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Need for certification of household water treatment products: examples from Haiti

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Abstract

OBJECTIVE—To evaluate four household water treatment (HWT) products currently seeking approval for distribution in Haiti, through the application of a recently-developed national HWT product certification process.

METHODS—Four chemical treatment products were evaluated against the certification process validation stage by verifying international product certifications confirming treatment efficacy and reviewing laboratory efficacy data against WHO HWT microbiological performance targets; and against the approval stage by confirming product composition, evaluating treated water chemical content against national and international drinking water quality guidelines and reviewing packaging for dosing ability and usage directions in Creole.

RESULTS—None of the four evaluated products fulfilled validation or approval stage requirements. None was certified by an international agency as efficacious for drinking water treatment, and none had data demonstrating its ability to meet WHO HWT performance targets. All product sample compositions differed from labelled composition by >20%, and no packaging included complete usage directions in Creole.

CONCLUSIONS—Product manufacturers provided information that was inapplicable, did not demonstrate product efficacy, and was insufficient to ensure safe product use. Capacity building is needed with country regulatory agencies to objectively evaluate HWT products. Products should be internationally assessed against WHO performance targets and also locally approved, considering language, culture and usability, to ensure effective HWT.

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The findings and conclusions in this report are the findings and conclusions of the authors and do not necessarily represent the official position of the Ministère de la Santé Publique et de la Population (MSPP) or the Centers for Disease Control and Prevention (CDC). Use of trade names and commercial sources is for identification only and does not imply endorsement by the Office of Workforce and Career Development, CDC, or the US Department of Health and Human Services.

Keywords

drinking water; water treatment; developing countries; regulation; household water treatment

Introduction

Worldwide, an estimated 748 million people drink water from unimproved sources such as unprotected springs, open wells and surface water (WHO/UNICEF 2014). The Joint Monitoring Programme classifies water sources as improved or unimproved as a proxy for water safety; however, another estimated 1.2 billion people drink contaminated water from 'improved' sources (Onda *et al.* 2012). Providing reliable, safely managed, piped water to every household is the ultimate goal (WHO/UNICEF 2014). Meanwhile, for those with unsafe supplies, WHO supports incremental improvements, such as household water treatment (HWT), to accelerate health gains associated with safer drinking water (WHO 2011a). A growing body of evidence demonstrates that HWT options improve the microbiological quality of household water and reduce the burden of diarrhoeal disease among users (Fewtrell *et al.* 2005; Clasen *et al.* 2007; Waddington *et al.* 2009), although there remains active debate over the magnitude of the effect (Hunter 2009; Schmidt & Cairncross 2009; Engell & Lim 2013).

Until recently, no international certification process existed for HWT products. Point-of-use drinking water treatment products, such as treatment chemicals and water filters, have been certified by the independent standards organisation NSF International (NSF) or registered in the United States (US) with the Environmental Protection Agency (EPA). NSF certification is voluntary and consists of product sample review to determine whether it meets standards, followed by periodic audits (NSF International n.d.-a). NSF certifies drinking water treatment chemicals under NSF/American National Standards Institute (ANSI) Standard 60 to ensure minimal health effects (NSF/ANSI 2012). EPA registers treatment chemicals in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and labels them as public health pesticides, which reduce organisms of public health concern; or non-public health pesticides, which control micro-organisms of economic or aesthetic significance (US EPA 2010). Registration helps ensure pesticides are used according to approved labels and will not cause environmental harm (US EPA 2012a). NSF and EPA catalogue certified chemical treatment products and pesticide product labels, respectively, in online databases. Additionally, WHO, EPA and European Union (EU) guidelines for drinking water quality recommend health-based and aesthetic limits for chemical contaminants.

