armorgard sanitiser wipes

Sheet dated 19/3/2020

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier

Product name **Protectus Ultimate Anti-Bacterial Multi Surface Disinfectant**
Part no. **PU-RTU**

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

A ready-to-use sanitising solution to provide general disinfection of hard surfaces for protection against common bacteria and other pathogens in the workplace and around the home. For professional and consumer use.

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Aquatic Chronic 3; H412

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms : None
Signal Word : None
Hazard statements
H412 : Harmful to aquatic life with long lasting effects.
Supplemental hazard statements
EUH208 : Contains Polyhexamethylene biguanide. May produce an allergic reaction.
Precautionary statements
Prevention:
P273 : Avoid release to the environment.
General:
P102 : Keep out of reach of children.
P103 : Read label before use.
Disposal:
P501 : Dispose of contents/container in accordance with local regulations.

2.3 Other hazards

None known.

SECTION 3: Composition and Information on Ingredients

3.2 Mixtures

Substance	CAS No. EC No. REACH No.	Classification	Range
Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7 (PHMB (1415; 4.7))	1802181-67-4 (32289-58-0) Polymer NA	Acute Tox. 4 (Oral); H302 Acute Tox. 2 (Inhal.); H330 Eye Dam. 1; H318 Skin Sens. 1B; H317 STOT SE 3; H335 Aquatic Acute 1; H400 (M=10) Aquatic Chronic 1; H410 (M=10)	< 0.15 %
Alkyl (C12-16) dimethylbenzyl ammonium chloride	68424-85-1 270-325-2	Acute Tox. 4 (Oral); H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 (M=10) Aquatic Chronic 1; H410	< 0.1 %
Didecyldimethylammonium chloride	7173-51-5 230-525-2 01-2119945987-15	Acute Tox. 3 (Oral); H301 Skin Corr. 1B; H314 Aquatic Acute 1; H400 (M=10) Aquatic Chronic 2; H411	< 0.1 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Eye contact — If irritation occurs, cautiously rinse eyes with lukewarm, gently flowing water for 5 minutes, while holding the eyelids open. If eye irritation persists, get medical advice.

Skin contact — Adverse reactions are not anticipated in normal handling and use. However, should a reaction occur, then wash the affected area with clean water and seek medical advice.

Inhalation — Exposure via inhalation is not anticipated. Move to fresh air and keep warm. Seek medical attention if feel unwell.

Ingestion — Rinse mouth. Do NOT induce vomiting. If you feel unwell or concerned, get medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Eyes: can cause redness, stinging, discomfort.

Skin: contains Polyhexamethylene biguanide. May produce an allergic reaction.

4.3. Indication of any immediate medical attention and special treatment needed

No specific recommendations.

SECTION 5: Fire Fighting Measures

5.1. Extinguishing media

No special requirements, as appropriate for the fire.

5.2. Special hazards arising from the substance or mixture

The product is non-combustible as it is water-based with non-flammable components. No special hazards.

5.3. Advice for firefighters

No special measures arising from the mixture.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes.

6.2. Environmental precautions

This product is harmful to aquatic life with long lasting effects. Keep away from drains, surface water and soil.

6.3. Methods and material for containment and cleaning up

Small spillages: mop up or absorb with an inert dry material (e.g. paper towel) and dispose of in bin. Large spillages: contain spillage, then absorb with liquid-binding material (e.g. sand, diatomite, acid binders, universal sawdust) and place in container for disposal according to local regulations.

6.4. Reference to other sections

No reference.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Avoid contact with eyes. Use in accordance with the product label.

7.2. Conditions for safe storage, including any incompatibilities

Store in original container. Protect from extreme temperatures and direct sunlight. Do not freeze.

7.3. Specific end use(s)

No additional information.

SECTION 8: Exposure Controls/ Personal Protection

8.1. Control parameters

Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Appropriate engineering controls:

No specific recommendations.

Personal protective equipment:

Eye protection	Not required.
Hand protection	Not required.
Skin and body protection	Not required.
Respiratory protection	Not required.

