SAFETY DATA SHEET

Probe America, Inc.

IMPORTANT NOTICE

The information contained in this Safety Data Sheet is to be used in conjunction with the additional information, precautions and instructions for use. It is the responsibility of the employer to ensure that all persons who use or handle this product should have access to, and be aware of, the information contained herein.

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

1.1 **Product Identifier**

Airopure (Berry); Airopure

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

Consumer Use (C); Cleaning Products (PC35)

Technical Functions: BIOCIDE; CLEANING AGENT; DEODORIZER

1.3 **Details of the Supplier of the Safety Data Sheet**

Probe America, Inc. One White Oak Trace Beckley, WV 25801

Telephone:

(304) 253-0777

Fax:

(304) 253-0719

Email:

sales@probeamerica.com

Web address:

www.probeamerica.com

SECTION 2 Hazards Identification

2.1 Classification of the substance or mixture

Airopure (as a mixture) does not meet the criteria for classification in any hazard class according to Regulation (EC) 1272/2008 (CLP). However, this SDS has been prepared as the formulation contains substances that could, if pure, require classification.

2.2 **Label Elements**

Labelling according to Regulation (EC) 1272/2008 (CLP):

Hazard Pictogram:

Not Applicable

Signal Word:

Not Applicable

Hazard Statements:

Not Applicable

Precautionary Statements: Not Applicable

2.3 Other Hazards

No substance contained within the Airopure formulation meets the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3 Composition/Information on Ingredients

3.2 **Mixtures**

The formulation of Airopure contains no substances classified as hazardous, at concentrations >1% w/w; in accordance with Regulation (EC) 1272/2008 (CLP), no further detail is required in this Section.

SECTION 4 First Aid Measures

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4.1 Description of First Aid Measures

INHALATION: In case of adverse reaction, remove casualty from area of

exposure. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If concerned or the victim continues to feel unwell, seek medical attention.

SKIN CONTACT: In

In case of adverse (allergic) reaction, drench the affected area with running water for 10 minutes, or longer if necessary. If concerned, symptoms persist or the victim feels unwell, seek

medical attention.

EYE CONTACT: Rinse cautiously with running water for 15 minutes. Remove

contact lenses if present and easy to do so. If concerned, symptoms persist or the victim feels unwell, seek medical

attention.

INGESTION: Give 1 pint of water to drink immediately and consult a doctor if

deemed necessary. Do not induce vomiting. If concerned or the

victim feels unwell, seek medical attention.

First Aider: Recommendations for Personal Protective Equipment

No significant hazard/risk has been identified in respect of the provision of first aid to victim. However, protective gloves are recommended to eliminate/reduce the potential exposure to the first aider.

4.2 Most Important Symptoms and Effects, both acute and delayed None Identified.

4.3 Indication of any Immediate Attention and Special Treatment Needed

Not applicable, however treatment should be based on relieving the symptoms.

SECTION 5 Fire Fighting Measures

5.1 Extinguishing Media

SUITABLE:

Water, Carbon Dioxide, Polymer Foam, Dry Chemical Powder.

UNSUITABLE:

Wet Chemical.

5.2 Special Hazards arising from the Substance of Mixture Hazards

May release oxygen on heating.

5.3 Advice for Fire Fighters

Wear standard firefighting protective clothing. No need for the use of specialist equipment is likely.

SECTION 6 Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Airopure does not represent a hazard in accordance with Regulation (EC) 1272/2008 (CLP).

For Non-Emergency Personnel:

In the event of accidental spills or release:

Follow company spillage instructions;

Prevent Airopure from entering drains;

The use of protective gloves is recommended when cleaning up accidental spills; Additional personal protection to prevent contact with eyes and/or contamination of clothing should be considered, commensurate to the size and nature of the spill.

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For Emergency Personnel:

See general provisions for Non-Emergency Personnel (above).

6.2 Environmental Precautions

Avoid spilled Airopure from entering storm drains or surface waterways.

