

SAFETY DATA SHEET

1 of 2 SDS – Solution

Section 1. Product And Company Identification

Product Name: REGIMEN® 28-Day Glutaraldehyde Solution
Manufacturer Number: 343 (1 QT bottle); 344 (1 GL bottle)

Distributed By: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

Information Line: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

Emergency Phone: 1-800-451-8346 (3E Company) Day or night

Section 2. Hazards Identification**GHS / HAZCOM 2012 Classification:**

Eye Damage Category 1

Respiratory Sensitization Category 1

Label Elements

Danger!

Hazard Phrases

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Prevention:

Avoid breathing mist, vapors or spray.

Wear eye protection and face protection.

In case of inadequate ventilation wear respiratory 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.

IF INHALED: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER.

Storage and Disposal

Dispose of contents and container in accordance with local and national regulations.

Section 3. Composition/Information On Ingredients

Component	CAS No.	Amount
Water and non-hazardous ingredients	Mixture	97.5%
Glutaraldehyde	111-30-8	3.4%

Section 4. First Aid Measures

Eye Contact: Hold eye open and rinse slowly and gently with water for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Seek immediate medical attention.

Skin Contact: Wash thoroughly with soap and water. If skin irritation develops, seek medical attention.

Inhalation: Move to fresh air. If ill effects occur, seek immediate medical attention.

Ingestion: If swallowed, get immediate medical advice by calling a Poison Control Center or hospital emergency room. If advice is not available, take victim and product container to the nearest emergency treatment center or hospital. Do not induce vomiting unless directed to do so by medical personnel. If the victim is alert, rinse their mouth with water. Do not attempt to give anything by mouth to an unconscious person.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Most important symptoms and effects, acute and delayed: Corrosive to eyes. May cause skin and respiratory tract irritation. Ingestion of glutaraldehyde may cause nervous system effects including nausea, dizziness, headache, and drowsiness. Repeated inhalation of vapors may cause asthmatic symptoms in some individuals.

Indication of immediate medical attention and special treatment, if needed: Treat symptomatically.

Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use any media that is suitable for the surrounding fire.

Specific Hazards Arising from the Chemical: None known.

Special Protective Equipment and Precautions for Fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored.

Section 6: Accidental Release Measures

Personal precautions, Protective equipment, and Emergency procedures: Wear appropriate protective clothing and equipment.

Methods and Materials for Containment and Cleaning up: Stop leak if it is safe to do so and move containers from the spill area. Collect material with an inert absorbent material and place in appropriate, labeled container for disposal.

Section 7. Handling and Storage

Precautions for Safe Handling: Avoid breathing vapors or mists. Prevent contact with eyes. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food. Use in a well-ventilated area in closed containers. Use in accordance with label directions.

Conditions for Safe Storage, Including any Incompatibilities: Store at room temperature. Keep containers closed.

Section 8. Exposure Controls / Personal Protection

Exposure Limits

Chemical	Exposure Limit
Glutaraldehyde	0.05 ppm Ceiling ACGIH TLV (SEN)

Appropriate Engineering Controls: Use general or local exhaust ventilation as needed to maintain airborne concentrations below the occupational exposure limits.

Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where exposure limits are exceeded, a NIOSH approved respirator with an organic vapor cartridge is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with 29 CFR 1910.134 and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

Hand protection: Protective gloves such as butyl rubber or nitrile are recommended to avoid skin contact.

Eye Protection: Safety goggles recommended.

Skin Protection: Wear protective clothing as needed to avoid skin contact.

Hygiene measures: Suitable eye wash and washing facilities should be available in the work area.

Section 9. Physical and Chemical Properties

Appearance:	Clear, colorless liquid	Odor:	Fruity odor.
Odor Threshold:	0.038 ppm (glutaraldehyde)	pH:	3.2-4.3 inactivated, 6.5-8.5 activated
Melting/Freezing Point:	Not available	Boiling Point/Range:	100°C (212°F)

Flash Point:	Not flammable	Evaporation Rate:	Not available
Flammability: (Solid, Gas)	Not applicable	Flammability Limits:	Not applicable
Vapor Pressure:	0.3 mmHg @20°C (glutaraldehyde)	Vapor Density:	Not available
Relative Density:	>1.0	Solubilities:	Soluble in Water
Partition Coefficient: (N-Octanol/Water)	Not available	Autoignition Temperature:	Not flammable
Decomposition Temperature:	Not available	Viscosity:	Not available

Section 10. Stability and Reactivity

Reactivity: None known.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to avoid: Avoid temperatures above 100°C. Do not allow significant evaporation.

