SEDiTROL® Erythrocyte Sedimentation Rate Control Safety Data Sheet

Section 1 - Identification

Trade Name: SEDiTROL® Erythrocyte Sedimentation Rate Control
Catalog/Product Number: DSC01, DSC06
Manufacturer/Supplier:

ALCOR Scientific LLC
20 Thurber Boulevard
Smithfield, RI 02917
Telephone: (401) 737-3774

Information Department: Technical Support, Customer Service

Emergency Information: Telephone: (401) 737-3774
Monday – Friday, 8:30am – 5:00pm Eastern US Time Zone (GMT -5)
Recommended Use: Clinical Laboratory, In-vitro diagnostics reagent or component

Section 2 – Hazard(s) Identification

2.1 Classification of the substance or mixture:

The product is not classified, according to the Globally Harmonized System (GHS)

Section 2.2 Labeling

Signal word: Not Applicable

Hazard-determining components of labeling: Not Applicable

Hazard statements: Not Applicable

Hazard pictograms: Not Applicable

NFPA (National Fire Protection Association) Rating – Scale 0-4

Health = 0
Fire = 0
Reactivity = 0

Precautionary Statements:

Contains human sourced and/or potentially infectious components

2.3 Other hazards:

Results of PBT and vPvB assessment are:
PBT = Not applicable
vPvB = Not applicable

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Section 3 – Composition/ Information on Ingredients

Chemical Characterization: Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Composition: 10-20% Human Red Blood Cells and 80-90% water.

Concentration varies based on batch-to-batch variation and level-to-level variation.

List of dangerous or hazardous components: Not applicable.

Additional information: Contains human sourced and/or potentially infectious components.

Section 4 – First Aid Measures

4.1 Description of first aid measures

General information:
No special measures required.

After inhalation:
Supply fresh air; consult a doctor in case of complaints.

After skin contact:
Immediately wash with water and soap and rinse thoroughly. Generally, the product does not irritate skin.

After eye contact:
Rinse opened eye for several minutes under running water. Consult a physician.

After swallowing:
Rinse mouth with water. Seek medical attention and appropriate follow-up.

4.2 Most important symptoms and effects, both acute and delayed

Eye irritation

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information.

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Section 5 – Fire-Fighting Measures

5.1 Extinguishing media
Suitable extinguishing agents: Use firefighting measures that suit the environment.
For safety reasons unsuitable extinguishing agents: None.

5.2 Special hazards arising from the substance or mixture
No further relevant information is available.

5.3 Advice for firefighters
No special measures required.

Section 6 – Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures
Handle as potentially infectious.

6.2 Environmental precautions:
Dilute with plenty of water.
Do not allow to enter sewers/surface or ground water.
Keep contaminated washing water and dispose of it appropriately.

6.3 Methods and material for containment and cleaning up:
Clean the affected area carefully.
Suitable cleaners or disinfectants.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

Section 7 – Handling and Storage

7.1 Precautions for safe handling: No special precautions are necessary, if used correctly.
Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities: Refer to IFU (315-09-011)

7.3 Specific end use(s): Clinical Laboratory professionals.

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Section 8 – Exposure Controls / Personal Protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Personal protective equipment:
General protective and hygienic measures:
Follow the usual biosafety practices for handling infectious materials.
Follow the usual biosafety practices for handling potentially infectious materials.

Breathing equipment:
Not required.



Protection of hands:
Protective gloves. The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a predation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application. The exact breakthrough time must be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:
Contact lenses should not be worn.
Safety glasses



Body protection: Personal Protective Clothing (i.e., lab coats).

Limitation and supervision of exposure into the environment
No further relevant information available.

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Section 9 – Physical and Chemical Properties

9.1 Information on basic physical and chemical properties
Form = Liquid
Color = Red
Odor = Light
Odor Threshold = Not determined
pH value at 20°C 7.5
Melting point/Melting Range: Undetermined
Boiling point/Boiling range: Undetermined
Flashpoint: Not applicable, Not determined
Flammability (solid, gaseous): Not applicable
Auto igniting: Product is not self-igniting
Danger of Explosion: None
Explosion limits: Not determined
Vapor pressure: Not determined
Density at 20°C (68°F): Not determined
Relative density: Not determined.
Vapor density: Not determined.
Evaporation rate: Not determined.
Relative density: Not determined
Solubility in / Miscibility with water: Fully miscible
Partition coefficient (in octanol/water): Not determined
Decomposition temperature: Not determined
Viscosity: Not determined (dynamic or kinematic)

9.2 Other Information: No further relevant information available.
Organic solvents = 0.3%
Water = 83.45
Solids Content = 16.4%

Section 10 – Stability and Reactivity

10.1 Reactivity: No further relevant information available.
10.2 Chemical stability: No decomposition if used according to specifications.
10.3 Possibility of hazardous reactions: No dangerous reactions known.
10.4 Conditions to avoid: No further relevant information available.
10.5 Incompatible materials: No further relevant information available.
10.6 Hazardous decomposition products: No dangerous decomposition products known.