6.3 Methods and Material for Containment and Cleaning Up

For Containment:

For larger spills, surround the extent of the spill with an inert absorbent material (e.g. sand).

For Cleaning Up:

For small spills, or larger spills that have been contained, take up with inert absorbent material;

Do not return spilled Airopure to the original container;

Water is recommended for removal of remaining trace amounts of product Airopure.

6.4 References to Other Sections

In the event of fire, see provisions within Section 5.

In the event of spillages, treat recovered material as per the provisions in Section 13.

SECTION 7 Handling and Storage

7.1 Precautions for Safe Handling

Advice on General Occupational Hygiene:

Avoid excessive direct inhalation;

Minimize direct contact with skin;

Wash hands (and other exposed areas of skin) thoroughly after use;

Avoid direct contact with eyes;

Do not ingest.

7.2 Conditions for Safe Storage, including any Incompatibilities

Technical Measures and Storage Conditions:

Store in a cool well ventilated area;

Keep containers tightly closed.

Packaging Materials:

Must only be kept in original packaging.

7.3 Specific End Use(s)

Consumer Use (C); Cleaning Products (PC35)

Technical Functions: BIOCIDE; CLEANING AGENT; DEODORIZER

Airopure is a proprietary blend of odor destructive reagents that can also be used as a multi-surface cleaner. The mixture is not intended for further formulation/re-packaging or to be incorporated into an article.

SECTION 8 Exposure Controls / Personal Protection

8.1 Control Parameters

No specific control parameters have been defined for Airopure.

8.2 Exposure Controls

Engineering Controls:

Refer to instructions for use.

Handle and store with care to avoid spillage.

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Personal Protection:

Not a hazard in normal use; no specific personal protective equipment required. Environmental Precautions:

Avoid spilled material from entering storm drains or surface waterways.

SECTION 9 Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Appearance: Liquid; Clear pale aqua.

Odor/Threshold: None. pH: 3 - 6

Melting point/Freezing Point:

Initial Boiling Point/Boiling Point Range:

Flash Point:

Evaporation Rate:

Not available.

Not Available.

Not Available.

Flammability (solid, gas):

Upper/Lower Flammability or explosive limits:

Vapor Pressure:

Vapor Density:

Relative Density:

N/A

N/A

1.015

Solubility(ies): Not Available.

Partition Coefficient, n-octanol/water: Not Available.

Auto-ignition Temperature: N/A

Decomposition Temperature: Not Available. Viscosity: Not Available.

Explosive Properties: N/A
Oxidizing Properties: N/A

9.2 Other Information

Miscibility: Miscible in all proportions.

SECTION 10 Stability and Reactivity

10.1 Reactivity

Not Available.

10.2 Chemical Stability

Under storage at normal conditions (e.g. ambient/room temperature), Airopure is stable.

10.3 Possibility of Hazardous Reactions

No hazardous reactions are expected if Airopure is used in accordance with the instructions for use.

10.4 Conditions to Avoid

Extremes of temperature and light.

10.5 Incompatible Materials

No know incompatible materials however, as per Section 7, Airopure is not intended for further formulation/re-packaging or to be incorporated into an article.

Do not mix with any other chemical product.

10.6 Hazardous decomposition products:

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Does not decompose is handled, stored and used in accordance with instructions for use.

May release oxygen on heating.

SECTION 11 Toxicological Information

11.1 Information on Toxicological Effects

Airopure (as a mixture) does not meet the criteria for classification in any hazard class according to Regulation (EC) 1272/2008 (CLP). However, this SDS has been prepared as the formulation contains substances that could, if pure, require classification.

Acute Toxicity:

Airopure is not expected to be toxic via dermal, oral or inhalation (dust/mists) exposures due to the

concentrations of the substances within the

formulation.

Skin Corrosion/Irritation:

Airopure is not expected to result in skin corrosion/irritation exposures due to the concentrations of the substances within the

formulation.

Serious Eye Damage/Irritation:

Airopure is not expected to result in serious eye

damage/irritation exposures due to the concentrations of the substances within the

formulation.

