Version: 3.1

Revision date: 23.04.2015

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Product name: UnoDent Imprep AC Wash Reg Body – ICU101 – Part A

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Identified uses: Medical / paramedical.
Uses advised against: None known.

1.3 Details of the supplier of the safety data sheet:

manufacturer/supplier: Made for UnoDent Ltd. Tel: 01376 500582 address: 10 Perry Way, Witham, Essex Fax: 01376 500581

CM8 3SX, UK

information sector: Technical Department Tel: 01376 500582

emergency information: Technical Department emergency e-mail: info@unodent.com

1.4 Further information obtainable from: Regulatory Affairs / Quality Assurance:

feedback@unodent.com

Emergency telephone numbers: +44 (0) 1376 500582

SECTION 2: Hazards identification

Classification of the substance or mixture:

The product has been classified according to the legislation in force.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended:

Xn; R48/20

Classification according to Regulation (EC) No 1272/2008 as amended:

Health Hazards:

Specific Target Organ Toxicity - Repeated Exposure Category 1 Causes damage to organs through prolonged or repeated exposure.

Hazard summary:

Physical Hazards: No specific recommendations.

Health Hazards:

Inhalation: Quartz: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation (CE)

1272/2008.

Eye contact: No specific symptoms noted.
Skin Contact: No specific symptoms noted.
Ingestion: No specific symptoms noted.
Other Health Effects: No other information noted.

Environmental hazards: Not regarded as dangerous for the environment.

2.2 Label Elements: Safety data sheet available on request.

2.3 Other hazards: No data available.

SECTION 3: Composition/information on ingredients

Mixtures:

General information: Mixture of Polyorganosiloxanes, fillers, additives.

(Chemical name	Concentration	CAS-No.	 REACH Registration No.	Notes
	Quartz (SiO2)	<=35%	14808-60-7		#

^{*} All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

This substance has workplace exposure limit(s).

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

Classification:

Chemical name	Classification		Notes
Quartz (SiO2)	DPD:	Xn; R48/20	
	CLP:	STOT RE 1;H372	

DPD: Directive 67/548/EEC. CLP: Regulation No. 1272/2008.:

The full text for all R/H-phrases is displayed in section 16.

SECTION 4: First aid measures

General: Get medical attention if symptoms occur. Contaminated clothing to be placed in closed container until disposal or decontamination.

Description of first aid measures:

Inhalation: Not relevant.

Eye contact: In the event of contact with the eyes, rinse thoroughly with clean water. Continue to rinse

for at least 15 minutes.

Skin contact: Remove contaminated clothing and shoes. Wash with soap and water.

Ingestion: Do not induce vomiting. Rinse mouth thoroughly.

Most important symptoms and effects, both acute and delayed: None known. Indication of any immediate medical attention and special treatment needed:

Hazards: No specific recommendations. **Treatment:** No specific recommendations.

SECTION 5: Firefighting measures

General fire hazards: No specific recommendations.

Extinguishing media:

Suitable extinguishing media:

Extinguish with foam, carbon dioxide or dry powder. Water spray.

Unsuitable extinguishing media:

None known.

Special hazards arising from the substance or mixture:

Combustible. For further information, refer to section 10: "Stability and Reactivity".

Advice for firefighters:

Special Fire Fighting

Procedures: Water spray should be used to cool containers.

Special protective equipment for fire-fighters:

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. See Section 8 of the MSDS for Personal Protective Equipment. **Environmental precautions:** Collect spillage. Do not discharge into drains, water courses or onto the ground.

Methods and material for containment and cleaning up:

Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Container must be kept tightly closed. Absorb with sand or other inert absorbent. To clean the floor and all objects contaminated by this material, use an appropriate solvent.(cf. : § 9) Flush area with plenty of water. Incinerate in suitable combustion chamber.

Notification Procedures: Caution: Contaminated surfaces may be slippery. For waste disposal, see section 13 of the MSDS.

SECTION 7: Handling and storage:

Precautions for safe handling: No specific precautions.

Conditions for safe storage, including any incompatibilities:

No special storage precautions noted. Material is stable under normal conditions. Avoid contact with oxidizing agents. Suitable containers: polyethylene. Plastic lined steel drum.

Specific end use(s): No specific recommendations.

SECTION 8: Exposure controls/personal protection

Control parameters:

Occupational exposure limits:

Quartz: When encapsulated in polymer, it is not expected to pose a health hazard when processed under normal conditions of use.

