Javel® AQUA

WATER PURIFICATION TABLETS

TECHNICAL DATA

Dossier established by JAVEL POLSKA –www.javel.pl

DETAILS OF THE APPLICANT

1.1 Details of the applicant/manufacturer/distributor

Name: JAVEL POLSKA
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2. IDENTITY

2.1 Commercial name of the product: JAVEL® AQUA

2.2 Composition of the product:

	60mg (8.5mg NaDCC)	60 mg (17 mg NaDCC)	350 mg (67 mg NaDCC)	1.08g (400mg NaDCC)	1.1g (500mg NaDCC)	3,25 4,72 i 9,7 g
Sodium dichloro-1,3.5-triazinetrione Anhydrous CAS No 2893-78-9	14.2%	28.3%	19.1 %	39.7%	45.5%	53%

2.3 Nature of the product:

Powder (blend) compressed to make a tablet.

JAVEL® AQUA's active ingredient, sodium dichloisocyanurate anhydrous (Sodium dichloro-1,3.5-triazinetrione Anhydrous) is formulated with effervescent salts to aid its dispersion in water. The volume of effervescent salts does not affect the ability of **JAVEL® AQUA** to generate hypochlorous acid (free available chlorine) in water.

The volume of effervescent salts varies to suit different in-use applications, water temperatures, markets and packaging method but the actual biocidal performance of the product is unimpaired. (E.G., Where strip foil packaging is required, additional effervescent salts are added to bulk out the tablet to make them large enough to withstand the strip packing activity).

3. NATURAL, CHEMICAL AND TECHNICAL QUALITIES

3.1 Appearance: White flat beveled tablet.

3.2 Explosive qualities: Not explosive.

3.3 Corrosive qualities: The product itself is not classified as corrosive.

3.4 Flash point: Not flashing.

3.5 pH value: pH (1% water) 5.0-6.0 approx.

3.6 Relative density: Not applicable.

3.7 Stability & Reactivity:

Conditions to Avoid: Do not store on or near heat sources or naked flame. Avoid moisture. NaDCC decomposes at temperatures above 240°C liberating toxic gases.

Materials to Avoid: Contact with water liberates chlorine and with nitrogen compounds may cause explosion. Avoid organic materials, oils, grease, sawdust, reducing agents, nitrogen containing compounds, calcium hypochlorite, other oxidizers, acids, alkalis, cationic and certain non-ionic surfactants.

Effects of dampness: If tablets become damp they will effervesce, evolving carbon dioxide and may decompose to give off chlorine fumes.

Shelf life: 5 years.

3.8 Technical characteristics:
Sodium dichloro-1,3,5-triazinetrione anhydrous Disinfectant base.
When the tablet is dissolved in water, Sodium dichloro-1,3,5-triazinetrione anhydrous (NaDCC) primarily forms hypochlorous acid (the active compound) and sodium cyanurate.

3.9 Compatibility with other products:
Compatible with non ionic and anionic surfactants.

4. METHODS OF IDENTIFICATION AND ANALYSIS

Analytical methods for defining concentration of the active ingredients in the biocidal product.

TEST METHOD STANDARD TITRATION

APPARATUS

Burette 50cm³ (class A)
One-mark pipettes (class A)
One-mark volumetric flask 500cm³ (class A)

REAGENTS

Chemicals of analytical reagent quality
Acetic acid (d= 1.05g/cm³)
Sodium thiosulphate solution 0.1M
Potassium iodide
Starch indicator 0.5% approximately, freshly prepared Water (distilled or deionised)

PROCEDURE

Place one tablet in a beaker containing approximately 200cm³ of water and allow to stand until the tablet has completely dissolved. Using a glass rod, ensure any coarse particles remaining are broken up and incorporated into the solution. Transfer the solution to a clean, dry 500cm³ one-mark volumetric flask. Rinse the beaker with two 50cm³ aliquots of water, adding the rinsings to the one-mark volumetric flask. Make up the solution to the mark with water and mix well.

Pipette 25cm³ of the 'chlorine' solution into a clean, dry 250cm³ conical flask. Add 25cm³ of water followed by approximately 2g of the potassium iodide and 10cm³ of the acetic acid. Titrate the liberated iodine with the sodium thiosulphate solution until a pale, straw colour is achieved. Add 2cm³ of the starch solution and titrate until the blue coloration just disappears (V).

CALCULATION

Available chlorine, mg per tablet = V x 3.546 x 20

Alternative test methods are described in the British Standards BS 3762: 1986 and BS EN ISO 7393-3: 2000.

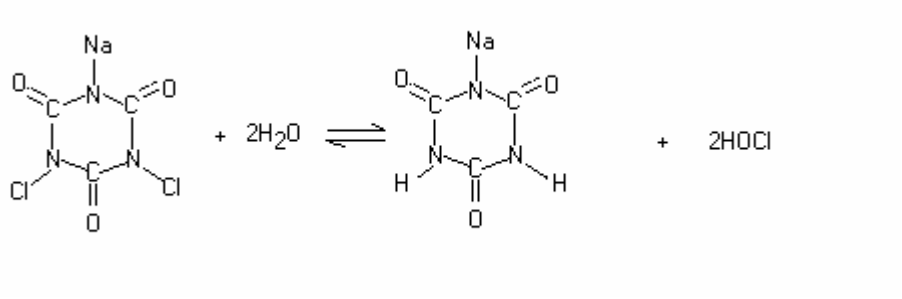
5. PROPOSED USES AND EFFECTIVENESS

5.1 Proposed type of product and application sphere

The product is made of three components. The active ingredient is sodium dichloro-1,3,5-triazinetrione anhydrous, which has biocidal properties.

The other two components, 1,6-hezane dioic acid and sodium hydrogen carbonate form the effervescent base.

When the tablet is dissolved in water, Sodium dichloro-1,3,5-triazinetrione anhydrous (NaDCC) primarily forms hypochlorous acid (the active compound) and sodium cyanurate.