Respiratory/Skin Sensitization:

Airopure is not expected to result in respiratory/skin

sensitization exposures due to the concentrations of

the substances within the formulation.

Germ Cell Mutagenicity:

Airopure is not germ cell mutagenic.

Carcinogenicity:

Airopure is not carcinogenic.

Reproductive Toxicity:

Airopure is not expected to result in reprotoxic

exposures.

STOT-Single Exposure:

Airopure is not expected to result in respiratory irritation (or any other specific organ toxicity) exposures due to the concentrations of the

substances within the formulation.

STOT-Repeated Exposure:

Airopure is not expected to result in specific organ toxicity due to repeated exposures due to the concentrations of the substances within the

formulation.

Aspiration Hazard:

Airopure is not expected to result in aspiration hazard exposures due to the concentrations of the

substances within the formulation.

SECTION 12 Ecological Information

12.1 Toxicity

This product is not expected to cause any significant adverse effects on the environment.

12.2 Persistence and Degradability

Airopure is readily biodegradable.

12.3 Bioaccumulative Potential

Airopure is not expected to bioaccumulate.

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12.4 Mobility in Soil

Airopure is fully miscible with water in all proportions therefore could be highly mobile in the presence of groundwater subject to the specific nature of the soil.

12.5 Results of PBT and vPvB Assessment

No substance contained within the Airopure formulation meets the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other Adverse Effects

No further adverse effects have been identified.

SECTION 13 Disposal Considerations

13.1 Waste Treatment Methods

Product Disposal:

The following waste codes may be relevant to disposal requirements:

20 01 29* / 20 01 30

Airopure

15 02 02* / 15 02 03

Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by hazardous substances / Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02

Hazardous wastes (*) should be stored in suitable secure containers prior to collection by a suitably licensed contractor for disposal at an appropriate facility. Hazardous wastes should never be disposed of in drains, surface water or on land.

Non-hazardous wastes may be disposed of in drains/sewers, subject to prevailing legislation and the holding of any relevant consent/permit.

Packaging Disposal:

Return packaging to the supplier wherever possible for recycling;

Dispose of as normal industrial waste.

Please ensure that you are aware of the possible existence of local, regional or national regulations regarding the disposal of wastes.

SECTION 14 Transport Information

14.1 UN Number

Not available/required.

14.2 UN Proper Shipping Name

Not available/required.

14.3 Transport Hazard Class(es)

Not available/required.

14.4 Packing Group

Not available/required.

14.5 Environmental Hazards

No substance contained within the Airopure formulation meets the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII. This product is not expected to cause any significant adverse effects on the environment.

14.6 Special Precautions for User

Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL and the IBC Code

Airopure is not expected to be transported in bulk.

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SECTION 15 Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation specific for the Substance or Mixture

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products;

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures.

The regulatory information given above only indicates the principal EU regulations specifically applicable to the product described in this Safety Data Sheet.

The user's attention is drawn to the possible existence of additional, related, provisions (such as national legislation that brings the above EU regulations into force in any particular Member State). Please refer to all applicable local, regional, national and international regulations or provisions.

15.2 Chemical Safety Assessment

No CSA has been carried out for the Airopure formulation by the Supplier of the Safety Data Sheet.

SECTION 16 Other Information

General

The application of Airopure may lead to floor wetness. Depending on the nature of the floor, and the quantity of application, such wet areas may be slippery and should be suitably marked as slip-hazard areas where appropriate.

Sources of Information

The potential hazards associated with the Airopure formulation and the substances therein have been taken from the Harmonized Classifications held by, and notifications made to, the European Chemicals Agency (ECHA)¹.

Procedure for Classification for Mixtures according to Regulation (EC) 1272/2008 (CLP)

The classification of Airopure according to Regulation (EC) 1272/2008 (CLP) has been undertaken using the calculation methods defined in Annex I for all hazards considered by the Regulation.