In 2012, WHO introduced a quantitative microbial risk assessment based methodology for evaluating HWT product microbiological performance. This method established tiered, health-based targets classifying HWT products as 'highly protective' (4-log bacteria and protozoa reduction and 5-log virus reduction), 'protective' (2-log bacteria and protozoa reduction and 3-log virus reduction) or 'limited protection' (achieving protective target for two pathogen classes and epidemiological evidence demonstrating disease reduction) (WHO 2011b). NSF adapted the methodology into protocol P415, and WHO launched a product

evaluation scheme in 2014 (WHO 2014). These methodologies provide unified guidance for third-party HWT product evaluations, but are not yet widely used. At this time, only first round testing on ten products has begun under the WHO scheme for evaluating household water treatment technologies (Beetsch, Personal Communication).

Household water treatment products have long been promoted in Haiti, particularly after the 2010 earthquake and subsequent cholera outbreak. In 2012, 59.9% of urban and 78.0% of rural Haitian households, which typically collect and store water in 1-gallon or 5-gallon containers, reported treating drinking water, and approximately 90% of those reported using chlorine products (Cayemittes *et al.* 2013). Chlorine-based HWT products improve microbiological water quality (Crump *et al.* 2005), reduce diarrhoeal disease incidence in developing countries (Arnold & Colford 2007) and may be an effective long-term HWT intervention in Haiti (Harshfield *et al.* 2012). Concerns about taste acceptability (Figueroa & Kincaid 2010) and trihalomethane formation (Lantagne *et al.* 2008) with chlorination have generated interest in alternative, non-chlorine-based products; and the HWT market has responded by introducing new, non-chlorine products, some of which are promoted in Haiti.

The Ministry of Health/Ministère de la Santé Publique et de la Population (MSPP) is responsible for approving HWT products in Haiti. In 2013, MSPP requested technical assistance from Tufts University and US Centers for Disease Control and Prevention (CDC) to develop a national HWT product certification process. The resultant process consists of a validation stage followed by an approval stage (Figure 1). To pass the validation stage, product efficacy must be demonstrated through either: (i) certification for drinking water use by an independent organisation requiring efficacy data or (ii) laboratory results demonstrating the product's ability to reduce bacteria, viruses and protozoa to WHO targets. Validated products are evaluated through an approval stage, to determine whether a product sample: (i) contains the labelled composition, (ii) would produce effluent treated water complying with chemical drinking water quality guidelines and (iii) is labelled with complete information in Haitian Creole and is able to deliver the recommended dosage. Products passing both stages are approved for distribution in Haiti, and MSPP informs manufacturers of the determination. Here we describe the review of four novel, chlorine-alternate HWT products (SAFI, SCI-62®, SilverDYNE® and Antinfek™10H) evaluated through this certification process in Haiti.

Methods

The Ministry of Health/Ministère de la Santé Publique et de la Population selected the four initial products for review because manufacturers were currently seeking approval for distribution. Product manufacturers provided MSPP with one or two product samples, and documentation of certifications, efficacy test results and/or technical manuals. To assess products for approval (Figure 1), we reviewed product certifications, efficacy information, sample composition, compliance with drinking water quality guidelines and packaging materials.

Online databases were searched to verify product listings with NSF/ANSI Standard 60 – Drinking Water Treatment Chemicals (NSF International n.d.-b) and registration with EPA

as a public health pesticide for drinking water treatment (US EPA n.d.). We independently investigated additional manufacturer-provided product certifications.

Laboratory efficacy was determined by reviewing manufacturer- provided test data and available literature on efficacy tests of the product (or others with similar composition). Data were considered valid if they: (i) documented results from the product/composition under review; (ii) tested the product at manufacturer-recommended dosage and contact time; and (iii) demonstrated reduction of bacteria, viruses, and protozoa as recommended by WHO and NSF. The product was considered efficacious if data confirmed its ability to meet the WHO *limited protection* target.

Metals scans (US EPA 1994) were performed on one sample of each product by an independent, Massachusetts Department of Environmental Protection-certified laboratory (New England Chromachem, Salem, MA, USA), identifying the four metals with highest concentrations. Primary constituent metal concentrations listed in product literature were compared with tested concentrations. The per cent difference was calculated between actual and expected concentrations, with a maximum acceptable difference of 20%.