Environmental exposure controls:

Prevent mixture from entering water courses.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	transparent to pale straw
Odour	characteristic
Odour threshold	no data
pH	6 – 7 (at 20°C with pH indicator strip)
Melting point	ca. 0°C
Initial boiling point and range	ca. 100°C
Flash point	above 100°C
Evaporation rate	not volatile
Flammability (solid, gas)	not applicable since the product is liquid
Upper/lower flammability or explosive limits	not applicable since the product is not flammable/explosive
Vapour pressure	no data
Vapour density	no data
Density (g/cm^3)	ca. 1.0
Solubility in water	completely miscible
Partition coefficient: n-octanol/water	not applicable for mixtures
Auto-ignition temperature	not applicable since the product is not volatile
Decomposition temperature	no data
Viscosity	no data
Explosive properties	not explosive
Oxidising properties	not classified as oxidising

9.2. Other information

No data available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

Stable and is not expected to have a hazardous reaction.

10.2. Chemical stability

Stable under normal temperature. Store in a cool dry place.

10.3. Possibility of hazardous reactions

Stable under normal conditions.

10.4. Conditions to avoid

Avoid direct sunlight.

10.5. Incompatible materials

Strong oxidising agents; Anionic materials.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

Acute toxicity:

Oral	Contains ingredients classified as Acute Tox. 3 and Acute Tox. 4 (section 3). Mixture is not classified as Acute Tox. by the conventional method using information derived from supplier's SDS.
Dermal	Does not contain any ingredients classified as Acute Tox.
Inhalation	Contains an ingredient classified as Acute Tox. 2 (section 3). Mixture is not classified as Acute Tox. by the conventional method using information derived from supplier's SDS.
Skin corrosion/irritation	Contains an ingredient classified as Skin Corr. 1B (section 3). Mixture is not classified as Skin Corr./Irrit. by the conventional method using information derived from supplier's SDS.
Serious eye damage/irritation	Contains an ingredient classified as Eye Dam. 1 (section 3). Mixture is not classified as Eye Dam./Irrit. by the conventional method using information derived from supplier's SDS.
Respiratory or skin sensitisation	Contains Polyhexamethylene biguanide. May cause sensitisation by skin contact.
Germ cell mutagenicity	Components do not exhibit mutagenic properties in reported in-vitro studies.
Carcinogenicity	Does not contain any ingredients classified as Carc.
Reproductive toxicity	Components do not exhibit reproductive toxicity effects in reported studies.
STOT-SE	Contains an ingredient classified as STOT-SE (section 3). Mixture is not classified as STOT-SE by the conventional method using information derived from supplier's SDS.
STOT-RE	Does not contain any ingredients classified as STOT-RE.
Aspiration hazard	Does not contain any ingredients classified as Asp. Tox.

Routes of exposure/ symptoms

Eye contact	Can cause redness, stinging, discomfort.
Skin contact	May produce an allergic reaction in sensitive individuals.
Inhalation	No harmful effects expected under normal use.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.

SECTION 12: Ecological Information

12.1. Toxicity

Harmful to the 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

This mixture does not contain any substance considered to be PBT (persistent, bioaccumulating and toxic) or vPvB (very persistent and very bioaccumulating).

12.6. Other adverse effects

No data available.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Product	Small quantities may be flushed to drains with plenty of water (subject to consent limits). Large quantities, dispose of in accordance with local regulations.
Contaminated packaging	Recycle containers wherever possible.

SECTION 14: Transport Information

ADR / RID / ADN / IATA / IMDG

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number : not applicable

14.2. UN proper shipping name : not applicable

14.3. Transport hazard class(es) : not applicable

14.4. Packing group : not applicable

14.5. Environmental hazards : not applicable

14.6. Special precautions for user

None.

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

SECTION 15: Regulatory Information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Regulation (EU) No. 2015/830. Label elements according to Regulation (EC) No. 1272/2008.

15.2. Chemical safety assessment

Not required.

SECTION 16: Other Information

The following ingredients were renamed in the Section 3.2:

Polymer of N-cyanocyanamide/1,6-hexanediamine hydrochloride (CAS 1802181-67-4/32289-58-0) to Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7 (PHMB (1415; 4.7))
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1) to Alkyl (C12-16) dimethylbenzyl ammonium chloride.

The chemical nature and composition of the product remain the same.

Full text of H-Statements referred to under Section 3.

H301: Toxic if swallowed.
H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H330: Fatal if inhaled.
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H411: Toxic to aquatic life with long lasting effects.