Legal Disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall only be used as a guide. Probe America, Inc. shall not be held liable for any damage resulting from handling of or from contact with the above product.

http://echa.europa.eu/information-on-chemicals/registered-substances http://echa.europa.eu/information-on-chemicals/cl-inventory-database - accessed June 2016



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Probe House Foxhunters Industrial Estate Whitley Bay Tyne and Wear NE25 8UG UK

Tel: 0191-251-1888

Contact: Victoria Browning: victoria@probeindustries.co.uk

5 July 2010

Report Number 10PRO01

Approval

Signature:	Signature: Abode
Name: Bushra Sim	Name: Dr Carol Barker
Date: 5 July 2010	Date: 5 July 2010
Principal Study Scientist (XCellR8 Ltd)	Study Director (XCellR8 Ltd)



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Dear Victoria

Report Number 10PRO01

I am pleased to provide our report for the study carried out as per your purchase order numbers 1923 and 1947.

Study Title

Human Skin Irritation Testing (Hazard Identification) of AiroPure Using the In Vitro Human Skin Model EpiDerm™

Executive Summary

Two test formulations were applied to the *in vitro* human skin model EpiDermTM using the "*In Vitro* Skin Irritation Protocol: Hazard Identification Method" (MK-24-007-0023) published by MatTek Corporation. The test formulations were:

AiroPure : neat formulationAiroPure: 50% dilution in water

Positive and negative controls were Sodium Dodecyl Sulphate (SDS) (5% w/v) and Phosphate Buffered Saline (PBS) respectively.

Each application was performed in triplicate.

Good reproducibility was observed throughout the study: coefficients of variation for each set of triplicate test samples ranged between 5.9% and 15.4%.

All positive and negative controls yielded results in line with historical and reference data.

The study data was processed in accordance with the protocol, whereby relative cell viability is calculated for each tissue as a percent of the mean of the negative control tissues. Skin irritation potential of the test material is predicted if the remaining relative cell viability is below 50%.

In this study, AiroPure was classified as a Non-Irritant, both as a neat formulation and as a 50% dilution in water.

The results of this study using the *in vitro* human skin model EpiDerm[™] should be considered together with other sources of data regarding the skin irritation potential of this formulation.

I hope that this study has provided valuable information for you. If you have any questions or would like to discuss any follow-up work, please do not hesitate to contact me.

Yours faithfully, Dr Carol Barker Managing Director, XCellR8 Ltd

Confidential



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Method

Skin Irritation Protocol: Hazard Identification Method (MK-24-007-0023).

For use with the EpiDerm[™] Tissue Model (EPI-200-SIT) from MatTek Corporation, Ashland, MA, USA.

This protocol utilises the MTT tissue viability assay. Relative cell viability is calculated for each tissue as a percent of the mean of the negative control tissues. Skin irritation potential of the test materials is predicted if the remaining relative cell viability is below 50%. MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) is a tetrazole compound that is reduced to a purple formazan product by mitochondrial reductase enzymes in living cells.

For full details, see the published protocol, available on reguest from XCellR8.

In summary:

- 1. EpiDerm[™] models received from MatTek Corporation, Ashland, MA, USA, were prepared and placed into a humidified 37°C / 5% CO₂ incubator for 1 hour. At the end of 1 hour, the inserts were transferred to wells containing fresh medium and further incubated overnight prior to dosing.
- 2. The test article was received from Probe Industries, Whitley Bay, UK, and used neat and diluted to 1:2 in ultrapure water prior to dosing. Samples were designated codes for the study as follows:

Test Article Description	Test Article Code for this Study					
AiroPure: neat formulation	TS Neat					
AiroPure: 50% dilution in water	TS 1:2					