Exposure controls:

Appropriate engineering controls:

No special precautions.

Individual protection measures, such as personal protective equipment:

General information: No specific precautions.

Eye/face protection: Safety Glasses

Skin protection:

Hand protection: Use protective gloves made of: Nitrile. Polyvinyl chloride (PVC). Rubber or plastic.

Other: No skin protection is ordinarily required under normal conditions of use. In

accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.

Respiratory Protection: No specific precautions.

Hygiene measures: Provide eyewash station and safety shower.

Environmental Controls: No data available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties:

Appearance:

Physical State: Liquid

Form: Viscous. Color: White Odor: Odorless

Odor Threshold: No data available.

pH: Not applicable

Freezing point: No data available. **Boiling Point:** No data available.

Flash Point: > 200 °C (Closed cup according to method ASTM D-56.)

Evaporation Rate: No data available.

Flammability (solid, gas): No data available.
Flammability Limit - Upper (%)-: No data available.

Flammability Limit - Lower (%)—: No data available.

Vapor pressure: < 0,1 hPa (20 °C) Vapor density (air=1): No data available. Relative density: 1,4 (20 °C) Approximate

Solubility(ies):

Solubility in Water: Practically Insoluble

Solubility (other): Diethylether.: Miscible (in all proportions).

Chlorinated solvents.: Miscible (in all proportions).
Aromatic hydrocarbons.: Miscible (in all proportions).
Aliphatic hydrocarbons.: Miscible (in all proportions).

Acetone.: Very slightly soluble. Ethanol.: Very slightly soluble.

Partition coefficient (n-octanol/water): No data available.

Autoignition Temperature: > 400 °C

Decomposition Temperature: > 200 °C

Viscosity: 220 000 mm2/s (20 °C)

Explosive properties: No data available.

Oxidizing properties: According to the data on the components Not considered as oxidizing. (evaluation

by structure-activity relationship)

SECTION 10: Stability and reactivity

Reactivity: Not relevant. **Chemical stability:** Stable

Possibility of hazardous reactions: No data available. **Conditions to avoid:** No other information noted. **Incompatible materials:** Strong oxidizing agents.

Hazardous decomposition products:

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

Amorphous silica.

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation: No data available.
 Ingestion: No data available.
 Skin contact: No data available.
 Eye contact: No data available.
 11.1 Information on toxicological effects:

Acute Toxicity:

Oral:

Product: Not classified for acute toxicity based on available data.

Dermal:

Product: Not classified for acute toxicity based on available data.

Specified substance(s):

Quartz (SiO2) No data available.

Inhalation:

Product: No effects expected (assessment based on ingredients).

Repeated dose toxicity:

Product: No effects expected (assessment based on ingredients).

Skin corrosion/irritation:

Product: No effects expected (assessment based on ingredients).

Serious eye damage/eye irritation:

Product: No effects expected (assessment based on ingredients).

Respiratory or skin sensitization:

Product: No effects expected (assessment based on ingredients).

Germ cell mutagenicity:

In vitro:

Product: No effects expected (assessment based on ingredients).

In vivo:

Product: No effects expected (assessment based on ingredients).

Carcinogenicity:

Product: No effects expected (assessment based on ingredients).

Reproductive toxicity (Fertility):

Product: No data available.

Developmental Toxicity (Teratogenicity):

Product: No data available.

Specific target organ toxicity - single exposure:

Product: No effects expected (assessment based on ingredients).

Specific target organ toxicity - repeated exposure:

Product: No effects expected (assessment based on ingredients).

Aspiration hazard:

Product: No effects expected (assessment based on ingredients).

Other adverse effects: None known.

SECTION 12: Ecological information

12.1 Toxicity:

Acute toxicity:

Fish:

Product: No effects expected (assessment based on ingredients).

Aquatic invertebrates:

Product: No effects expected (assessment based on ingredients).

Chronic Toxicity:

Fish:

Product: No effects expected (assessment based on ingredients).

Aquatic invertebrates:

Product: No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants:

Product: No effects expected (assessment based on ingredients).

12.2 Persistence and degradability:

Biodegradation:

Product: Not applicable

BOD/COD ratio:

Product: No data available.