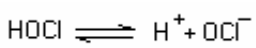


NaDCC Sodium Cyanurate Hypochlorous acid

It is generally accepted that nonionised hypochlorous acid is responsible for the lethal action on micro-organisms. This action is attributed to the chlorination of the cell protein or enzyme systems. ( )

One of the major factors affecting the antimicrobial activity of the resultant chlorine solutions is the pH.

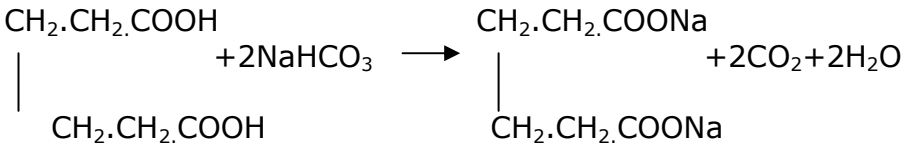
Hypochlorous acid (HOCl) dissociates according to the following equilibrium



The hypochlorite ion (OCl^-) and hypochlorous acid (HOCl) contribute the free available chlorine. It should be noted that the hypochlorite ion only has 1/100th of activity of hypochlorous acid. Therefore those solutions liberating the largest amount of hypochlorous acid will have the greatest biocidal activity. **JAVEL® AQUA** effervescent chlorine tablets have a pH range of 5.0 to 6.0 favouring undissociated HClO (> 95%) in the solution.

The aim of the effervescent base is to speed the dissolution of the tablet in the water.

As the acid effervescent salt, 1,6-hexanedioic acid reacts stoichiometric ally with alkaline effervescent salt (sodium hydrogen carbonate) in water as follows:



The applications of the product are:

- Drinking water disinfection:
  - Chlorination of animals drinking water
  - Emergency water purification

5.2 Use dilutions, including descriptions of the proposed method of application

Guidelines for the use of JAVEL® AQUA for water purification:

- **JAVEL® AQUA** tablets destroy harmful bacteria found in contaminated water and protect against illness, caused by waterborne diseases.

- Dissolve 1 tablet per 1L of drinking water.

- Leave for 30 minutes before drinking.

Note: In areas where Schistosomiasis (Bilharzia) is prevalent, it is recommended that 30 minutes is allowed for purification.

5.3 Spheres of application and the use dilutions of the product and of the active material[s] for each specific purpose according to the method by which the product is to be applied

Applications and dilutions are covered in 5.1, 5.2 and 5.4.

5.4 Number of application times and contact times and, if necessary or applicable, all special and specific information relevant to the geographical and climatic fluctuations or necessary waiting times for the protection of human beings or animals:

5.5 Activity

JAVEL® AQUA active constituent, sodium dichloroisocyanurate has biocidal activity against the following microorganisms amongst others:

- Bacteria and Fungi
- Spores
- Mycobacteria
- Viruses

The improved biocidal capacity of **JAVEL® AQUA** tablets relative to other halogen based products is a consequence of the following factors:

A) **JAVEL® AQUA** tablets are formulated such that on dissolution in water they yield a solution with a pH in the range of approximately 5.5 to 6.0. This ensures that the more effective undissociated hypochlorous acid predominates giving a solution of optimum biocidal activity. In contrast, other halogen based products are produced in alkaline form (eg sodium hypochlorites (bleach), Halazone), having an elevated pH value, resulting in a reduced proportion of undissociated hypochlorous acid, and consequently diminished biocidal activity.

B) With sodium dichloroisocyanurate (NaDCC-Sodium dichlor-1,3,5-triazmetrione anhydrous), the active ingredient of **JAVEL® AQUA** tablets, only 50% of the total hypochlorous acid is "free" – the balance is "combined" in the form of mono or dichloroisocyanurates. The equilibrium between "free" and "combined" hypochlorous acid remains stable until a hypochlorous acid demand is placed on the solution by microorganisms, organic matter or nitrogenous material.

This demand utilizes the hypochlorous acid and displaces the chemical equilibrium such that additional hypochlorous acid is generated to replenish that utilized by the hypochlorous acid demand. The existence of this equilibrium provides for the progressive and controlled release of hypochlorous acid resulting in enhanced efficiency and safety when compared with other hypochlorous acid products. As a consequence of this unique chemical equilibrium, **JAVEL® AQUA** tablets are better equipped to cope with an organic demand.

Many studies confirm the superior biocidal activity of sodium troclosene. (3,4,5,6).
Biocidal activity against a range of organisms has been reviewed by Dychdala (1) as shown in the table overleaf:

ACIDAL EFFECT OF FREE AVAILABLE CHLORINE ON VARIOUS ORGANISMS (1)

Organism	pH	Temp °C	Exposure Time, Min	ppm Av.Cl_2	Biocidal Results	References
ALGAE						
Chlorella variegata	7.8	22	-	2.0	Growth	Palmer et al,
Gomphonema	8.2	22	-	2.0	controlled	1955
parvulum	8.2	22	-	2.0	Growth	Palmer et al,
Microcystis					controlled	1955
aeruginosa					Growth	Palmer et al,
					controlled	1955
BACTERIA						
A. metalcaligenes	6.0	21	15 secs	5.0	100%	Hays et al, 1963
B. anthracis	7.2	22	120	2.3-2.4	100%	Brazis et al, 1958
B. globigii	7.2	22	120	2.5-2.6	99.99%	Brazis et al, 1958
C. botulinum toxin	7.0	25	30 secs	0.5	100%	Brazis et al, 1959
type A	7.0	20 – 25	1	0.055	100%	Butterfield et al,
E. coli	8.5	20 – 25	1	0.1–0.29	100%	1943
E. typhosia	8.4	50 – 60	30 secs	50	100%	Butterfield et al,
M. tuberculosis	6.0	21	15 secs	5.0	100%	1943
P. fluroescens IM	7.0	20 –25	3	0.046–0.055	100%	Costigan, 1936
S. dysenteriae	7.2	25	30 secs	0.8	100%	Hays et al, 1963
S. aureus	7.5	20 – 25	2	0.5	100%	Butterfield et al,
S. faecalis	9.0	25	30 secs	0.2	100%	1943
All vegetative						Dychdala, 1960
bacteria						Stuart et al, 1964
						Snow, 1956
BACTERIOPHAGE						
S. Cremoris phage strain 144F	6.9-8.2	25	15 secs	25	100%	Hays et al, 1959
FISH						
Carassius auratus	7.9	Room	96 hours	1.0	Killed	Davis, 1934
Daphnia magna	7.9	Room	72 hours	0.5	Killed	Davis, 1934
FROGS						
Rana pipiens	8.3	21	4 days	10	100%	Kaplan, 1962
FUNGI						
A. Niger	10-11	20	30 – 60	100	100%	Dychdala, 1961
B. Rhodotorula flava	10-11	20	5	100	100%	Dychdala, 1961
NEMATODES						
Quadrilabiatus	6.6-7.2	25	30	95-100	93%	Chang et al, 1960
Nudicapitatus	6.6-7.2	25	30	95-100	97%	Chang et al, 1960
PLANTS						