- 3. Following the overnight pre-incubation period, the EpiDermTM models were transferred to fresh wells containing pre-warmed assay medium and dosed with 30μl of neat or diluted test sample, 30μl positive control (sodium dodecyl sulphate, SDS, 5% w/v) or 30μl negative control (phosphate buffered saline, PBS). All samples were tested in triplicate.
- 4. EpiDerm[™] models were then placed into a humidified 37°C / 5% CO₂ incubator. Samples were incubated for 35 minutes. At the end of the incubation period, EpiDerm[™] models were removed from the incubator and placed into a sterile cabinet until the designated period of 1 hour was completed.
- 5. After the 1 hour incubation period, the EpiDerm[™] models were washed with PBS, blotted dry on sterile gauze and each tissue surface carefully dried using sterile cotton tipped swab.
- 6. EpiDerm[™] models were then transferred to fresh wells containing assay medium and placed into a humidified 37°C / 5% CO₂ incubator for a further 24 hour period.
- 7. At the end of the 24 hour period, EpiDerm[™] models were transferred to fresh wells containing assay medium and placed into a humidified 37°C / 5% CO₂ incubator for an additional 18 hour post-incubation period.
- 8. At the end of the incubation period, EpiDerm[™] models were transferred to fresh wells containing 300µl of MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) and then placed into a humidified 37°C / 5% CO₂ incubator for 3 hours.



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- 9. After the 3 hour incubation period, the EpiDerm[™] models were washed with PBS and incubated in 2ml extractant solution in the dark for a period of 2 hours at room temperature. Plates were sealed to minimise evaporation.
- 10. Optical density was measured by removing 200µl of each sample to a 96-well plate and reading at a wavelength of 570nm. 200µl extractant was used as a blank.
- 11. To verify that the test articles did not directly reduce MTT, 30µl of test article was added to 1ml of the MTT medium. The mixtures were incubated in a 37°C / 5% CO₂ incubator for 60 minutes. Untreated MTT medium was tested concurrently as a control. The absence of any darkening to a blue / purple colour indicated that the test articles did not directly reduce MTT.
- 12. Optical density values were exported into Microsoft Excel for data processing. Means and standard deviations for triplicate samples were calculated and the percentage viability values at each time point determined by comparison to the negative control (set at 100%).

Results

This report presents the study results in final format. Raw data is securely held on file at XCellR8 and is available upon request.

Summary of Skin Irritancy Classifications

Test Article Code	Test Article Description	Percentage Viability (mean of triplicate samples)	Standard Deviation	CV%	Skin Irritancy Classification			
TS Neat	AiroPure:	97.50%	10.29	10.56%	Non-Irritant			
	Neat Formulation							
TS 1:2	AiroPure: 50% Dilution in Water	106.85%	16.42	15.36%	Non-Irritant			
NC	Negative Control (Phosphate Buffered Saline)	100.00%	5.88	5.88%	Non-Irritant			
PC	Positive Control (5% w/v Sodium Dodecyl Sulphate)	7.78%	0.65	8.35%	Irritant			

A percentage viability value of more than 50% correlates with a "Non-Irritant" classification. A percentage viability value of less than 50% correlates with an "Irritant" classification.



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Conclusions

- The neat formulation of AiroPure was classified as a Non-Irritant when assessed for skin irritation (hazard identification) using the EpiDermTM human tissue model, according to the established protocol number MK-24-007-0023.
- The 50% dilution in water of AiroPure was also classified as a Non-Irritant when assessed for skin irritation potential using the EpiDerm[™] human tissue model, according to the established protocol number MK-24-007-0023.
- The results of this study using the *in vitro* Human Skin Model EpiDerm[™] should be considered together with other sources of data regarding the skin irritation potential of these formulations.

EpiDermTM has been widely used as a successful *in vitro* model for human skin irritation / hazard identification, and a large amount of published data using common ingredients and formulations is available, which may provide additional useful reference. Further information is available from XCellR8 upon request.

XCellR8 Terms and Conditions:

XCellR8 provides independent, impartial advice to customers and recommends what we believe to be the best solution for each project. We provide information to assist and guide key decisions but cannot be held responsible for problems arising from equipment, other items, services or procedures recommended by us. In its dealings with Business Customers, XCellR8 Ltd shall under no circumstances be liable for any consequential or indirect damage or loss, however caused, including (but not restricted to) loss of business or profits, loss of goodwill, damage to trading relationships loss of data and other financial loss. XCellR8's liability in respect of all other losses shall be limited to the invoiced amount of the relevant order.