12.3 Bioaccumulative potential:
Product: No data available.

12.4 Mobility in soil: No data available.

12.5 Results of PBT and vPvB assessment: None Reported

12.6 Other adverse effects: None known.

SECTION 13: Disposal considerations

Waste treatment methods:

General information: The user's attention is drawn to the possible existence of local regulations regarding disposal.

Disposal Methods: Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion chamber.

Contaminated packages should be as empty as possible. Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Recycle following cleaning or dispose of at an authorised site.

SECTION 14: Transport information

This material is not subject to transport regulations.

Other information: Packaging with a breathing/venting bung are FORBIDDEN for transport by air. 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture: National Regulations:

Chemical safety assessment: No data available.

SECTION 16: Other information

Revision Information:Not relevant. **Key literature references and sources for data:**No data available.

Wording of the R-phrases and H-statements in section 2 and 3:

H372 Causes damage to organs through prolonged or repeated exposure. R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Training information: No data available.

Inventory Status

Australia AICS:

Canada DSL Inventory List:

On or in compliance with the inventory

On or in compliance with the inventory

On or in compliance with the inventory

China Inv. Existing Chemical Substances:

Korea Existing Chemicals Inv. (KECI):

On or in compliance with the inventory

Issue Date: 23.04.2.15

SDS No:

SAFETY DATA SHEET

Date/Revision – 13.01.2012 Version – 3.0

1 Product and company identification.

PRODUCT NAME: UnoDent Imprep AC Wash Reg Body – ICU101 – Part B Relevant identified uses of the substance or mixture and uses advised against:

Identified uses: Medical / paramedical. Uses advised against: None known.

manufacturer/supplier: Made for UnoDent Ltd. Tel: 01376 500582 address: 10 Perry Way, Witham, Essex Fax: 01376 500581

CM8 3SX, UK

information sector: Technical Department Tel: 01376 500582

emergency information: Technical Department emergency e-mail: info@unodent.com

Further information obtainable from: Regulatory Affairs / Quality Assurance: feedback@unodent.com

Emergency telephone numbers: +44 (0) 1376 500582

2 Hazards identification

Classification of the substance or mixture:

The product has been classified according to the legislation in force.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended:

Xn; R48/20

Hazard summary:

Physical hazards: Combustible. Chemical compounds containing silicon - hydrogen bonds

(SiH). During Storage, This product may generate hydrogen gas. For further information, refer to section 10: "Stability and Reactivity".

Health hazards:

Inhalation: Quartz: When encapsulated in polymer, it is not expected to pose a health

hazard when processed under normal conditions of use.

Eye contact: No specific symptoms noted.
Skin contact: No specific symptoms noted.
Ingestion: No specific symptoms noted.
Other Health Effects: No other information noted.

Environmental hazards: Not regarded as dangerous for the environment.

Label elements:

Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation (CE) n°1272/2008.

Safety data sheet available for professional user on request.

Other hazards: No data available.

SECTION 3: Composition/information on ingredients

Mixtures:

General information: Mixture of Polyorganosiloxanes, fillers, additives.

Chemical name	Concentration	CAS-No.	 REACH Registration No.	Notes
Quartz (SiO2)	<=35%	14808-60-7		#

^{*} All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

This substance has workplace exposure limit(s).

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

Classification:

Chemical name	Classification		Notes
Quartz (SiO2)	DPD:	Xn; R48/20	
	CLP:	STOT RE 1;H372	

DPD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.:

The full text for all R/H-phrases is displayed in section 16.

SECTION 4: First aid measures

General: Get medical attention if symptoms occur. Contaminated clothing to be placed in closed

container until disposal or decontamination.

Description of first aid measures:

Inhalation: Not relevant.

Eye contact: In the event of contact with the eyes, rinse thoroughly with clean water. Continue to

rinse for at least 15 minutes.

Skin contact: Remove contaminated clothing and shoes. Wash with soap and water.

Ingestion: Do not induce vomiting. Rinse mouth thoroughly.

Most important symptoms and effects, both acute and delayed: None known. Indication of any immediate medical attention and special treatment needed:

Hazards: No specific recommendations.

Treatment: No specific recommendations.

SECTION 5: Firefighting measures

General fire hazards: No specific recommendations.

Extinguishing media:

Suitable extinguishing media: Foam. Powder. Carbon dioxide (CO2).

Unsuitable extinguishing media: Do not use water jet as an extinguisher, as this will spread the fire.