For each product, expected chemical concentrations in treated drinking water were calculated using the tested sample chemical concentrations and recommended product dose [liquid drop equal to 0.05 ml (Rowlett 2012)], and compared to WHO Guidelines for Drinking Water Quality (WHO 2011a), US EPA Drinking Water Regulations (US EPA 2009) and EU water quality guidelines (European Commission 1998).

Product bottles and labels were reviewed for complete information necessary for a household to correctly use the product, including: (i) writing in Haitian Creole; (ii) usage directions, including dosage; (iii) a mechanism to deliver the dose; and (iv) listing of chemical contents, manufacturing lot number, and manufacture and expiration dates.

Results

SAFI

SAFI, also known as SafeWaterDrops™ (Safe Water Drops 2013), is a HWT product marketed by Clean Water Environmental, LLC and manufactured by Haviland Products (Grand Rapids, MI, USA) (Clean Water Environmental n.d.). Produced in several formulations of zinc sulphate and/or copper sulphate in solution, it is marketed (although not MSPP-approved) in Haiti, Rwanda and Pakistan (Hilbrands & Hoogewerf 2012). Directions are to add one drop/gallon of water and wait 60 min before drinking.

SAFI is not currently listed with NSF/ANSI Standard 60 (NSF International n.d.-b), although the NSF logo appears on the label and the manufacturer provided an out-of-date registration certificate. SAFI was listed with NSF/ANSI Standard 60 in 2011 (Beetsch, Personal Communication). The product is not EPA-approved for drinking water, but registration is ‘pending approval for use in wastewater treatment and swimming pools’ (Clean Water Environmental n.d.). The manufacturer provided documentation of facility

ISO 9001:2008 certification and US Food and Drug Administration (FDA) registration; neither certification is relevant to HWT products.

The SAFI manufacturer did not provide MSPP with laboratory efficacy data. Metals such as ionic copper are known to be effective bactericides in aqueous systems, and a literature review of the combined use of copper and zinc for HWT identified two publications. One, a preliminary study of combined copper and zinc efficacy, demonstrated the WHO *limited protection* target can be met; however, results were achieved with 2 mg/l copper and zinc (four times the copper and six times the zinc recommended for SAFI dosing) and 6-h contact (six times that recommended) (Komandur *et al.* 2013). The second publication, a study of bacterial removal by several SAFI formulations, demonstrated varying performance – dependent on dosage, product pH and composition – but suggested a contact time of 1–4 h may be required to meet WHO-recommended bacterial removal (virus and protozoa data unavailable) (Hoogewerf & Johnson 2011).

The SAFI sample copper concentration was 68% more than expected, and zinc concentration was >99% less than expected (Table 1). Small amounts of aluminium and iron were identified (<150 mg/l).

Water treated with SAFI at the recommended dose would meet EPA, WHO and EU guidelines for copper ingestion, and applicable EPA and EU guidelines for zinc, iron and aluminium content (no WHO guidelines exist) (Table 2).

SAFI usage directions and dose were listed in English, and the bottle contained a dropper to deliver the recommended dose. Product contents, manufacturing lot number, and dates of manufacture and expiration were missing.

SCI-62®

SCI-62 is a copper sulphate pentahydrate solution manufactured by Chem-A-Co Inc., (Monticello, IN, USA) and marketed by SMG Global Partners, LLC. This algicide/bactericide is promoted in the United States to control odour and algae growth in wastewater treatment (Chem-A-Co Inc. n.d.), and (although not MSPP-approved) in Haiti for drinking water treatment to prevent and eradicate cholera (SMG Global, Haiti n.d.). The product manufacturer provided no HWT instructions; however, the most conservative dose in product literature was one gallon per 60 000 gallons of water (approximately one drop/3 l), with no contact time given.