Laboratory Report

Report No. 4039/0150/F2

Page 1

Prepared for:

Victoria browning Probe Industries Probe House Foxhunters Road Whitley Bay Tyne & Wear NE25 8UG

Sample(s) described as:

AIROPURE

Customer reference no:

Date received:

22/03/10

Date(s) tested:

23/03/10-08/06/10

Observation:

I certify that Probe Industries Ltd may make the following claims regarding their 'Airopure' product;

- 99% killing activity against bacteria following the results of EN 1276 protocol
- 99% killing activity against bacteria following the results of EN 1656 protocol (Veterinary area)
- 99% killing activity against mycobacteria following the results of EN 14204 protocol (Veterinary area)
- 99% killing activity against Herpes simplex virus (HSV) following the results of EN 14476 protocol
- 99% killing activity against Feline calicivirus Norovirus surrogate (FCV) following the results of EN 14476 protocol

Please refer to the following page for a summary of the results.

Certified by me on 2 nd July 2010

Samantha Duffy Consultant

The reported results relate exclusively to the tested sample(s) The analysis was subcontracted to a laboratory within Eurofins



For the attention of:

Victoria Browning Probe Industries Probe House Foxhunters Road Whitley Bay Tyne & Wear NE25 8UG

Commercial in Confidence

Submission ID 1318896

Intertek Analytical Sciences Group PO Box 42, Hexagon House, Blackley Manchester, M9 8ZS Tel: +44 (0) 161 721 2307

Fax: +44 (0) 161 721 1654

Author: Wendy Callaghan: Business Development Manager



Test carried out: Study to determine the reduction of known odour compounds by the interaction with the Airopure product. The known odours studied are; Hydrogen sulphide

Samples:

- Airopure

Description of analytical method

Equipment used: Gas chromatography / Mass spectrometry (Agilent GC 7890A /5975C MSD, GERSTEL MPS), Headspace injection.

Preparation of sample:

The samples were prepared at a concentration of equimolar proportions (10ppm for each compound) in water and/or DMSO. The different solutions were stored at 4°C. The resulting solutions were analysed after 1 hour.

Headspace parameter

Temperature incubation: 40°C

Incubation time: 1800 s

Instrument parameters:

Volume injection 750µl T°C injector : 320°C

Carrier Gas Helium 1 ml/min

Mode Splitless

Oven GC:

T°C initial 30°C (during 5min) to 60°C (rate 5°C/min), then 25°C/min until T°C final 300°C.

T°C Auxiliaire: 280°C

Column used: DB624 L 30m x 0.25mm id x 0.25µm df.

MS Conditions:

Ionisation method EI+ in SCAN and SIM mode. We operated for the qualitative analysis in SIM mode.

RESULTS

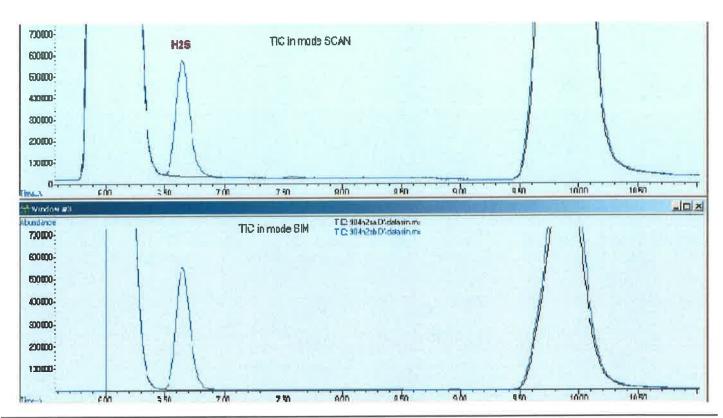
Hydrogen Sulphide (H2S)

Cf. chromatogram in annex A

The peak associated with the hydrogen sulphide does not appear to present in the sample containing the Airopure product, it can therefore be concluded that at this level the product has completely eliminated the hydrogen sulphide.