Cabomba caroliniana	6.3-7.7 6.3-7.7	Room Room	4 days 4 days	5 5	100% 100%	Zimmerman et al, 1934 Zimmerman et al, 1934
PROTOZOA						
E. histolytica cysts	7.0	25	150	0.08-0.12	99-100%	Clarke et al, 1956
VIRUSES						
Purified adenovirus 3	8.8-9.0 6.9-7.1	25 27-29	40-50 secs	0.2 0.92-1.0	99.8% 99.6%	Clarke et al, 1956 Clarke et al, 1959
Purified Coxsackie A_2	7.0	25	3	0.31-0.40	99.9%	Kelly et al, 1958
Purified Coxsackie B_1	7.0	25-28	2	0.21-0.30	99.9%	Clarke et al, 1959
Purified Coxsackie B_5	6.7-6.8	Room	1	3.25	Protected	Clarke et al, 1959
Infectious hepatitis	7.0	25-28	30	0.21-0.30	all 12 volunteers	Clarke et al, 1959
Purified poliovirus I (Mahoney)	7.4-7.9	19-25	3 10	1.0-0.5	99.9% Protected	Clarke et al, 1959
Purified poliovirus II (Lensen)	7.0 6.5-7.0	25-28 25-27	2 5	0.11-0.2 4-6	all 164 inoculated mice	Clarke et al, 1959 Clarke et al, 1959
Purified poliovirus III (Sankett)					99.9%	
Purified Theller's					99%	

5.6 Objects which must be protected: Corrosion

One of the main problems with sodium hypochlorite (NaOCl) disinfectants is that they tarnish or corrode many metals because in NaOCl solutions all the available chlorine (av.Cl) is free. However, in sodium dichloroisocyanurate (NaDCC) solutions an equilibrium exists between free av. Cl (50%) and bound av.Cl (50%). Hence, NaDCC solutions are less corrosive.

In order to investigate this possibility, standardised strips of six metal: mild steel, galvanised mild steel, stainless steel 316, copper, aluminium and brass, were immersed for 4 periods of 25 h in either tap water, aqueous solutions of NaOCl (Chloros: Imperial Chemical Industries) containing 5, 125 and 1,000 ppm av.Cl, or aqueous solutions of NaDCC (**JAVEL® AQUA**) containing 5, 125 and 1,000 ppm av.Cl. Four parameters were recorded before and after each immersion: available chlorine content of solutions, pH of solutions, weight of metal strips, and the degree of tarnishing or corrosion of the strips.

The metals were found to vary markedly in their resistance to tarnishing and corrosion. Stainless steel 316 was unaffected by 100 h immersion; aluminium and brass were tarnished but not corroded; galvanised mild steel and copper were tarnished by NaDCC and moderately corroded by NaOCl; whilst mild steel was heavily tarnished by NaDCC and heavily corroded by NaOCl. With the exception of brass all the metals were much more tarnished or corroded by NaOCl than by NaDCC.

It is concluded that for most metals NaDCC solutions cause less tarnishing or corrosion than NaOCl solutions of the same strength. (7)

SUMMARY OF TARNISHING/CORROSION FINDINGS

IMMERSION	METAL	WATER	BIOSPOT (ppm av.Cl)			CHLOROS (ppm av.Cl)		
			5	125	1000	5	125	1000
First	Mild Steel	-	-	++	+++	+	+++	++++
	Galvanized Mild Steel	+	+	+	+	+	+	++
	Copper	-	+	+	++	+	+	+++
	Brass	-	-	-	++	-	-	+
	Aluminium	-	-	-	-	-	+	++
	Stainless Steel 316	-	-	-	-	-	-	-
Second	Mild Steel	+++	+++	+++	+++	+++	+++	+++++
	Galvanized Mild Steel	+	+	+	+	++	++	+++
	Copper	-	+	++	++	+	+++	++++
	Brass	-	-	+	+++	-	-	++
	Aluminium	-	-	+	-	+	++	+++
	Stainless Steel 316	-	-	-	-	-	-	-
Third	Mild Steel	+++	+++	+++	+++	+++	+++	+++++
	Galvanized Mild Steel	+	+	+	+	++	++	++++
	Copper	-	+	++	++	+	+++	++++
	Brass	-	-	+	+++	-	-	++
	Aluminium	+	-	+	+	+	++	+++
	Stainless Steel 316	-	-	-	-	-	-	-
Fourth	Mild Steel	+++	+++	+++	+++	+++	+++	++++++
	Galvanized Mild Steel	+	+	+	+	++	++	+++++
	Copper	+	++	++	+++	++	++++	+++++
	Brass	-	-	+	+++	-	-	++
	Aluminium	+	-	+	+	+	++	+++
	Stainless Steel 316	-	-	-	-	-	-	-

Key

-	No effect
+	Mild tarnishing
++	Moderate tarnishing
+++	Pronounced tarnishing
++++	Mild corrosion
+++++	Moderate corrosion
++++++	Pronounced corrosion

LOW CORROSION CHARACTERISTICS

The results for the different metals submerged in 1000 ppm available chlorine solution for 4 periods of 25 hours extracted from the previous table are:

METAL	WATER	ECT RATED 1000PPM/L	SODIUM HYPO
MILD STEEL	+++	+++	++++++
GALV. MILD STEEL	+	+	+++++
COPPER	+	+	+++++
BRASS	-	+++	++
ALUMINIUM	+	+	+++
STAINLESS STEEL 316	-	-	-

KEY:

- NO EFFECT
+ MILD TARNISHING
++ MODERATE TARNISHING
+++ PRONOUNCED TARNISHING
++++ MILD CORROSION
+++++ MODERATE CORROSION
++++++ PRONOUNCED CORROSION

5.7 Effects/Influences on target organisms

Physiological chemistry has been used to determine the manner in which chlorine exercises its bactericidal action. It has been found that the trace level at which chlorine is effective implies that it must inhibit a key enzymatic process.