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Test Report: EN 14476. Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension modified for Human Herpes Virus (Herpes Simplex Virus - 1)

Test Laboratory

BluTest Laboratories Ltd
Robertson Incubator (Level 4)
Robertson Building
56 Dumbarton Road
Glasgow, G11 6NU

Identification of sample

Name of the product	**RBT247 Protectus Ultimate**
Batch number	N/A
Client	**Residual Barrier Technology Ltd,** Broad March, Daventry, NN11 4HE
Project Code	BT-RBT-01
Date of Delivery	9 November 2012
Storage	Room temperature
Active substances	N/A

Test Method and its validation

Method	1 part interfering substance + 1 part virus suspension + 8 parts biocide were mixed and incubated at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, interference control, neutralization control and a formaldehyde internal standard.
Neutralization	Dilution-neutralization/gel filtration; Dulbecco's modified Eagles medium + 5% v/v foetal bovine serum at 4°C

Experimental Conditions

Period of analysis	12 to 20 December 2012
Product diluent used	Sterile, synthetic hard water
Product test concentrations	1:30 v/v; 1:50 v/v; 1:100 v/v
Contact times (minutes)	15 ± 10s
Test temperature	20°C ± 1°C
Interfering substance	0.3g/l bovine serum albumin + 0.3%V/V sheep erythrocytes
Stability of mixture	Cloudy after inoculation at all concentrations
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification of virus	Herpes Simplex Virus 1 (ATCC VR-733)/ VERO cells (ATCC CCL-81)

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PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with three concentrations of disinfectant at a 5 minute contact time. Virus, one part, is mixed with interfering substance, one part, and 8 parts of test product. Test product is tested at 80.0% V/V. Virus is exposed to disinfectant in 24-well plates, then neutralized, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious $dose_{50}$ ($TCID_{50}$) of surviving virus. $TCID_{50}$ is determined by the method of Karber[1].

Cytotoxicity control

The neutralized disinfectant is measured for its effects on the host cells used to propagate the virus, to determine the sensitivity of the assay.

Interference control

The end point titration of the virus is exposed to three different sub-lethal concentrations of neutralized disinfectant to measure the effect of sub-lethal concentrations of disinfectant on virus infectivity in relation to the titre achieved on untreated cells.

Disinfectant suppression control

Virus is added to the highest concentration of disinfectant and then the mixture immediately removed and neutralized. The neutralized virus titre is then determined to assess the efficiency of the neutralization procedure.

Virus recovery control

Virus titre is determined for virus in contact with sterile hard water at t=0 and at t = 60 (or the longest contact time). The virus titre after 60 minutes (or the longest contact time) is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre.

Reference virus inactivation control

Virus is in contact with 0.7% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 5, 15, 30 and 60 minutes, in order to assess that the test virus has retained reproducible biocide resistance. In addition, the formaldehyde cytotoxicity of neutralized formaldehyde is determined, to measure assay sensitivity.

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Suspension test results for RBT247 from Residual Barrier Technology Ltd against Herpes Simplex Virus-1 under DIRTY conditions

Exposure Time	Virus Recovery 0 min		Virus Recovery 15 min		Cytotoxicity		Disinfectant Suppression		1:100 (v/v)		1:50 (v/v)		1:30 (v/v)	
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
	4.17	**4.68E+05**	4.50	**1.00E+06**	0.50	**1.00E+02**	0.00	**3.16E+01**						
		4.68E+05		**1.00E+06**		**1.00E+02**		**3.16E+01**						
log		**5.67**		**6.00**		**2.00**		**1.50**						
log difference								**4.50**						

	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml		raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
t = 15						0.00	**3.16E+01**	0.00	**3.16E+01**	0.00	**3.16E+01**
							3.16E+01		**3.16E+01**		**3.16E+01**
log							**1.50**		**1.50**		**1.50**
log difference							**4.50**		**4.50**		**4.50**

Table of results of virucidal activity for RBT247 from Residual Barrier Technology Ltd against Herpes Simplex Virus-1 under DIRTY conditions

