Section 1 - Identification

Trade Name: iWASH®, miniiWASH®, iWASH PRO, MizarWash®
Catalog/Product Number: 112-12-001, 112-12-003, 112-12-006, 115-12-003
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

Trade name: iSED Wash Solutions

Section 3 – Composition/ Information on Ingredients

Chemical Characterization: Water

Description: Ultrapure, Type I.

Composition: 100% water, H_2O

CAS-No: 7732-18-5

List of dangerous or hazardous components: Not applicable.

Additional information: Not applicable.

Section 4 – First Aid Measures

4.1 Description of first aid measures
General information: No special measures required.
After inhalation: Not applicable.
After skin contact: Not applicable.
Eye contact: Not applicable.
Ingestion: Not applicable.

4.2 Most important symptoms and effects, both acute and delayed: None

4.3 Indication of any immediate medical attention and special treatment needed
No further relevant information.

Section 5 – Fire-Fighting Measures

The product is not flammable.

5.1 Extinguishing media: Not applicable.

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.

Trade name: iSED Wash Solutions

Section 6 – Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures
No special precautionary measures necessary.

6.2 Environmental precautions:
No special precautionary measures necessary.

6.3 Methods and material for containment and cleaning up:
Wipe up with a damp cloth and place in container for disposal.

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 (112-09-080)

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

Section 8 – Exposure Controls / Personal Protection

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: None required.

Breathing equipment:
Not required.

Trade name: iSED Wash Solutions

Section 8 – Exposure Controls / Personal Protection

8.2 Exposure controls (cont'd) *From page 3*

Personal protective equipment:
General protective and hygienic measures: None required.
Protection of hands: Not required for normal use of this product.
Eye protection: Not required for normal use of this product.
Respiratory Protection: Not required for normal use of this product.
Ventilation: Not required for normal use of this product.
Body protection: Personal Protective Clothing (i.e., lab coats). Safety shower and eye was facilities should be made available in laboratory setting.
Limitation and supervision of exposure into the environment: No further relevant information available.

Section 9 – Physical and Chemical Properties

9.1 Information on basic physical and chemical properties
Form = Liquid
Color = Colorless
Odor = Odorless
Odor Threshold = Not determined
pH value at 20°C 8.0
Melting point/Melting Range: 0.0^0C
Boiling point/Boiling range: 100^0C
Flashpoint: Not applicable, Not determined
Flammability (solid, gaseous): Not applicable, not determined
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.

Trade name: iSED Wash Solutions

Section 10 – Stability and Reactivity

10.1 Reactivity: No further relevant information available.
10.2 Chemical stability: Product is chemically stable under ambient conditions
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.

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: No information provided.

Carcinogenic categories
IARC (International Agency for Research on Cancer): None of the ingredients are listed.
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.

Trade name: iSED Wash Solutions

Section 12 – Ecological Information (non-mandatory)

12.1 Toxicity
Aquatic toxicity: No harmful effects on aquatic organisms are expected.
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.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

Trade name: iSED Wash Solutions

Section 13 – Disposal Considerations (non-mandatory)

13.1 Waste treatment methods
Recommendation: Dispose of waste in accordance with 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

Trade name: iSED Wash Solutions

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

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.

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)

112-09-085 (DOC-2570) 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
Scott VanAlst	October 5, 2022 11:38 AM EDT	CO-3237	0	Superseded