT SE 3: Resp. Irrit.; STOT RE 2	NDA
Gentian Violet	548-62-9	< 6%	NDA	UN GHS: Eye Dam. 1; Acute Tox. 4 (orl); Skin Irrit. 3; Skin Sens. 1 EU CLP: Annex VI, Table 3.1: Carc. 2, H351; Acute Tox. 4 *, H302; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 OSHA HCS 2012: Eye Dam. 1; Acute Tox. 4 (orl); Skin Sens. 1	NDA

Relevant Phrases (code & full text)

H225 - Highly flammable liquid and vapor

H302 - Harmful if swallowed

H318 - Causes serious eye damage

H319 - Causes serious eye irritation

H336 - May cause drowsiness or dizziness

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Section 4 - First Aid Measures**4.1 Description of first aid measures**

Inhalation • Move victim to fresh air. Get medical attention if symptoms occur.

Skin • First-aid is not expected to be necessary under normal conditions of use.

Eye • If contact with eyes directly, flush with gently flowing fresh water thoroughly. Get medical attention if symptoms occur.

Ingestion • Obtain medical attention immediately if ingested.

4.2 Most important symptoms and effects, both acute and delayed

- * Refer to Section 11 - Toxicological Information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician * No specific actions or treatments recommended related to exposure to this material.

Section 5 - Firefighting Measures**5.1 Extinguishing media**

Suitable Extinguishing Media * Water, Carbon Dioxide, or Dry Chemical.

Unsuitable Extinguishing Media * No data available.

5.2 Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards * None

Hazardous Combustion Products * No data available.

5.3 Advice for firefighters

- * Wear positive pressure self-contained breathing apparatus (SCBA).
Structural firefighters' protective clothing will only provide limited protection.

Section 6 - Accidental Release Measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal Precautions * Use appropriate Personal Protective Equipment (PPE).

Emergency Procedures * No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental precautions

- * Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Containment/Clean-up Measures * Wipe or mop up.

6.4 Reference to other sections

- * Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage**7.1 Precautions for safe handling**

Handling * Good housekeeping and sanitary procedures. Do not get in eyes. Do not ingest. Wash thoroughly with soap and water after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage * Store in a cool, dry place.

7.3 Specific end use(s)

- * Refer to Section 1.2 - Relevant identified uses.

Section 8 - Exposure Controls/Personal Protection**8.1 Control parameters**

	Result	Exposure Limits/Guidelines			
		ACGIH	Korea	NIOSH	OSHA
Isopropyl alcohol (67-63-0)	STELs	400 ppm STEL	400 ppm STEL (Serial No. 471); 980 mg/m ³ STEL (Serial No. 471)	500 ppm STEL; 1225 mg/m ³ STEL	Not established

	TWAs	200 ppm TWA	200 ppm TWA (Serial No. 471); 480 mg/m ³ TWA (Serial No. 471)	400 ppm TWA; 980 mg/m ³ TWA	400 ppm TWA; 980 mg/m ³ TWA
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8.2 Exposure controls

Engineering Measures/Controls • No special engineering measures/controls expected to be necessary under normal conditions of use.

Personal Protective Equipment

Respiratory • None required under normal conditions of use.

Eye/Face • Wear appropriate eye protection.

Skin/Body • Wear appropriate gloves.

Environmental Exposure Controls • Follow best practice for site management and disposal of waste.

Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygiene

STEL = Short Term Exposure Limits are based on 15-minute exposures

NIOSH = National Institute of Occupational Safety and Health

TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

OSHA = Occupational Safety and Health Administration

Section 9 - Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Marker containing liquid ink.
Color	Violet	Odor	Alcohol-like
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Density	No data available
Water Solubility	No data available	Viscosity	No data available
Explosive Properties	No data available	Oxidizing Properties:	No data available
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	129°C (264.2°F)	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

9.2 Other Information

• No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

10.1 Reactivity

• No dangerous reaction known under normal conditions of use.

10.2 Chemical stability

- Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

- Hazardous polymerization will not occur.