Product: RBT247	Interfering substance	Concentration	Level of cytotoxicity	lg TCID50					>4 lg reduction after .. Min
				0 min	5 min	15 min	30min	60 min	
	3.0g/l BSA + 3.0% erythrocytes	1:100 (v/v)	2.00	5.67	n.a.	1.50	n.a.	n.a.	15
		1:50 (v/v)	2.00	5.67	n.a.	1.50	n.a.	n.a.	15
		1:30 (v/v)	2.00	5.67	n.a.	1.50	n.a.	n.a.	15
	3.0g/l BSA	1:100 (v/v)	2.00	6.50	n.a.	1.50	n.a.	n.a.	15
		1:50 (v/v)	2.00	6.50	n.a.	1.50	n.a.	n.a.	15
		1:30 (v/v)	2.00	6.50	n.a.	2.50	n.a.	n.a.	>15[1]
Formaldehyde		0.7% (w/v)	3.50	5.67	5.33	3.50	3.50	3.50	>60
Virus Control		n.a.	n.a.	5.67	n.a.	n.a.	n.a.	6.00	n.a.

Parallel control test

Exposure Time	Virus Recovery 0 min		Virus Recovery 15 min		1:100 (v/v)		1:50 (v/v)		1:30 (v/v)	
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
	5.00	**3.16E+06**	4.50	**1.00E+06**						
		3.16E+06		**1.00E+06**						
log		**6.50**		**6.00**						
log difference										

	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
t = 15	5.00	**3.16E+06**	4.50	**1.00E+06**	0.00	**3.16E+01**	0.00	**3.16E+01**	1.00	**3.16E+02**
		3.16E+06		**1.00E+06**		**3.16E+01**		**3.16E+01**		**3.16E+02**
log		**6.50**		**6.00**		**1.50**		**1.50**		**2.50**
log difference						**4.50**		**4.50**		**3.50**

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Stock Virus ($TCID_{50}$)	6.00	3.16E+07

Formaldehyde reference inactivation control

Exposure time	Virus recovery 0 min		Virus recovery 60 min		Cytotoxicity		0.7% Formaldehyde							
							5		15		30		60	
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
60 min	4.17	4.68E+05	4.50	1.00E+06	2.00	3.16E+03	3.83	2.14E+05	2.00	3.16E+03	2.00	3.16E+03	2.00	3.16E+03
		4.68E+05		1.00E+06		3.16E+03		2.14E+05		3.16E+03		3.16E+03		3.16E+03
log		5.67		6.00		3.50		5.33		3.50		3.50		3.50
log difference								0.67		2.50		2.50		2.50

No Column Control

Virus Recovery t min (PC Control)	
raw data	$TCID_{50}$/ml
4.67	1.48E+06
	1.48E+06
	6.17

Interference control

Virus dilution	Cytoxicity dilution			
	-1	-2	-3	Mock
-5	3	3	3	3
-6	3	3	3	3
-7	3	1	0	1

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Verification of the methodology

A test is only valid if the following criteria are fulfilled:

a) Test virus suspension has $TCID_{50}$ 10^6/ml, or possesses at least a concentration which allows the determination of a 4 log_{10} reduction of the virus titre;
b) Detectable titre reduction is at least 4 log_{10}.
c) Difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test is between – 2 and – 4.5 after 60 min.
d) Cytotoxicity of the product solution does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4 log_{10} reduction of the virus comparative virus titration on cells treated with test mixture dilutions result in a difference of < 1 log_{10} of virus titre; dilutions of disinfectant to sub-acute levels did not interfere in the generation of viral cytopathic effect (interference control)
e) Neutralisation validation. This is called the disinfectant suppression test in this protocol. In this case the rapidity of action of the disinfectant against the virus precludes the use of this control.
f) The interference control; dilutions of disinfectant to sub-acute levels did not interfere in the generation of viral cytopathic effect in comparison to untreated virus-infected cells.

Conclusion

According to a modified EN 14476 protocol, **RBT247 from Residual Barrier Technology Ltd** at a dilution of 1/100, 1/50 and 1/30 possesses virucidal activity (> 4.0 Log_{10} reduction) in 15 minutes at 20°C under **DIRTY** conditions (0.3 g/l bovine serum albumin + 0.3% V/V sheep erythrocytes), for Human Herpes virus-1 (Herpes Simplex Virus-1) F1 strain ATCC VR-733 (Vero cells).

Signed

Dr Chris Woodall
Director, BluTest Laboratories Ltd
Glasgow, UK
7 January 2013