

Expertise Report

For the

ULTRASTREAM



Ion Life Pty Ltd t/a Alkaway

Certification Experts B.V.

Weesp

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Expertise report

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Subject UltraStream

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Annex 2

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SUMMARY

The Technical and Legal certification company Certification Experts B.V. has been commissioned by Ion Life Pty Ltd t/a Alkaway. to carry out applicable test to the UltraStream, to determine if this product is compliance with the essential requirements out of the Drinking Water Directive (DWD) 98/83/EC, the Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs, the General Product Safety Directive (GPSD) 2001/95/EC and other applicable European legislation and standards.

The sample is, in accordance to article 1 subsection 2 of the regulation (EC) 1935/2004 a commodity because it is intended and foreseen to come into contact with foodstuff.

There have been two tests performed on the water of the UltraStream. The first test was performed on the extract taken immediately after commissioning of the appliance. The second test was performed on the extract that was taken after 5 minutes flushing of the appliance.

Both of the extracts meet the limit values for the migration of metals according to the Drinking Water Directive (DWD) 98/83/EC and current World Health Organization recommendations.

Results given in this report refer only to the samples and documentation submitted for analysis and tested by Certification Experts B.V. Comments are for guidance only. Certification Experts B.V. cannot be held responsible if the production is not of the same quality or composition as the delivered samples or the delivered information is incorrect.

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1 Introduction

1.1 Description of the Investigation

The technical and legal certification company Certification Experts B.V. has been commissioned by Ion Life Pty Ltd t/a Alkaway to carry out a safety evaluation on the UltraStream to see if the UltraStream is in compliance with the essential requirements out of the applicable European Legislation. The investigation was based on practical testing. Test samples the UltraStream have been provided by Ion Life Pty Ltd t/a Alkaway and have been received in good order by Certification Experts B.V.

The safety evaluation has occurred in compliance with the essential requirements of Drinking Water Directive (DWD) 98/83/EC, the Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs, the General Product Safety Directive (GPSD) 2001/95/EC and other applicable European legislation and standards.

The investigation only relates to the samples and information that were provided by Ion Life Pty Ltd t/a Alkaway and was received by Certification Experts B.V. Certification Experts B.V. therefore cannot be held responsible nor guarantee that the production will be of the same quality as the received samples.

Name of the product

- UltraStream

1.2 Scope of work

The product investigation has been applied to the following item:

UltraStream

Manufacturer	Ion Life Pty Ltd t/a Alkaway
Type	UltraStream

The tests have been carried out on the UltraStream under the following test conditions:

1. Demineralised water, extract was taken immediately after commissioning of the appliance.
2. Demineralised water, extract was taken after 5 minutes flushing of the appliance.

1.3 Application of legislation

Summary of the Drinking Water Directive (DWD) 98/83/EC

The objective of the Drinking Water Directive is to protect the health of the consumers in the European Union and to make sure the water is wholesome and clean.

To make sure drinking water everywhere in the EU is healthy, clean and tasty, the Drinking Water Directive sets standards for the most common substances that can be found in drinking water. In the DWD a total of 48 microbiological and chemical parameters must be monitored and tested regularly.

Summary of the Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs

The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

- a) are intended to be brought into contact with food
- b) are already in contact with food and were intended for that purpose
- c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use

Summary of the General Product Safety Directive (GPSD) 2001/95/EC

The purpose of this Directive is to ensure that products placed on the market are safe.

Where products are subject to specific safety requirements imposed by Community legislation, this Directive shall apply only to the aspects and risks or categories of risks not covered by those requirements.

The GPSD is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. toys, chemicals, cosmetics, machinery). The Directive also complements the provisions of sector legislation which do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks.

The Directive provides a generic definition of a safe product. Products must comply with this definition. If there are no specific national rules, the safety of a product is assessed in accordance with:

- a) European standards,
- b) Community technical specifications,
- c) codes of good practice,
- d) the state of the art and the expectations of consumers.

2. Requirements

2.1 General requirements

In Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs the general and specific requirements for the UltraStream are set out.

Ion Life Pty Ltd t/a Alkaway must ensure that the water of the UltraStream is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health. Ion Life Pty Ltd t/a Alkaway must include a documentation which states that the UltraStream does not contain any of these substances.

Ion Life Pty Ltd t/a Alkaway must make sure that the materials and articles of the UltraStream shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, the UltraStream will not endanger the human health.

Further the labelling, advertising and presentation of the UltraStream shall not mislead the consumers.

The quality standards for drinking water have been set out in the Drinking Water Directive. In Annex II of this report you will find these quality standards. These requirements include certain maximum migration values which are determined as essential for the safety and quality of the water and product. These maximum values are shown in Annex II of this report.

Certification Experts B.V. has tested all relevant migration values for the UltraStream. The results of these tests can be found in Chapter III of this report and must be included into the file of Ion Life Pty Ltd t/a Alkaway in order to ensure compliance with related European regulation.