SCI-62 complies with NSF/ANSI Standard 60 as an algicide and bactericide (NSF International n.d.-b). It has been EPA-registered since 1990 as a pesticide for controlling odours, bacteria and algae in ponds, flooded rice fields, reservoirs, swimming pools and wastewater applications. Its registration is for non-public health claims, and the approved label states that ‘for applications in waters destined for use as drinking water, those waters must receive additional and separate potable water treatment’ (US EPA 2012b).

The SCI-62 manufacturer did not provide MSPP with efficacy test data. Copper is a known bactericide, and a literature review identified two studies of HWT with uncharged copper

documenting bacterial reduction; however, in these studies, water was left in contact with copper storage containers for 8–24 h (Sudha *et al.* 2009; Sharan *et al.* 2011). No additional data were identified to demonstrate this product's efficacy for HWT.

The SCI-62 sample had 22% higher copper concentration than expected (Table 1), and small amounts of iron, zinc and aluminium (<150 mg/l).

Water treated with SCI-62 would meet EPA, WHO and EU drinking water guidelines for copper and applicable EPA and EU guidelines for zinc, iron and aluminium content (no WHO guidelines exist) when dosed with one drop/3 l (Table 2).

SCI-62 was labelled in English. The bottle had a dropper; however, directions, recommended dosage, product contents, manufacturing lot number, and dates of manufacture and expiration were missing.

SilverDYNE®

SilverDYNE is a liquid colloidal silver suspension distributed by World Health Alliance International, Inc., (Las Vegas, NV, USA) and marketed in Mexico, Africa, Asia and (although not MSPP-approved) Haiti to disinfect household drinking water and prevent cholera (World Health Alliance International 2009, World Health Alliance International n.d.-a). Instructions on the bottle were to add one drop/2 l of water (or two drops for 'very contaminated' water) and wait 30 min before drinking. The manufacturer's website offered a conflicting dose of two drops/litre of 'disaster quality' water (World Health Alliance International n.d.-a).

SilverDYNE is not registered with NSF or EPA. It is approved to disinfect drinking water for human consumption under Mexican Norm NOM 127 SSA1 of 1994, which lists allowable limits of bacteriological contamination, physical characteristics, chemical components and radioactive materials, but does not discuss HWT or silver ingestion guidelines (El Director General de Salud Ambiental 1994).

The SilverDYNE manufacturer provided efficacy data from five laboratories. Four sets of data were not considered: three provided no contact time and one tested silver- treated earthenware jars with unknown dosage and contact time. A fifth test used six times the recommended dose, and while results indicated 5-log removal of four bacteria types, they lacked virus or protozoa data (World Health Alliance International n.d.-b). A literature review identified an independent study demonstrating that Silver- DYNE could meet the WHO *limited protection* target at a dose of three drops/litre (six times the recommended dose) and 90-min contact time (three times that recommended); protozoa removal would require longer contact time at that dose (Gerba & Maxwell 2012).

The tested SilverDYNE sample had 27% less silver than expected (Table 1), and small copper, zinc and boron concentrations (<30 mg/l).

Water treated with SilverDYNE would meet WHO guidelines and EPA secondary standard for silver when used at the recommended dose (Table 2). However, twice the dose is

recommended for ‘very contaminated’ water, which would surpass those limits. No EU guideline exists for silver.

The SilverDYNE sample bottle listed product contents and usage directions in French and provided a dropper to deliver the listed dose. Lot number, manufacture date and expiration date were missing.

Antifek™ 10H

Antifek 10H is a liquid disinfectant manufactured by Dove Biotech (Bangkok, Thailand). This product, with active ingredient poly(hexamethylene biguanide) hydrochloride (PHMB), is marketed for eliminating bacteria and fungi in drinking water, natural waters, pools, sewage and industrial water; and treating drinking water to prevent waterborne diseases (Dove Biotech n.d.). Antifek 10H drinking water dosage is 0.4 mg/l (no contact time provided), although product literature also listed a conflicting dose of 0.2 mg/l (Dove Biotech 2012).