Incompatible Materials: Strong oxidizing agents, acids and bases.

Hazardous decomposition products: Thermal decomposition will produce carbon monoxide and carbon dioxide.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: Vapors may cause irritation of the nose, throat and upper respiratory tract. Repeated inhalation of glutaraldehyde vapors may cause asthmatic symptoms in some individuals, including cough, wheezing and difficulty breathing.

Skin Contact: May cause skin irritation. No signs of toxicity were observed in a dermal toxicity study in rabbits. Irritating in a primary irritation study with rabbits, effects reversed in 72 hrs. Negative in a skin sensitization study with guinea pigs.

Eye Contact: Causes severe irritation and possible eye damage. Corrosive in an eye irritation study in rabbits.

Ingestion: Do not ingest. If swallowed, may irritate mouth, throat and intestinal tract. Ingestion of glutaraldehyde may cause nervous system effects including nausea, dizziness, headache, and drowsiness.

Chronic Hazards: No adverse effects expected based on the available data.

Carcinogen: None of the components is listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

Acute Toxicity Values for MetriCide:

LD50 Oral Rat 3450 mg/kg; LD50 Dermal Rabbit >2000 mg/kg

Section 12. Ecological Information

This product is classified as toxic to the aquatic environment.

Toxicity: No toxicity data available for product.

Glutaraldehyde: LC50 fathead minnow 10.8 mg/L/96 hr; EC50 daphnia magna 0.69 mg/L/48 hr; EbC50 green algae 2.64 mg/L/72 hr.

Persistence and degradability: Glutaraldehyde is readily biodegradable.

Bioaccumulative Potential: Glutaraldehyde: log Kow -0.333, potential for bioaccumulation is low

Mobility in Soil: Glutaraldehyde: highly mobile in soil.

Other Adverse Effects: None known

Section 13. Disposal Considerations

Solution Disposal: Refer to product label for disposal information. Dispose in accordance with national, state/provincial and local regulations.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, discard in accordance with hospital policy.

Section 14. Transport Information

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
US DOT	None	Not Regulated			None
EU ADR/RID	None	Not Regulated			None
IMDG	None	Not Regulated			None
IATA/ICAO	None	Not Regulated			None

Section 15. Regulatory Information

U.S. Federal Regulations:

EPA SARA 311/312 Hazard Classification: Acute Health

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Protection Of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

CERCLA SECTION 103: This product is not subject to CERCLA reporting requirements; however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.



SDS Date: 4/12/2016

California Prop 65: This product may contain a chemical known to the State of California to cause cancer or birth defects or other reproductive harm .

International Inventories

US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL) or exempt.

Section 16. Other Information

NFPA Rating: Fire: 1 Health: 3 Instability: 0

Effective Date: 4/12/16

Supersedes Date: 12/3/14

Revision Summary: New GHS Formatted SDS

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer’s knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user’s responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.

SAFETY DATA SHEET

2 of 2 SDS - Activator

Section 1. Product And Company Identification

Product Name: REGIMEN® 28-Day and Plus 30 Glutaraldehyde Solution Liquid Activator
Manufacturer Number: 343 (1 QT bottle); 344 (1 GL bottle)

Distributed By: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

Information Line: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

Emergency Phone: [1-800-451-8346 \(3E Company\) Day or night](tel:1-800-451-8346)

Section 2. Hazards Identification

GHS / HAZCOM 2012 Classification:
Not hazardous under the GHS criteria

Label Elements
None required

Section 3. Composition/Information On Ingredients

Component	CAS No.	Amount
Water and non-hazardous ingredients	Mixture	95-99%
Sodium Nitrite	7632-00-0	1-5%

Section 4. First Aid Measures

Eye Contact: Hold eye open and rinse slowly and gently with water. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. If irritation develops or persists, seek medical advice.

Skin Contact: Wash with soap and water. If skin irritation develops and persists, seek medical attention.

Inhalation: Move to fresh air if effects occur. Seek medical attention if effects persist.

Ingestion: If swallowed, seek medical advice by calling a Poison Control Center or hospital emergency room. Do not induce vomiting. Do not attempt to give anything by mouth to an unconscious person.

Most important symptoms and effects, acute and delayed: May be irritating to eyes, skin and respiratory tract.

Indication of immediate medical attention and special treatment, if needed: Treat symptomatically.

Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use any media that is suitable for the surrounding fire.

Specific Hazards Arising from the Chemical: None known.

Special Protective Equipment and Precautions for Fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored.

Section 6: Accidental Release Measures

Personal precautions, Protective equipment, and Emergency procedures: Wear appropriate protective clothing and equipment.