This process is determined to be the oxidation of glucose by the bacterial cell; once the power of glucose oxidation is lost, the bacterial cells die – the suspension becomes sterile. The reaction is not reversible; that is, that bacteria once inactivated by chlorine cannot be reactivated (22).

5.8 Method of Activity

Already covered in 5.7.

5.9 User Information

This information has been already provided on 5.2 guidance for the use of the product and on point 9 Material Safety Data Sheet.

5.10 Claims on the product label and details of the effectiveness of the product to justify these claims, including possible standard test protocols used, laboratory testing or, according to the circumstances, in vivo or in situ trials undertaken

The biocidal activity of hypochlorous acid has been well estabilished. The following tables provide evidence of its effectiveness against a range of frequently encountered water-borne pathogens.

BACTERIA

Effectiveness of hypochlorous acid (free available chorine) against a range of water-borne bacteria.						
ORGANISM	PH	TEMP °C	EXPOSURE TIME	AVAILABLE CHLORINE mgs/litre	BIOCIDAL RESULT	REF
Campylobacter jejuni	8.0	4	1 min	0.1	>99.9%	9
Escherichia coli	7.0	20-25	1 min	0.055	100%	1
Salmonella dysenteriae	7.0	20-25	3 mins	0.055	100%	1

The mycobactericidal activity of **JAVEL® AQUA** (NaDCC) was proved under clean and dirty conditions using a quantitative suspension test. The results foundare as follows:

MYCOBACTERIA Time taken (mins) to achieve a log_{10} Reduction > 5					
	1000 ppm clean conditions	1000 ppm dirty conditions (10% horse serum)	10000 ppm clean conditions	10000 ppm dirty conditions (10% horse serum)	REF
M. chelonae	1	1	1	1	45
M. chelonae epping	4	60	1	1	45
M. fortuitum NCTC 10394	10	10	1	1	45
M. tuberculosis H37 Rv	1	4	1	1	45
M. avium-intracellulare (MAI) -clinical isolate-	60	60	1	10	45

Comparative tests using different type of disinfectants against mycobacteria have led to recommend NaDCC as the best disinfectant for water treatment and pipework. (45)

Independent tests carried out with NaDCC tablets against other important water-borne pathogens at Public Health Laboratory Service (PHLS) has shown the following results (14); the report includes the test protocol used.

BACTERICIDAL ACTIVITY OF JAVEL® AQUA

ORGANISM	PH	TEMP °C	EXPOSURE TIME*	AVAILABLE CHLORINE	BIOCIDAL RESULT
Salmonella Typhi	7.4	22.5	30 min	14.8 approx	>99.9%
Vibrio Chlolerae	7.4	22.5	30 min	14.8 approx	>99.9%
S Sonnei	7.4	22.5	30 min	14.8 approx	>99.9%
S Faecalis	7.4	22.5	30 min	14.8 approx	>99.9%
E Coli	7.4	22.5	30 min	14.8 approx	>99.9%

**The 30 minutes exposure time was part of the procedure followed to carry out this test in order to allow enough time for disinfection to occur. It does not necessarily reflect the time to eradicate the bacteria.*

Further tests were carried out using 3 strains of Methicillin Resistant Staphylococcus Aureus (16). The results proved that **JAVEL® AQUA** dissolved in water and diluted to a strength of 1000 ppm available chlorine achieved a >6 lg_{10} kill of all 3 test strains in 2 minutes under both clean conditions and in the presence of 5% horse serum.

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST 3 STRAINS OF METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS UNDER CLEAN CONDITIONS					
MRSA STRAIN	AV CHLORINE	TEMP °C	EXPOSURE TIME	REDUCTION	REF
Epidemic Strain 15 (PHLS)	1000 ppm	20	2 mins	>99.9%	16
Fresh Clinical isolate (Preston PHL)	1000 ppm	20	2 mins	>99.9%	16
NCTC 12493	1000 ppm	20	2 mins	>99.9%	16

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST 3 STRAINS OF METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS UNDER DIRTY CONDITIONS (5 % HORSE SERUM)					
MRSA STRAIN	AV CHLORINE	TEMP °C	EXPOSURE TIME	REDUCTION	REF
Epidemic Strain 15 (PHLS)	1000 ppm	20	2 mins	>99.9%	16
Fresh Clinical isolate (Preston PHL)	1000 ppm	20	2 mins	>99.9%	16
NCTC 12493	1000 ppm	20	2 mins	>99.9%	16

9Recent tests have been carried out by an independent laboratory using **JAVEL® AQUA** effervescent tablets (13). The results are shown in the following tables:

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING A MODIFICATION OF EN 1040 UNDER CLEAN CONDITIONS		
Bacteria	Av Chlorine	Reduction
Bordetella bronchiseptica	2.8 ppm	>99.9%
Enterobacter cloacae	2.8 ppm	>99.9%
Erysipelothrix rhuspathie	2.8 ppm	>99.9%
Listeria monocytogenes	2.8 ppm	>99.9%
Pasteurella multicoda	2.8 ppm	>99.9%
Pseudomonas aeruginosa	2.8 ppm	>99.9%
Yersinnia enterolytica	2.8 ppm	>99.9%