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Section 11 – Toxicological Information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification: None.

Primary irritant effect:

· **on the skin:** No irritant effect.

· **on the eye:** No irritant effect.

Sensitization: No sensitizing effects known.

Subacute to chronic toxicity: No further relevant information available.

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Carcinogenic categories

IARC (International Agency for Research on Cancer): Proprietary Reagent.

NTP (National Toxicology Program): None of the ingredients are listed.

OSHA-Ca (Occupational Safety & Health Administration: None of the ingredients are listed.

Acute effects (acute toxicity, irritation, and corrosivity): None.

Repeated Dose Toxicity: No further relevant information available.

Section 12 – Ecological Information (non-mandatory)

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: No further relevant information is available.

12.3 Bio accumulative potential: No further relevant information is available.

12.4 Mobility in soil: No further relevant information is available.

General notes:

Water hazard class 1 (German regulation) (Self-assessment): Slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

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Section 13 – Disposal Considerations (non-mandatory)

13.1 Waste treatment methods
Recommendation:
Dispose of waste in accordance to applicable national, regional, and local regulations.
Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

Section 14 – Transport Information (non-mandatory)

14.1 UN number (DOT, ADR, IMDG, IATA): Not regulated

14.2 UN proper shipping name (DOT, ADR, IMDG, IATA): Not regulated

14.3 Transport hazard class(es) (DOT, ADR, IMDG, IATA): Not regulated

14.4 Packing group (DOT, ADR, IMDG, IATA): Not regulated

14.5 Environmental hazards: Marine pollutant: No

14.6 Special precautions for user: Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:
Not applicable.

UN "Model Regulation": Not regulated

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Section 15 – Regulatory Information (non-mandatory)

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

SARA (Superfund Amendments and Reauthorization Act of 1986- USA)
Section 302/304 (40CFR355.30/40CFR355.40): Substance not listed.
Section 313 (40CFR372.65): Substance not listed.
TSCA (Toxic Substance Control Act)
7732-18-5: Water – Active
7647-14-5: Sodium chloride – Active
122-99-6: 2-Phenoxyethanol - Active
7558-79-4: Disodium hydrogen orthophosphate - Active
7447-40-7: Potassium chloride – Active
Proprietary Reagent T –
6381-92-6: Ethylenediaminetetraacetic acid disodium salt dihydrate – Active
7558-80-7: Monosodium phosphate – Active
Proprietary Reagent E – Active

California Proposition 65
Chemicals known to cause cancer: This product does not contain listed components.
Chemicals known to cause reproductive toxicity for females: None
Chemicals known to cause reproductive toxicity for males: None
Developmental toxicity: Proprietary Reagent J15
Section 313 (40CFR372.65): Substance not listed.

Carcinogenic categories
EPA (Environmental Protection Agency): None of the ingredients listed
TLV (Threshold Limit Value established by ACGIH): None of the ingredients listed.
MAK (German Maximum Workplace Concentration): None of the ingredients listed.
NIOSH-CA (National Institute for Occupational Safety and Health): None

National regulations – Technical instructions (air):

Class	Share in %
NK	0.1 – 1 %

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

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Section 16 – Other Information

This information is based on the original manufacturer's present knowledge. This shall not constitute a guarantee for any specific product features and shall not establish a legal contractual relationship.

Sources and Guidance:

OSHA Brief, Hazard Communication Standard (HCS) based on 29 CFR 1910.1200, 2012
Regulation (EC) 1907/2006 (REACH)
Regulation (EC) 1272/2008 (CLP)

315-09-020 (DOC-1675) Ver. 1

Approved By:

(CO-3752) ALCOR Safety Data Sheets

Description

Create and approve the safety data sheet for the new deepCLEAN product utilizing the Regulation (EU) 2020-878 (REACH) requirements. Update the existing SDS's for Wash Solutions and SEDiTROL to ensure compliance to the REACH following the template from the standard. Obsolete the MSDS Exemption Letter (112-09-078) and create a Deviation to for the Wash Solution manufacturing, qc, and packaging.

Justification

Due to hazardous nature, a safety data sheet is required for the deepCLEAN (Bleach). In addition, the ALCOR SDS's needed to be revised to match the format of the REACH Regulation.

Assigned To:	Initiated By:	Priority:	Impact:
Scott VanAlst	Scott VanAlst	Medium	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Scott VanAlst	August 6, 2024 7:45 AM EDT	CO-3752	1	Published
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