Methods and Materials for Containment and Cleaning up: Collect material with an inert, non-combustible, absorbent material and place in appropriate, labeled container for disposal.

Section 7. Handling and Storage

Precautions for Safe Handling: Avoid generating and breathing airborne mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. Use in accordance with label directions.

Conditions for Safe Storage, Including any Incompatibilities: Store at room temperature. Avoid prolonged exposure to heat and/or humidity as this reduces product effectiveness. Keep containers closed.

Section 8. Exposure Controls / Personal Protection

Exposure Limits

Chemical	Exposure Limit
Sodium Nitrite	None Established

Appropriate Engineering Controls: General ventilation should be adequate for normal use. For operations where the exposure levels are exceeded, mechanical ventilation such as local exhaust may be needed.

Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where exposure levels of mists are excessive and irritation is experienced, a NIOSH approved respirator with particulate filter is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with 29 CFR 1910.134 and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

Hand protection: Protective gloves such as rubber or nitrile are recommended.

Eye Protection: Safety goggles recommended.

Skin Protection: Wear protective clothing as needed to avoid skin contact.

Hygiene measures: None required for normal use.

Section 9. Physical and Chemical Properties

Appearance:	Green liquid.	Odor:	No odor.
Odor Threshold:	Not available	pH:	10.0 – 10.8
Melting/Freezing Point:	Not available	Boiling Point/Range:	Not applicable
Flash Point:	Not flammable	Evaporation Rate:	Not applicable
Flammability: (Solid, Gas)	Not flammable	Flammability Limits:	Not applicable
Vapor Pressure:	Same as water	Vapor Density:	Same as water
Relative Density:	>1.384	Solubilities:	Soluble in Water
Partition Coefficient: (N-Octanol/Water)	Not available	Autoignition Temperature:	Not flammable
Decomposition Temperature:	Not available	Viscosity:	Not available

Section 10. Stability and Reactivity

Reactivity: None known.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to avoid: None known.

Incompatible Materials: Strong oxidizing agents, reducing agents, metals and strong acids.

Hazardous decomposition products: Thermal decomposition will produce oxides of carbon, nitrogen and phosphorus.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: May cause irritation of the nose, throat and upper respiratory tract.

Skin Contact: May cause skin irritation.

Eye Contact: May cause irritation. Eye damage is not expected.

Ingestion: Do not ingest. If swallowed, may irritate mouth, throat and intestinal tract. Ingestion of sodium nitrite may cause methemoglobinemia and affect the ability of the blood to transport oxygen. Symptoms include nausea, dizziness, weakness, cyanosis (blue color of the skin and mucous membranes) and collapse.

Chronic Hazards: No adverse effects expected based on the available data.

Carcinogen: None of the components is listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

Acute Toxicity Values:

Sodium Nitrite: LD50 Oral Rat 180 mg/kg
Non-Hazardous Ingredients: Oral rat LD50 3530 mg/kg.

Section 12. Ecological Information

This product is not classified as harmful to the environment.

Toxicity: No toxicity data available for product.

Sodium Nitrite: LC50 rainbow trout >100 mg/L/96 hr; EC50 daphnia magna >100 mg/L/48 hr

Non-Hazardous Ingredients: LC50 fish >100 mg/L/96 hr; EC50 daphnia magna ~50 mg/L/48 hr; IC50 algae >100 mg/L/72 hr.

Persistence and degradability: No data available. Biodegradation does not apply to inorganic substances such as sodium nitrite.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: None known

Section 13. Disposal Considerations

Solution Disposal: Refer to product label for disposal information. Dispose in accordance with national, state/provincial and local regulations.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, discard in accordance with hospital policy.

Section 14. Transport Information

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
US DOT	None	Not Regulated			None
EU ADR/RID	None	Not Regulated			None
IMDG	None	Not Regulated			None
IATA/ICAO	None	Not Regulated			None

Section 15. Regulatory Information

U.S. Federal Regulations:

EPA SARA 311/312 Hazard Classification: Not hazardous

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): Sodium Nitrite 1-5%

Protection Of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

CERCLA SECTION 103: This product has an RQ of 2,000 lbs based on the RQ of the sodium nitrite of 100 lbs. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Canadian Regulations

National Pollutant Release Inventory (NPRI): This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements NPRI: None

WHMIS Classification: Class D-2-B

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

International Inventories

US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL) or exempt.

Section 16. Other Information

NFPA Rating: Fire: 1 Health: 1 Instability: 0

Effective Date: 4/12/16

Supersedes Date: 12/3/14

Revision Summary: New SDS

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