Candida albicans	2.8 ppm	>99.9%

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING A MODIFICATION OF EN 1040 UNDER DIRTY CONDITIONS (50% BOVINE SERUM)		
Bacteria	Av Chlorine	Reduction
Bordetella bronchiseptica	1100 ppm	>99.9%
Enterobacter cloacae	1100 ppm	>99.9%
Erysipelothrix rhuspathie	1100 ppm	>99.9%
Listeria monocytogenes	1100 ppm	>99.9%
Pasteurella multicoda	1100 ppm	>99.9%
Pseudomonas aeruginosa	1100 ppm	>99.9%
Yersinnia enterolytica	1100 ppm	>99.9%
Candida albicans	1100 ppm	>99.9%

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING BS EN 1276 UNDER CLEAN CONDITIONS				
BACTERIA	AV CHLORINE	TEMP °C	EXPOSURE TIME	REDUCTION
Pseudomonas aeruginosa	110 ppm	20	5 mins	>99.9%
Escherichia coli	110 ppm	20	5 mins	>99.9%
Staphylococcus aureus	110 ppm	20	5 mins	>99.9%
Enterococcus hirae	110 ppm	20	5 mins	>99.9%

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING BS EN 1276 UNDER DIRTY CONDITIONS (3g/l bovine albumin)				
BACTERIA	AV CHLORINE	TEMP °C	EXPOSURE TIME	REDUCTION
Pseudomonas aeruginosa	500 ppm	20	5 mins	>99.9%
Escherichia coli	500 ppm	20	5 mins	>99.9%
Staphylococcus aureus	500 ppm	20	5 mins	>99.9%
Enterococcus hirae	500 ppm	20	5 mins	>99.9%

VIRUSES

Effectiveness of hypochlorous acid (free available chorine) against a range of water borne viruses						
ORGANISM	PH	TEMP °C	EXPOSURE TIME	AVAILABLE CHLORINE mgs/litre	BIOCIDAL RESULT	REF
Adenovirus (type 3)	7.8	22	5 mins	0.5	>99.9%	10
Enteroviruses:						
Poliovirus (type 1)	7.8	22	5 mins	0.5	>99.9%	10
Coxsackievirus (type A9)	7.8	22	5 mins	0.5	>99.9%	10
Coxsackievirus (type B5)	6.0	5	13.2 mins	0.5	>99.9%	27
Coliphages MS2	6.0	5	1.2 mins	0.5	>99.9%	27
Coliphages 0X174	6.0	5	0.5 mins	0.5	>99.9%	27
Echovirus (type 7)	7.8	22	5 mins	0.5	>99.9%	10
Reovirus (type 3)	7.8	22	5 mins	0.5	>99.9%	10
Hepatitis A	7.0	5	3.6 mins	0.5	>99.9%	11
Infectious hepatitis	6.8	Room	30 mins	3.25	Protected all 12 volunteers	1
Simian rotavirus SAII	6.0	5	15 secs	0.11-0.67	100%	12

TOXICITY AND VIRUS TESTS ON JAVEL® AQUA CHLORINE TABLET

ORGANISM	TEST STANDARD	TEMP °C	EXP TIME	AVAILABLE CHLORINE mgs/litre	BIOCIDAL RESULT	REF
Avian Influenza	UK MAFF	4	30 mins	333	>99.9%	38
Newcastle Disease	UK MAFF	4	30 mins	700	>99.9%	38
Infectious Bursal Disease	UK MAFF	4	30 mins	500	>99.9%	38
Laryngo-tracheitis infection	UK MAFF	4	30 mins	700	>99.9%	38
Avipox virus	UK MAFF	4	30 mins	700	>99.9%	38
Foot and mouth disease virus	UK MAFF	4	30 mins	354	>99.9%	39
Swine vesicular disease virus	UK MAFF	4	30 mins	709	>99.9%	39

ALGAE AND FUNGI

Fungi can present a health hazard by the water-borne route. Algae growth can be controlled by the use of **JAVEL® AQUA**, to prevent fouling of systems and slime build-up. The effectiveness of chlorine against a range of these agents is given below:

ORGANISM (FUNGI)	PH	TEMP °C	EXPOSURE TIME	PPM AV.CL.	BIOCIDAL RESULT	REF
Aspergillus fumigatus conidia	7.0	23-27	10 mins	10	100%	15
Aspergillus niger conidia	7.0	23-27	60 mins	3	100%	15
Cladosporium sp. Conidia	7.0	23-27	30 mins	2	100%	15
Cryptococcus laurentii cells	7.0	23-27	10 mins	2	100%	15
Rhodotorula glutinis cells	7.0	23-27	30 mins	2	100%	15
Rhodotorula rubra cells	7.0	23-27	30 mins	2	100%	15

ORGANISM (ALGAE)	PH	TEMP °C	EXPOSURE TIME	PPM AV.CL.	BIOCIDAL RESULT	REF
Chlorella varigata	7.8	22	-	2	Growth controlled	1
Gomphonema parvulum	8.2	22	-	2	Growth controlled	1
Microcystis aeruginosa	8.2	22	-	2	Growth controlled	1

Recent tests have been carried out by an independent laboratory using **JAVEL® AQUA** effervescent tablets (13). The results are shown in the following tables:

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING BS EN 1650 UNDER CLEAN CONDITIONS				
FUNGAL STRAIN	AV CHLORINE	TEMP°C	EXPOSURE TIME	REDUCTION
Candida albicans	200 ppm	20	30 mins	>99.9%
Aspergillus niger	200 ppm	20	30 mins	>99.9%

EFFECTIVENESS OF **JAVEL® AQUA** AGAINST BACTERIA USING BS EN 1650 UNDER DIRTY CONDITIONS (0.3g/l bovine albumin)				
FUNGAL STRAIN	AV CHLORINE	TEMP°C	EXPOSURE TIME	REDUCTION
Candida albicans	2000 ppm	20	30 mins	>99.9%
Aspergillus niger	2000 ppm	20	30 mins	>99.9%

PROTOZOA

Effectiveness of hypochlorous acid (free available chorine) against a range of protozoan cysts.						
ORGANISM	PH	TEMP °C	EXPOSURE TIME	AVAILABLE CHLORINE mgs/litre	BIOCIDAL RESULT	REF
Entamoeba histolyitica cysts	5.0	30	10 mins	2	99.9%	17
Giardia lamblia cysts	6.0	15	10 mins	3	100%	18
Naegleria fowleri	7.3	25	15 mins	2	100%	19

Note: Not effective against Cryptosporidium. Boiling water recommended.