Antifek 10H is not registered with NSF or EPA; however, other PHMB products are EPA-registered as antimicrobial pesticides for swimming pools, oil field injection water, cut flower preservation and hard surface disinfectants (US EPA 2004). Antifek is registered with the Thai FDA (FDA Thailand n.d.-a), but we were unable to verify the 10H formulation is the one registered. Registration under the Thai Hazardous Substances Control Group as an antimicrobial disinfectant requires antimicrobial efficacy data (FDA Thailand n.d.-b); however, we were unable to determine whether registration indicates safety for human consumption.

The Antifek manufacturer provided MSPP with five sets of laboratory test data. Results demonstrated bacterial removal, but none exhibited the product’s efficacy at the recommended dose, as: (i) one test used Antifek 30P, a different product; (ii) one test reported the microbiological content of packaged drinking water, without treatment process information; (iii) one test dosed at 1500 mg/l (3750 times the recommended dose) and contact time of 6 h; (iv) one test dosed at 10 mg/l (25 times the recommended dose); and (v) one test reported bacteria removal in one sample, in a water treatment plant with 700 l/h throughput and 1.0 mg/l dose (2.5 times the recommended dose).

The Antifek 10H sample PHMB concentration was unverified, but at 9 mg/l, silver concentration was substantially higher than the 0.00001 mg/l target concentration (Table 1). Small concentrations of copper, zinc and boron were identified (<30 mg/l).

There is no recommended PHMB drinking water limit, but EPA recommends a maximum dietary ingestion of 0.2 mg per kg body mass per day (14 mg/day for average adults) (US EPA 2004). Expected daily PHMB ingestion from treated water is 0.11 mg, assuming two litres consumed at 0.4 mg/l product dose. Neither WHO nor EU guidelines for PHMB exist (Table 2).

The Antifek 10H bottle was labelled in English. It provided no usage directions, but listed product contents, manufacturing lot number, expiration and manufacturing dates and recommended dosage. The listed dose presents three problems: (i) users would not know

what volume to add, because dose is given in mg/l; (ii) users would need to add one drop to 125 litres of water to obtain the recommended dose and would be unlikely to have a vessel that size; and (iii) product packaging provides no way to measure drops.

Results summary

None of the four products were recommended for approval for HWT distribution in Haiti (Table 3), as: (i) only SCI-62 had NSF certification for drinking water use, but not as a final treatment chemical, and none were registered with EPA for treating drinking water; (ii) no product demonstrated its ability to meet the WHO *limited protection* microbiological performance target at the recommended dosage and contact time; (iii) no tested sample composition was within 20% of labelled product composition; (iv) dosages were not easily attainable on Antinfek 10H and SCI-62 due to missing instructions or dispensing method; and (v) no product was labelled in Haitian Creole or with complete information (contents, usage instructions, dosage, lot number, manufacturing date and expiration date).

Discussion

This work established country-level HWT certification requirements and evaluated chemical treatment products based on efficacy (ability to remove reference pathogens when used according to product instructions); toxicity (compliance with drinking water chemical content recommendations); manufacturing consistency and accountability (availability of product contents, lot numbers and expiration dates); and usability (appropriate language, dosing ability). In this review of four HWT products seeking approval for distribution in Haiti, none fulfilled prescribed requirements, and products were not recommended for approval.

Further, misleading product information proved difficult to distinguish from pertinent information. Manufacturers gave MSPP documentation of irrelevant product certifications (that had expired, were for a different product, were not for drinking water applications, or simply unrelated) and non-applicable laboratory test results (tests performed on a different product, with a different use, or at higher dose or contact time). Conflicting dosing information was identified between manufacturer websites, product literature and product bottles, and unsubstantiated claims were recognised.