Ion Life Pty Ltd t/a Alkaway shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out, in order to check that the water available to consumers meets the requirements of the Drinking Water Directive 98/83/EG and in particular the parametric values set in accordance with Annex II of this Report. Samples should be taken so that they are representative of the quality of the water consumed throughout the year. In addition, Ion Life Pty Ltd t/a Alkaway shall take all measures necessary to ensure that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified, and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection.

2.2 *Specific requirements*

Ion Life Pty Ltd t/a Alkaway must compile specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents.

These specific limits are set out in the Drinking Water Directive 98/83/EG in Annex I. The relevant migration limits of the UltraStream have been tested. These results are set out in Chapter 4 of this report.

3. Testing and evaluation

3.1 Testing results

Testing results

Test conditions:

Demineralised water, extract was taken immediately after commissioning of the appliance.

Re-test performance

Sample	UltraStream Waterfilter		
Sample Designation	Extract (demineralized water)		
Method	EN ISO 17394-2 (ICP-MS)		
Parameter	Unit	Extract	LQ
Aluminium (Al)	mg/L	0.001	0.001
Arsene (As)	mg/L	0.001	0.001
Barium (Ba)	mg/L	< LQ	0.001
Cadmium (Cd)	mg/L	< LQ	0.001
Chromium (Cr)	mg/L	0.001	0.001
Cobalt (Co)	mg/L	< LQ	0.001
Copper (Cu)	mg/L	< LQ	0.001
Iron (Fe)	mg/L	< LQ	0.001
Lead (Pb)	mg/L	< LQ	0.001
Lithium (Li)	mg/L	< LQ	0.001
Manganese (Mn)	mg/L	0.001	0.001
Nickel (Ni)	mg/L	< LQ	0.001

Silver (Ag)	mg/L	< LQ	0.001
Tin (Sn)	mg/L	< LQ	0.001
Zinc (Zn)	mg/L	< LQ	0.001

Test Conditions:
Demineralised water, extract was taken after 5 minutes flushing of the appliance.

Sample	UltraStream Waterfilter		
Sample Designation	Extract (demineralized water)		
Method	EN ISO 17394-2 (ICP-MS)		
Parameter	Unit	Extract	LQ
Aluminium (Al)	mg/L	0.001	0.001
Arsene (As)	mg/L	<LQ	0.001
Barium (Ba)	mg/L	<LQ	0.001
Cadmium (Cd)	mg/L	<LQ	0.001
Chromium (Cr)	mg/L	<LQ	0.001
Cobalt (Co)	mg/L	<LQ	0.001
Copper (Cu)	mg/L	<LQ	0.001
Iron (Fe)	mg/L	<LQ	0.001
Lead (Pb)	mg/L	<LQ	0.001
Lithium (Li)	mg/L	<LQ	0.001
Manganese (Mn)	mg/L	<LQ	0.001
Nickel (Ni)	mg/L	<LQ	0.001
Silver (Ag)	mg/L	<LQ	0.001

Tin (Sn)	mg/L	<LQ	0.001
Zinc (Zn)	mg/L	<LQ	0.001

Definitions:

- **LQ:** **Limit of quantification**
- **<LQ:** **Measurement result below Limit of Quantification**

Results:

Both extracts meet the limit values for the migration of metals according to the Drinking Water Directive 98/83/EC and current WHO recommendations.

The test results refer exclusively to the samples provided to Certification Experts B.V. by Ion Life Pty Ltd t/a Alkaway.

Conclusion:

The tested sample is determined to comply with the value limits and requirements out of the Drinking Water Directive 98/83/EC and Regulation 1935/2004/EC in accordance with the applicable European Standards in specific the EN-ISO 17394-2.

4. Packaging

In the applicable European Legislation the requirements for the packaging and labelling of the UltraStream are set out. These requirements are stated in the Regulation (EC) No 1935/2004 Materials and articles intended to come into contact with foodstuffs.

In article 15 of Regulation (EC) No 1935/2004 Materials and articles intended to come into contact with foodstuffs the requirements for the labelling are set out.

The labelling of the UltraStream needs to contain the information mentioned here below:

1. The words ‘for food contact’, or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex I
2. If necessary, special instructions to be observed for safe and appropriate use
3. The name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the
4. Adequate labelling or identification to ensure traceability of the material or article
5. In the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food, including the provisions on food labelling.
6. The information required on the packaging/labelling shall be conspicuous, clearly legible and indelible.
7. Retail trade in materials and articles shall be prohibited if the information mentioned here above is not given in a language easily understood by purchasers.
8. Within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community.

The information required on the packaging shall be displayed on the:

- the materials and articles or on their packaging
- labels affixed to the materials and articles or to their packaging

5. Conclusion and recommendation

5.1 Conclusion

The Technical and Legal certification company Certification Experts B.V. has carried out the applicable test on the UltraStream, to determine if the UltraStream is in compliance with the essential requirements out of the Drinking Water Directive (DWD) 98/83/EC, the Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs, the General Product Safety Directive (GPSD) 2001/95/EC and other applicable European legislation and standards.