A comparative study of the antibacterial properties of sodium dichloroisocyanurate effervescent tablets and sodium hypochlorite formulations (3) has shown the higher activity of sodium dichloroisocyanurate (NaDCC) against a range of organisms compare to sodium hypochlorite.

From the same investigation it can be concluded overall that sodium dichloroisocyanurate (NaDCC) effervescent tablet has a high disinfection capacity against a wide range of organisms and it should represent adequate safety margins for disinfection of infant feeding utensils under normal use.

In another study, (20) solutions prepared from effervescent tablets of sodium dichloroisocyanurate (NaDCC) have shown to be effective for the sterilisation of infant feeding bottles and teats. Solutions containing not less than 125 ppm available chlorine have been recommended for this purpose. It was also proved that the NaDCC solution retains a bactericidal capacity of more than 10^8 organisms/ml even in the presence of 2% milk which should be well in excess of that required under "in use" conditions.

The effect of Sodium Dichloroisocyanurate (NaDCC) on the activity of DNA polymerase (DNA-P) associated with hepatitis B virus in serum was evaluated by the "Servicio of Microbiologia" in Barcelona, Spain (25), using In-vitro test. DNA-P positive and negative stock virus. Inhibition of DNA-P activity by NaDCC was found to be concentration dependent.

The same team has tested the antiviral activity of NaDCC against human immunodeficiency virus type 1 (HIV-1) using a quantitative suspension test method (26).

The results have shown:

Organism	Av. Chlorine	Time	Inactivation
HBV	1000 ppm	2 minutes	100%
HIV-1	100-120 ppm	5 minutes	100%

There have been extensive studies relating to these cases, which support the above finding. References (30,31,32,33).

The virucidal efficiency of free chlorine in water against enteric viruses is shown in Appendix 1. (28,29) Also see effectiveness of hypochlorous acid against a range of waterborne viruses.

List of tests that were carried out as regards the biocidal capacity of JAVEL disinfection tablets containing an active constituent – sodium dichloroisocyanurate.
Trading permission for the biocidal product issued by the Polish Ministry of Health (No. 933/04 and 3776/09).

1. Evaluation of the virucidal activity towards the virus adeno type 5 by Department of Virology, National Institute of Hygiene according to the PN-EN 14476 dated 08.01.2007.

2. Evaluation of the virucidal activity towards the virus *polio type 1* by Department of Virology, National Institute of Hygiene according to the PN-EN 14476 dated 08.01.2007.

3. Evaluation of the fungicidal activity towards *Candida albicans* and *Trichophyton mentagrophytes var.gypseum* by Department of Biological Contamination Control, National Institute of Hygiene according to the procedure PZH DF 01/03 dated 08.12.2006.

4. Evaluation of the bactericidal activity towards *Staphylococcus aureus* and *Pseudomonas aeruginosa* by Department of Biological Contamination Control, National Institute of Hygiene according to the procedure PZH DF 01/03 dated 31.10.2006.

5. Evaluation of the sporocidal activity towards *Bacillus cereus* by Department of Biological Contamination Control, National Institute of Hygiene according to the procedure PZH DF 03/03 dated 08.12.2006.

6. Evaluation of the antituberculotic activity with 1% protein burden – *M.tubelculosis* by Department of Microbiology, Institute of Tuberculosis and Lung Diseases in Warsaw.

7. Tests for bactericidal and fungicidal activity according to the standards EN 1040 and EN 1275 carried out by IRM COFRAC in France.

8. Evaluation of the bactericidal activity according to the standard EN-PN 13727 dated 23.01.2008 by National Medicines Institute in Warsaw towards *S.aureus, P.aeruginosa, E.hirae.*

9. Evaluation of the fungicidal activity according to the standard EN-PN 13624 dated 23.01.2008 by National Medicines Institute in Warsaw towards *C.albicans, A.niger.*

10. Evaluation of the virucidal activity towards the virus *adeno type 5* and *polio type 1* by Department of Virology, National Institute of Public Health, National Institute of Hygiene according to the standard PN-EN 14476 dated 04.04.2008.

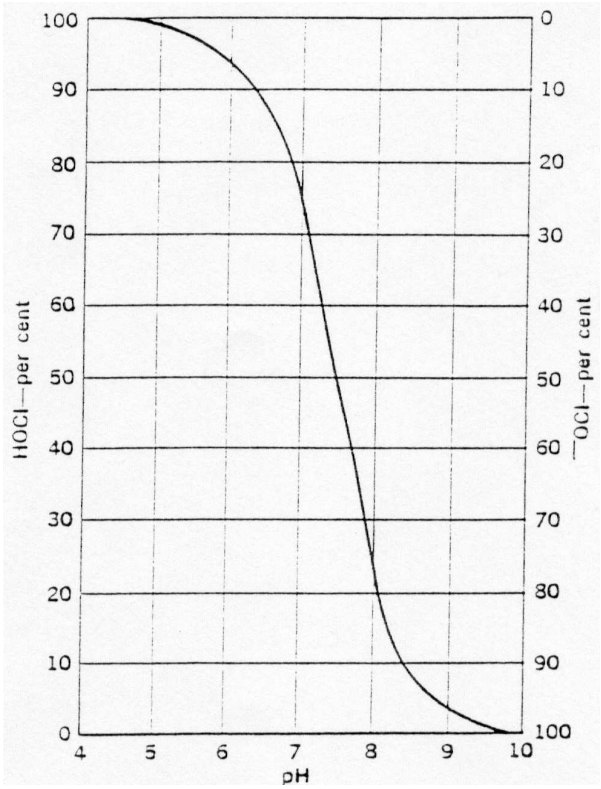
11. Evaluation of the antituberculotic activity with 1% protein burden – *M.tubelculosis* by Department of Microbiology, Institute of Tuberculosis and Lung Diseases in Warsaw dated 21.01.2008.