Alkaline powders.

Special hazards arising from the substance or mixture:

Combustible. This product may generate hydrogen gas. For further information, refer to section 10:

"Stability and Reactivity".

Advice for firefighters:

Special Fire Fighting Procedures: Water spray should be used to cool containers.

Special protective equipment for fire-fighters:

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Eliminate all sources of ignition. Use personal protective equipment. See Section 8 of the MSDS for Personal Protective Equipment. Keep away from Alkalis and caustic products.

Environmental precautions: Collect spillage. Do not discharge into drains, water courses or onto the ground. Explosive; mass explosion hazard.

Methods and material for containment and cleaning up:

Use explosion-proof electrical/ventilating/lighting/.../equipment. Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Container must be kept tightly closed. Suitable containers: equipped with a degassing device. Absorb with sand or other inert absorbent. Do NOT use products which are basic. To clean the floor and all objects contaminated by this material, use an appropriate solvent.(cf. : § 9)

Flush area with plenty of water. Incinerate in suitable combustion chamber.

Notification Procedures: Caution: Contaminated surfaces may be slippery. For waste disposal, see section 13 of the MSDS.

SECTION 7: Handling and storage:

Precautions for safe handling: Use mechanical ventilation in case of handling which causes formation of vapors. Do not mix with Incompatible materials. For further information, refer to section 10: "Stability and Reactivity". Read and follow manufacturer's recommendations.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Store in tightly closed original container. equipped with a degassing device. Suitable containers: polyethylene. Steel drums coated with epoxy-resin.

Specific end use(s): No data available.

SECTION 8: Exposure controls/personal protection

Control parameters:

Occupational exposure limits: Quartz: When encapsulated in polymer, it is not expected to pose a health hazard when processed under normal conditions of use.

Exposure controls: Appropriate engineering controls: Avoid inhalation of vapors and spray mists. Individual protection measures, such as personal protective equipment: General information: No specific precautions.

Eye/face protection: Safety Glasses

Skin protection:

Hand protection: Use protective gloves made of: Nitrile. Polyvinyl chloride (PVC). Rubber or plastic.

Other: It is a good industrial hygiene practice to minimize skin contact. Wear suitable protective clothing.

Respiratory Protection: No specific precautions.

Hygiene measures: Provide eyewash station and safety shower.

Environmental Controls: No data available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties:

Appearance:

Physical State: Liquid

Form: Viscous. Color: Violet Odor: Odorless

Odor Threshold: No data available.

pH: Not applicable

Freezing point: No data available. Boiling Point: No data available.

Flash Point: > 200 °C (Closed cup according to method ASTM D-56.)

Evaporation Rate: No data available. Flammability (solid, gas): No data available.

Flammability Limit - Upper (%)—: 74 %(V) Hydrogen.

Flammability Limit - Lower (%)—: 4 %(V) Hydrogen.

Vapor pressure: < 0,1 hPa (20 °C)

Vapor density (air=1): No data available.

Relative density: 1,4 (20 °C) Approximate

Solubility(ies):

Solubility in Water: Practically Insoluble

Solubility (other): Diethylether.: Miscible (in all proportions).

Chlorinated solvents.: Miscible (in all proportions).

Aromatic hydrocarbons.: Miscible (in all proportions).

Aliphatic hydrocarbons.: Miscible (in all proportions).

Acetone.: Very slightly soluble.

Ethanol.: Very slightly soluble.

Partition coefficient (n-octanol/water): No data available.

Autoignition Temperature: > 400 °C

Decomposition Temperature: > 200 °C

Viscosity: 220 000 mm2/s (20 °C) Explosive properties: No data available.

Oxidizing properties: According to the data on the components Not considered as

oxidizing. (evaluation by structure-activity relationship)

SECTION 10: Stability and reactivity

Reactivity: No other information noted.

Chemical stability: Stable

Possibility of hazardous

reactions: During Storage, This product may generate hydrogen gas.

Conditions to avoid: No other information noted.

Incompatible materials: Strong oxidizing agents. A fire or explosion hazard arises since highly flammable

gas (hydrogen) is released when it is in contact with: Alkalis and caustic

products. Chemical compounds with mobile hydrogen, in the presence of metal

salts and complexes.

Hazardous decomposition

products: Thermal decomposition or combustion may liberate carbon oxides and other

toxic gases or vapors. Amorphous silica.