10.4 Conditions to avoid

- No data available

10.5 Incompatible materials

- No data available

10.6 Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

11.1 Information on toxicological effects

GHS Properties	Classification
Acute toxicity	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•Acute Toxicity - Oral 5 - ATEmix (oral) = 3875 mg/kg
Aspiration Hazard	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•Aspiration 2
Carcinogenicity	EU/CLP•Carcinogenicity 2 OSHA HCS 2012•No data available UN GHS•No data available
Germ Cell Mutagenicity	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
Skin corrosion/Irritation	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
Skin sensitization	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
STOT-RE	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
STOT-SE	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
Toxicity for Reproduction	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
Respiratory sensitization	EU/CLP•No data available OSHA HCS 2012•No data available UN GHS•No data available
Serious eye damage/Irritation	EU/CLP•Serious Eye Damage 1 OSHA HCS 2012•Serious Eye Damage 1 UN GHS•Serious Eye Damage 1

Potential Health Effects

Inhalation

Acute (Immediate) • Under normal conditions of use, no health effects are expected.

Chronic (Delayed) • No data available

Skin

Acute (Immediate) * Under normal conditions of use, no health effects are expected.

Chronic (Delayed) * No data available.

Eye

Acute (Immediate) * Causes serious eye damage.

Chronic (Delayed) * No data available.

Ingestion

Acute (Immediate) * May be harmful if swallowed. Material may be aspirated into lungs during ingestion and/or subsequent vomiting. Aspiration of this material will cause severe lung injury, chemical pneumonitis, pulmonary edema or death.

Chronic (Delayed) * No data available.

Carcinogenic Effects * Repeated and prolonged exposure may cause cancer.

Section 12 - Ecological Information

12.1 Toxicity

* Toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

* No data available.

12.3 Bioaccumulative potential

* No data available.

12.4 Mobility in Soil

* No data available.

12.5 Results of PBT and vPvB assessment

* No PBT and vPvB assessment has been conducted.

12.6 Other adverse effects

* No studies have been found.

Section 13 - Disposal Considerations

13.1 Waste treatment methods

Product waste * Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste * Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	14.1 UN number	14.2 UN proper shipping name	14.3 Transport hazard class(es)	14.4 Packing group	14.5 Environmental hazards
DOT	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	NDA

14.6 Special precautions for user • None specified.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • Acute

Inventory						
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	EU ELNICS	Korea KECL
Gentian Violet	548-62-9	Yes	No	Yes	No	Yes
Isopropyl alcohol	67-63-0	Yes	No	Yes	No	Yes
Inventory (Con't.)						
Component	CAS	TSCA				
Gentian Violet	548-62-9	Yes				
Isopropyl alcohol	67-63-0	Yes				

Canada

Environment

Canada - CEPA - Priority Substances List

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

Korea

Labor

Korea - ISHA - Harmful Substances Prohibited for Manufacturing, Importing, Transferring, or Supplying

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

Korea - ISHA - Harmful Substances Requiring Permission

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

Korea - ISHA - Name, Toxicity and Protective Measures of New Chemical Substances

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

Environment

Korea - MOE - Toxic Chemicals Control Act (TCCA) - Observational Chemicals

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Isopropyl alcohol 67-63-0 Not Listed
 •Gentian Violet 548-62-9 Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - CERCLA/SARA - Section 313 - Emission Reporting		
•Isopropyl alcohol	67-63-0	1.0 % de minimis concentration (only if manufactured by the strong acid process, no supplier notification)
•Gentian Violet	548-62-9	Not Listed
U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
United States - California		
Environment		
U.S. - California - Proposition 65 - Carcinogens List		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Isopropyl alcohol	67-63-0	Not Listed
•Gentian Violet	548-62-9	Not Listed

15.2 Chemical Safety Assessment

- No Chemical Safety Assessment has been carried out.

Section 16 - Other Information

Last Revision Date • 26/April/2019

Preparation Date • 06/July/2015

Disclaimer/Statement of Liability • The information presented herein is based on data considered to be accurate as of the date of preparation of this Safety Data Sheet. However, no warranty or representation, express or implied is made as to the accuracy or completeness of the foregoing data and safety information, nor is any authorization given or implied to practice any patented invention without a license. In addition, no responsibility can be assumed by vendor for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices, or from any hazards inherent in the nature of the product.

Key to abbreviations

NDA = No data available