12. Tests for bactericidal and fungicidal activity according to the standards EN 1275 and EN 1276 carried out by the accredited analytical and testing laboratory Dordogne in France dated 18.04.2007.

13. Tests carried out by Military Institute of Hygiene and Epidemiology in Warsaw dated 27.05.2010.

5.11 Limitations of Effectiveness

Germicidal effectiveness will largely depend on the concentration of undissociated hypochorous acid in water solution and the relationship between pH and the degree of dissociation of HOCl as shown in the following graph:

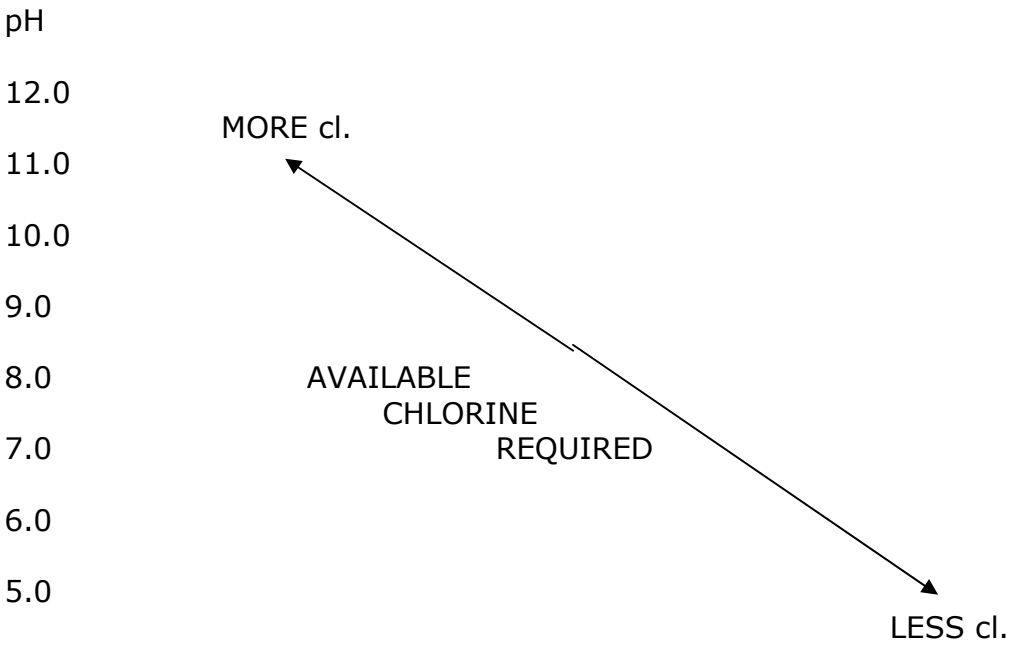


Relationships among HOCl, -OCl, and pH, (After Baker, 1959.) fromChlorine and chlorine compounds, G.R. Dychdala, B.S. (1) Studies carried out by several scientists have shown that the bactericidal and virucidal activity of NaOCL solution were affected by the pH. In addition to pH, various other environmental factors, alone or in combination, will determine the antimicrobial action of chlorine:

- Temperature
- Organic material
- Hardness
- Addition of Ammonia or Amino compounds
- Surfactants.

They attributed the striking changes in killing to changes in concentrations of undissociated hypochlorous acid and concluded that the concentration of HOCl is closely related to the speed of kill by hypochlorites solution. (1)

pH AFFECTS PERFORMANCE



The amount of chlorine required to kill the same amount of bacteria dramatically increases if the pH is high.

Liquid bleach if 9.0 – 12.0 pH

Chlorine tablets are c6.0 – 6.5 pH

Effect of Temperature

The effect of temperature was demonstrated by (Ostigan (1936)) on Hycobacterium Turberculosis and Rudolph et al. (1941). These workers observed a 60 to 65% reduction in killing time with a 10°C rise in temperature. Later, Weber et al. (1944), in other related work with hypochlorite solutions at 25 ppm available chlorine and three different pH levels (pH=10, pH=7 and pH=5), concluded that a rise of 10°C produced a reduction of 50 to 60% in killing time, and that a drop of 10°C increased the necessary exposure time by about 2.1 to 2.3 times. (1)

Effect of Temperature on Lethal Activity of Hypochlorite Solutions from the Halogens, J.R.Trueman ( )					
Data of	Avalable chlorine (ppm)	Temp (°C)	Time for Effective kill of bacteria (min)	PH	Increase in lethal activity per 10°C rise %
Rudolph and Lovine (1941) (Using B. metiens spores)	25 25 25 25	20 30 35 50	121 65 39 9	10 10 10 10	--- 46 80 51
Weber and Lovine (1944) (Using B.metiens	25 25 25	0-30 0-30 20-50	10-1.2 12.9-1.4 570-46	5 7 10	50 52 57

spores)					
Allen (1950) after Butterfield et al. (1943) (Using E.coli)	0.03 0.03 0.07 0.07 0.40 0.40 0.75 0.75	2-5 20-25 2-5 20-25 2-5 20-25 2-5 20-25	5 3 10 5 11 3 20 3	7 7 8.5 8.5 9.8 9.8 10.7 10.7	 Approx. 20 Approx. 25 approx. 36
Collins (1955) (Using a Pseudomonad)	3 3	4.4 21	10 4	-- --	-- 35

The data in this table shows a general increase in activity for 10°C rise in temperature, of between 50-60% for spores, and rather less for vegetative bacteria. It can also be seen that the effect of temperature is rather more marked at higher pH values, particularly with the vegetative organisms.

In considering stability of the diluted solutions, it has been found that although a rise in temperature increase the germicidal activity, it does not result in loss of available chlrine. Hadfield (1954) recorded that solutions of sodium hypochlorite could be kept at 55°C for up to 3 hours without any loss in available chlorine.