Quantity of hydrogen potentially released (I/kg of product): <7

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation:No effects expected (assessment based on ingredients).Ingestion:No effects expected (assessment based on ingredients).Skin contact:No effects expected (assessment based on ingredients).

Eye contact: No effects expected (assessment based on ingredients).

Information on toxicological effects:

Acute Toxicity:

Oral:

Product: No effects expected (assessment based on ingredients).

Dermal:

Product: No effects expected (assessment based on ingredients).

Specified substance(s):

Quartz (SiO2) No data available.

Inhalation:

Product: No effects expected (assessment based on ingredients).

Repeated dose toxicity:

Product: No effects expected (assessment based on ingredients).

Skin corrosion/irritation:

Product: No effects expected (assessment based on ingredients).

Serious eye damage/eye

irritation:

Product: No effects expected (assessment based on ingredients).

Respiratory or skin sensitization:

Product: No effects expected (assessment based on ingredients).

Germ cell mutagenicity:

In vitro:

Product: No effects expected (assessment based on ingredients).

In vivo:

Product: No effects expected (assessment based on ingredients).

Carcinogenicity:

Product: No effects expected (assessment based on ingredients).

Reproductive toxicity:

Product: No effects expected (assessment based on ingredients).

Specific target organ toxicity - single exposure:

Product: No effects expected (assessment based on ingredients).

Specific target organ toxicity - repeated exposure:

Product: No effects expected (assessment based on ingredients).

Aspiration hazard:

Product: No effects expected (assessment based on ingredients).

Other adverse effects: None known.

SECTION 12: Ecological information

Toxicity:

Acute toxicity:

Fish:

Product: No effects expected (assessment based on ingredients).

Aquatic invertebrates:

Product: No effects expected (assessment based on ingredients).

Chronic Toxicity:

Fish:

Product: No effects expected (assessment based on ingredients).

Aquatic invertebrates:

Product: No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants:

Product: No effects expected (assessment based on ingredients).

Persistence and degradability:

Biodegradation:

Product: Not applicable

BOD/COD ratio:

Product: No data available.

Specified substance(s):

Quartz (SiO2) No data available.

Bioaccumulative potential:

Product: No data available.

Specified substance(s):

Quartz (SiO2) No data available. Mobility in soil: No data available.

Known or predicted distribution to environmental compartments: Quartz (SiO2) No data available.

Results of PBT and vPvB assessment: None Reported Other adverse effects: None known.

SECTION 13: Disposal considerations

Waste treatment methods:

General information: The user's attention is drawn to the possible existence of local regulations regarding disposal.

Disposal Methods: Dispose of waste at an appropriate treatment and disposal facility inaccordance with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion chamber.

Contaminated packages should be as empty as possible. Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Recycle following cleaning or dispose of at an authorised site.

European Waste Codes:

SECTION 14: Transport information

This material is not subject to transport regulations.

Environmental hazards: Not regulated.

Special precautions for user: Transport by air is FORBIDDEN if the packaging has a

breathing/venting bung.

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

SECTION 15: Regulatory information

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

National Regulations:

Chemical safety assessment: No data available.

SECTION 16: Other information

Revision Information: Not relevant.

Key literature references and sources for data: No data available.

Wording of the R-phrases and H-statements in section 2 and 3:

H372 Causes damage to organs through prolonged or repeated exposure.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation. Training information: No data available.

Inventory Status

Australia AICS:

On or in compliance with the inventory

Canada DSL Inventory List:

Not in compliance with the inventory.

EU EINECS List:

On or in compliance with the inventory

China Inv. Existing Chemical Substances: On or in compliance with the inventory

Korea Existing Chemicals Inv. (KECI):

Not in compliance with the inventory.

Philippines PICCS:

Not in compliance with the inventory.

US TSCA Inventory:

On or in compliance with the inventory

New Zealand Inventory of Chemicals: Not in compliance with the inventory.

Issue Date: 13.01.2012

SDS No:

Disclaimer: The information given is based on data available for the material, the components of the material, and similar materials. The information is believed to be correct. It is given in good faith. This information should be used to make an independent determination of the methods to safeguard workers

and the environment.

Disclaimer: The information given is based on data available for the material, the components of the material, and similar materials. The information is believed to be correct. It is given in good faith. This information should be used to make an independent determination of the methods to safeguard workers and the environment.