All the relevant migrations of the UltraStream have been tested. The tested sample is determined to comply with the value limits and requirements out of the Drinking Water Directive 98/83/EC and Regulation 1935/2004/EC in accordance with the applicable European Standards in specific the EN-ISO 17394-2.

The specific requirements that must be put on the packaging/labelling of the UltraStream are set out in chapter 3. These requirements are stated in the Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs.

The information required on the packaging shall be displayed on the:

- the materials and articles or on their packaging
- labels affixed to the materials and articles or to their packaging

Results given in this report refer only to the samples and documentation submitted for analysis and tested by Certification Experts B.V. Comments are for guidance only.

5.2 *Recommendation*

Ion Life Pty Ltd t/a Alkaway must ensure that the water of the UltraStream is free from the micro-organisms and parasites and from any substances which, in numbers or concentration, constitute a potential danger to human health. Ion Life Pty Ltd t/a Alkaway must include a documentation which states that the UltraStream does not contain any of these substances.

Further Ion Life Pty Ltd t/a Alkaway shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out.

Ion Life Pty Ltd t/a Alkaway must also make sure that the labelling, advertising and presentation of the UltraStream shall not mislead the consumers. Also Ion Life Pty Ltd t/a Alkaway must ensure that the labelling or identification of the UltraStream is sufficient enough to ensure traceability of the material or article.

Annex I: Graphical symbol for the indication food contact



Symbol

Picture 1: Symbol from Regulation (EC) 1935/2004 Materials and articles intended to come into contact with foodstuffs

Annex II: Parametric values

This annex shows the maximum parametric values for the UltraStream in accordance with the Drinking Water Directive 98/83/EG.

Parameter	Parametric value (number/100 ml)
<i>Escherichia coli</i> (<i>E. coli</i>)	0
Enterococci	0

The following applies to water offered for sale in bottles or containers:

Parameter	Parametric value
<i>Escherichia coli</i> (<i>E. coli</i>)	0/250 ml
Enterococci	0/250 ml
<i>Pseudomonas aeruginosa</i>	0/250 ml
Colony count 22 °C	100/ml
Colony count 37 °C	20/ml

Parameter	Parametric value	Unit
Acrylamide	0,10	$\mu\text{g/l}$
Antimony	5,0	$\mu\text{g/l}$
Arsenic	10	$\mu\text{g/l}$
Benzene	1,0	$\mu\text{g/l}$
Benzo(a)pyrene	0,010	$\mu\text{g/l}$
Boron	1,0	mg/l
Bromate	10	$\mu\text{g/l}$
Cadmium	5,0	$\mu\text{g/l}$
Chromium	50	$\mu\text{g/l}$
Copper	2,0	mg/l
Cyanide	50	$\mu\text{g/l}$
1,2-dichloroethane	3,0	$\mu\text{g/l}$
Epichlorohydrin	0,10	$\mu\text{g/l}$
Fluoride	1,5	mg/l
Lead	10	$\mu\text{g/l}$
Mercury	1,0	$\mu\text{g/l}$
Nickel	20	$\mu\text{g/l}$
Nitrate	50	mg/l
Nitrite	0,50	mg/l
Pesticides	0,10	$\mu\text{g/l}$
Pesticides – Total	0,50	$\mu\text{g/l}$
Polycyclic aromatic hydrocarbons	0,10	$\mu\text{g/l}$
Selenium	10	$\mu\text{g/l}$
Tetrachloroethene and Trichloroethene	10	$\mu\text{g/l}$
Trihalomethanes – Total	100	$\mu\text{g/l}$
Vinyl chloride	0,50	$\mu\text{g/l}$

Aluminium	200	$\mu\text{g/l}$
Ammonium	0,50	mg/l
Chloride	250	mg/l
<i>Clostridium perfringens</i> (including spores)	0	number/100 ml
Colour	Acceptable to consumers and no abnormal change	
Conductivity	2 500	$\mu\text{S cm}^{-1}$ at 20 °C
Hydrogen ion concentration	$\geq 6,5$ and $\leq 9,5$	pH units
Iron	200	$\mu\text{g/l}$
Manganese	50	$\mu\text{g/l}$
Odour	Acceptable to consumers and no abnormal change	
Oxidisability	5,0	mg/l O_2
Sulphate	250	mg/l
Sodium	200	mg/l
Taste	Acceptable to consumers and no abnormal change	
Colony count 22°	No abnormal change	
Coliform bacteria	0	number/100 ml
Total organic carbon (TOC)	No abnormal change	
Turbidity	Acceptable to consumers and no	
Tritium	100	Bq/l
Total indicative dose	0,10	mSv/year