Because of the complex nature of existing international certification processes, regulatory officials in many countries may not be equipped to evaluate the validity of provided information, which is often not written in their native language, pertaining to unfamiliar regulations and provided as 'official-looking' documentation. Country regulators may be presented with limited staffing and financial resources, limited laboratory facilities, language barriers, and time constraints to develop both the minimum submission requirements for product certification requests and to review the provided information.

The availability of a clear, international process for HWT product evaluation, such as the WHO microbiological performance based evaluation scheme, would lessen the decision-making burden for country regulators, particularly with regard to evaluating product efficacy. There is additional opportunity for inclusion of toxicity and manufacturing

consistency requirements in an international process. However, country-level approval processes may remain necessary to evaluate context-specific product usability – considering language, cultural norms and domestic habits.

Further technical assistance may be beneficial as countries build capacity to objectively evaluate HWT products. This assistance could include training in understanding international drinking water quality and product efficacy standards and certifications, online product database searches, laboratory test procedures to verify product composition locally and establishing metrics to evaluate product usability. Some countries may have higher capacity to do more locally, and others may require more assistance and reliance on internationally facilitated processes.

A limitation of this study is that only the one sample provided to MSPP was analysed for composition and packaging, and manufacturers were not explicitly contacted to provide additional data and validation information. Thus, our data are not comprehensive and, as more information becomes available, may not inform potential future certifications of evaluated products.

While Haiti's post-emergency setting may currently represent an outlier in terms of novel HWT product promotion, these results are more generally applicable to other contexts, because at least two products described herein are available in other countries. Locally produced HWT products, such as flocculant/disinfectants and ceramic filters, could have similar efficacy and quality challenges to those presented here; and there is intense interest in developing novel HWT products for emergency response, and new options may be promoted in future emergencies.

More work may be needed to advise similar schemes in other countries using HWT products, and in Haiti to apply this evaluation method to other HWT products and ensure the sustainability of the certification process. Dissemination of information contained herein about currently-available HWT products may benefit the public and encourage the use of safe and efficacious household water treatment products.

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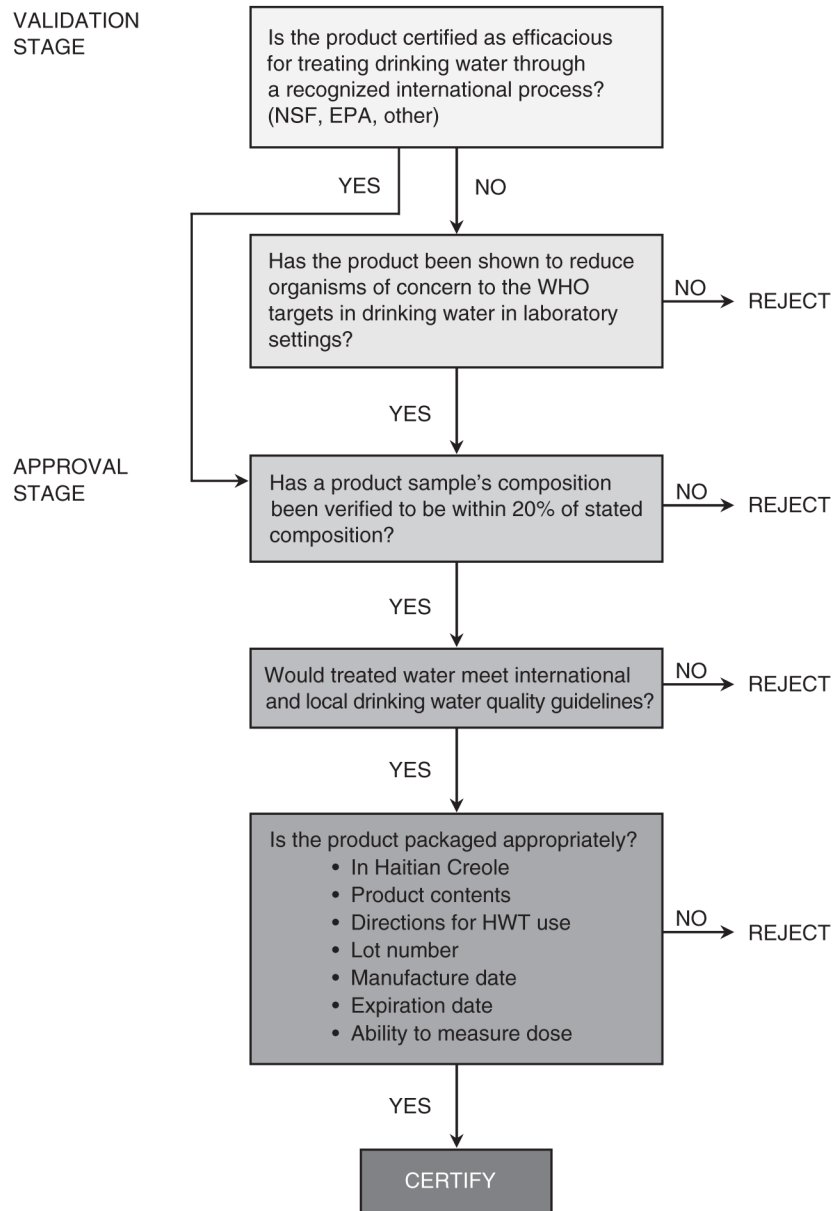