ANNEX A: chromatogram of -12S



Chromatogram in black = sample + solution of H2S (concentration equimolalia)

Chromatogram in Blue = solution of H2S at 19ppm



Intertek Capabilities

Intertek is a UK Public Limited Company, with head office registered at 25 Savile Row, London, W1X 1AA. (see www.intertek.com). With over 300 laboratories and 500 offices around the world, Intertek is one of the world's largest independent inspection and testing organisations. It was floated successfully on the London Stock Exchange in May 2002 at 400p per share and is trading today at around 1200p per share with a market capitalisation of £1,492M.

Intertek has build up a vast network of well equipped laboratories and can provide services ranging from the most advanced levels of GxP/R&D, problem solving and regulatory support to high volume/ routine QC assays and cargo inspection work. Intertek employs several thousand scientists of which at least 500 are graduates and over a 100 hold a PhD, of which 2 also act as visiting professor at well respected universities.

Intertek ASG is a specialist CRO providing a broad range of advanced analytical and characterisation services to home, personal care, pharmaceutical and biopharmaceutical clients. Services include method development, product performance, validation, and batch release analysis (e.g. for product and process related impurities), stability studies, extractables / leachables studies and regulatory characterization work (e.g. proof of structure, impurity characterization, detailed biopharmaceutical comparability studies, biopharmaceutical aggregation studies etc). Intertek ASG has experience across a diverse range of products including fully formulated homecare and personal care products to small molecule therapeutics, oligonucleotides, peptides, recombinant proteins, antibodies, vaccines and viral vectors. Intertek ASG is working with companies of all sizes – providing specialist expertise for companies and providing flexible capacity options for our clients. The laboratory has been inspected to GLP and GMP by the UK MHRA and to GMP by the US FDA.

Intertek Toxicology Assessment (ITA) was founded as an independent consultancy in 1992 and joined the Intertek Group in 2002.

ITA specializes in the safety assessment of industrial and household products and specializes particularly in cosmetics where the company has an established reputation as a leader in the field. A dedicated and experienced staff in Leicester is supplemented by expert consultants offering our customers the benefit of over 150 years combined experience in Product Safety, with backgrounds in toxicology, cancer research, product development, pathology, environmental management and quality assurance.

The work of ITA is governed by legislation that requires that, in the case of cosmetics the products are safe for purpose and for industrial and household chemicals, that they are correctly packaged and labelled. ITA's opinion is sought by government departments, Trading Standards, and industrial clients. As well as carrying out product assessments, ITA staff act as expert witnesses in litigation involving a range of cases including occupational health issues and personal injury and serve on industry committees as experts in developing standards for toys and cosmetics.

Intertek ASG

Within the EU, Household and Industrial Products are subject to the Dangerous Substance Directive (67/548/EEC as amended) and the Dangerous Preparations Directive (1999/45/EC as amended). Both directives require manufacturers to be able to supply a Material Safety Data Sheet (MSDS) as per the Data Sheet Directive (2001/58/EC). Regulation (EC) No 648/2004 further covers Detergents and sets out specifications for the labelling of such items along with the necessity to provide Ingredient Datasheets.

Preliminary Evaluation of Probe Industries AiroPure System for Antimicrobial Activity