Figure 1. Household water treatment (HWT) product certification process framework for treatment chemicals in Haiti.

Table 1

Composition verification of primary chemical constituents of all products

HWT product	Chemical constituent	Target concentration (mg/l)	Tested concentration (mg/l)	% Diff
SAFI	Copper	36 000	60 300	67.5
	Zinc	24 000	113	99.5
SCI-62 [®]	Copper	50 290	61 500	22.3
SilverDYNE [®]	Silver	3600	2640	26.7
Antinfek [™] 10H	Silver	0.00001	9	>100
	PHMB	140 000	Not tested	Not tested

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Summary of expected chemical concentrations in water treated with each product and corresponding international, United States and European Union drinking water guidelines

Table 2

HWT product	Chemical constituent	Drinking water concentration* (mg/l)	WHO guideline (mg/l)	US EPA standard [†] (mg/l)	EU standard (mg/l)
SAFI	Copper	0.8	2	1.3	2
	Zinc	0.001	–	5	–
	Aluminum	0.001	–	(0.05–0.2)	0.2
	Iron	0.002	–	0.3	0.2
SCL-62 [®]	Copper	1.03	2	1.3	2
	Zinc	0.002	–	5	–
	Aluminum	0.001	–	(0.05–0.2)	0.2
Iron		0.002	–	0.3	0.2
	SilverDYNE [®] ‡	0.07	0.1§	0.1	–
Antifek [™] 10H¶	PHMB	0.056	–	7 ^{**}	–

* Calculated from recommended dose and tested sample concentration (except PHMB, which is expected concentration).

† Primary, but non-enforceable, maximum contaminant level goal (MCLG) for copper. Secondary, non-enforceable maximum contaminant level (MCL) for zinc, aluminum, iron and silver.

‡ Negligible amounts of copper, zinc and boron.

§ Non health-based guideline for average adult, based on 10 g/lifetime recommended limit.

¶ Negligible amounts of copper, silver, zinc and boron.

** Adult average based on dietary recommendation of 0.2 mg per kg body mass per day, and 2 l/day drinking water.

Table 3

Results summary

Certification criteria	Products reviewed			
	SAFI	SCI-62 [®]	SilverDYNE [®]	Antifek [™] 10H
National certifications for drinking water	No	Yes	No	No
Could meet WHO limited protection target at recommended dose	No	No	No	No
Composition verification (within 20%)	No	No	No	Not tested
Treated water meets chemical contaminant guidelines	Yes	Yes	Yes	Yes
Achievable dosage by user	Yes	No	Yes	No
Appropriate labelling	No	No	No	No
Recommend approval	No	No	No	No

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