Dilution in agar		1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	1/512	1/1024	1/2048	1/4096	Control	MIC
-	Reference														
1 Escherichia coli	NCTC 10418	-	8		2	-	-	-	=	-	+	+	+	+	1/512
2 Klebsiella pneumoniae	NCTC 9528		*	*	177	-5	100	300	3	*	+	+	+	+	1/512
3 Providencia rettgeri	NCTC 7475	\approx	*	96	\approx		38	200	*	20	-	+	+	+	1/1024
4 Enterobacter cloacae	NCTC 11936	-	*		3	9	34		*		+	+	+	+	1/512
5 Serratia marcescens	NCTC 10211	-	-		4					¥3	+	+	+	+	1/512
6 Salmonella typhimurium	NCTC 74	-	=	-	-		-	-	-	2	+	+	+	+	1/512
7 Pseudomonas aeruginosa	NCTC 10662		*	2.53	*	35		*		75	+	+	+	+	1/512
8 Staphylococci epidermidis	NCTC 11047	*	*	0.00	100	26	25			200	-	-	+/-	+	1/2048
9 Streptococcus pyogenes	NCTC 8306		32	1	9	-	-		€	*	-	(+)	-	+	≤ 1/4096
10 Enterococcus faecalis	NCTC 775	-	22	223	-	-	-		9	23	-	-	+/-	+	1/2048
11 Enterococcus faecium	NCTC 7171		70	272	-						+/-	+/-	+	+	1/512
12 Listeria monocytogenes	NCTC 11994	*	*	100			2	282		*	-	+/-	+	+	1/1024
13 Staphylococcus aureus	NCTC 6571	~	*		=	34	100	200	=	*	-	-	+	+	1/2048
14 Yersinia enterocolitica	NCTC 11176	-	23	0.00	-	-	-		22	**	+/-	+/-	+	+	1/512
15 Staphylococcus aureus (MRSA)	NCTC 11939	-	-	-	9	2	12	12	3	12	-	-	+/-	+	1/2048
16 Burkholderia cepacia	LMG 1222	-	2.			-	25	300	9		+/-	+	+	+	1/512
17 Bacillus subtilis	NCTC 9372	=	-		-	-	58		-	**	-	-	+	+	1/2048
18 Acinetobacter baumannii	ATCC 19606	\simeq	-	300	3	-	100		\approx	-	-	+	+	+	1/1024
19 Candida glabrata	NCPF 9725	-	20		2	1	1			+/-	+/-	+/-	+/-	+	1/256
20 Candida albicans	ATCC 90028	-	4	-		7	-	~	ੁ	+/-	+/-	+	+	+	1/256
		Annotation:		5	No growth +		+/-	+/- Weak growth		+	+ Unrestricted growth		th		
(%)															
MIC Studles with Legionella spp)														
21 Legionella bozemanii	NCTC 11368		23	540		-	-	96	×	*	(a)	+	+	+	1/1024
22 Legionella pneumophila	NCTC 11406	-	2	2	2	2	-		2	13	+/-	+	+	+	1/512
23 Legionella micdadei	NCTC 11371	-	-		-	-		-	÷	£	+/-	+	+	+	1/512
24 Legionella pneumophila	NCTC 12821	~	-		-	-	-	0.00	*	-	151	+	+	+	1/1024
24 Legionolia pricamophila	11010 12021														
MIC Studies with Anaerobic bac	teria.														
25 Bacteroides fragilis	NCTC 8560		_					100	+/-	+/-	+	+	+	+	1/128
26 Peptostreptococcus anaerobius	NCTC 11460		2		8		-		-	-		+	+	+	1/1024
27 Clostridium perfringens	NCTC 10240	0	2	525	-		10		=	2: 2:	+/-	+	+	+	1/512
28 Clostridium difficile	NCTC 10240 NCTC 11204		2	528	2	-	-		÷	25	+/-	+	+	+	1/512
	1401011204														

Method summary

ndicated,
nd suspension).
7

Comments

MIC = Minimum Concentration of Product required to inhibit microbial growth.

As the concentration of active ingredients is unknown, this is expressed as a dilution factor of 'neat' product.

- 1 to 18: The growth of all 18 test bacteria was inhibited at a dilution of 1/512 in Isosensitest agar.
- 19 & 20: Two species of yeasts were inhibited by a dilution of 1/256. Gram positive bacteria were generally more susceptible than Gram negative bacteria.
- 21 to 24: Show the completed studies with Legionella species. Legionella was inhibited at a dilution of 1/512. Airopure is highly active against Legionella

"Sestem"

25 to 28: The first three species are representative of the commonest anaerobic species found in the gut and in faeces. C. difficile is perhaps the commonest anaerobic species implicated in human disease.

Tests performed in FAA medium plus 5% horse serum (blood excluded due to catalase activity).

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