Effect of Organic Material

Organic material in chlorine solution consumes available chlorine and reduces its capacity for bactericidal activity; this is evident especially in solutions with low levels of chlorine.

If the organic matter contains proteins, the chlorine reacts and forms chloramines, retaining some of its antibacterial activity, even though the available chlorine levels are reduced considerably.

It appears that sugars and starches do not affect the germicidal activity of chlorine. Shere (1948) reported that 500 ppm of alkyl aryl sulfonate did not exhibit any slowing action on the germicidal effectiveness of the hypochlorite solutions. Other organic materials such as tyrosine, tryptophan, cystine, egg albumin, peptone, body fluids, tissues, microbes, and vegetable matter when present in a sanitizing solution, will consume chlorine to satisfy the organic water demand; in this case, the chlorine may lose its function as a germicidal agent unless it forms chloramines or unless the chlorine dosage is adjusted to overcome this demand. This loss of chlorine due to organic matter may be significant in cases in which minute amounts of chlorine are employed. Higher levels of chlorine, however, tend to produce a safety reserve for performing the desired bactericidal action. (1)

In the presence of organic matter, more concentrated solutions are required, to compensate for the available chlorine used in breaking down or reactivity with the soiling material. In situations where organisms are protected by an organic barrier, hypochlorite disinfectants have a considerable advantage due to their ability to attack and penetrate the

barrier, forming a dispersion, in which the infecting organisms can be reached and kill. (2)

Using horse serum, it has been shown (Coates, 1988a) that the degree of neutralisation of both NaOCl and NaDCC disinfectants is directly proportional to the concentration of serum present. However, the degree of neutralisation of NaOCl disinfectants and the disparity increases with the concentration of serum. Hence, where there is a high concentration of organic material present, NaDCC will be very much more effective with NaOCl (see table overleaf).

ppm av. Cl required to achieve a 5 log^{10} reduction of Pseudomonas aeruginosa in two minutes at 25°C (Coates, 1988a)

% Serum	NaDCC	NaOCl
0	5	5
1	90	100
2	200	180
10	1,100	2,700
20	x	12,000
30	4,000	17,000
40	x	20,000
50	6,250	x
70	10,000	x

A comparison made of the activity against Pseudomonas aeruginosa of sodium hypochlrite (NaOCl) and sodium dichoroisocyanurate (NaDCC) solutions containing 0-40% and 0-70% horse serum respectively. The degree of inactivation of NaOCl and of NaDCC solutions by different concentrations of horse serum is expressed in terms of a neutralization coefficient (figs), which demonstrate that NaDCC solutions are less prone to inactivation by serum than are NaOCl solutions, the dsiparity diverging as serum concentration is increased. In 30% serum and NaDCC solution containing 4000 ppm of available chlorine exhibited similar bactericidal activity to an NaOCl solution containing 17,000 ppm available chlorine (Coates, 1987).

Effect of Hardness

The calcium and magnesium ions in hard water do not inactivate chlorine disinfectants but ferrous or manganous cations, and nitrite or sulphide anions reduce active hypochlorous acid to inactive chloride. Small amounts of potassium bromide may potentiate the action of hypochlorite (Shere et al, 1962).

Effect of Addition of Ammonia or Amino Compounds

The bactericidal activity of free chlorine is considerably diminished when chlorine is added to water containing ammonia or amino compounds.

Weber et al (1944) concluded that if the ammonia concentration is less than one eighth of the total available chlorine added, the ammonia will be

destroyed and the excess chlorine will remain as free available chlorine, exhibiting fast bactericidal action. However, if the concentration of ammonia is greater than one fourth that of free chlorine, the available chlorine will exist in the form of chloramines and thus will be slow in bactericidal activity. Water temperature has an effect on the antibacterial action of the ammonia-chlorine treatment, the efficiency decreasing with lowering of the temperature. (1)

Surfactants

Small amounts (1 to5%) of dodecylbenzene sodium sulphonate may be incorporated into products, but non-ionic surfactants generally should be avoided because they will react rapidly and decompose the chloroisocyanurates (Industrial uses of ACL, 1979; Thompson, 1964) (1)

Organisms resistant to Chlorine

Various types of bacteria, viruses, fungi and algae exhibit different resistance to hypochlorites under diverse practical conditions. This selective resistance of organisms to chlorine may be compensated for either by increased concentration, by lowering of pH, or by raising of temperature. Tonney et al. (1928 and 1930), found that vegetable cells are less resistant to chlorine than the spore-forming group, and that 0.15 to 0.25 ppm available chlorine was sufficient to destroy the vegetative group within 30 seconds. The spore-forming organisms were about 10 to 1000 times more resistant to chlorine than vegetative forms. Phillips (1952), in comparing the relative resistance of spores versus vegetative bacterial organisms, attributed this resistance of spores to changes in molecular configuration of proteins protecting the sulfhydryl groups of essential enzymes, whereas in the case of vegetative forms, these groups seemed to be unprotected. Clarke et al. (1954, 1959) disclosed that some viruses, being more resistant to chlorine, would require considerably higher chlorine levels to inactivate them. Working with Aspergillus niger and Trichophyton rosaceum, Costigan (1931, 1941) showed that mold spores are considerably more resistant to chlorine and that 135 to 500 ppm of hypochlorite solution was necessary to inactivate a high density of spores in several minutes (1).

6. TOXICOLOGICAL STUDIES

6.1 Acute toxicity

6.1.1 Oral

Dichloroisocyanurates are considered no more than slightly toxic when administered as single oral doses in rats. The LD_{50} values range from 600 to 1520 mg/kg (37).

Concentrated sodium dichloroisocyanurate causes gastrointestinal irritancy and is therefore likely to be more toxic orally than the diluted material.

When diluted to 10% or below in water, oral LD_{50}s are rat 740 mg/kg, rabbit 2000=2500 mg/kg, mouse 1230 mg/kg.

The oral human LDLO, lethal dose low = 3570 mg/kg

The oral LD_{50}s of cyanuric acid to rats and mice were 7700 and 3400 mg/kg, rats survived doses of up to 10,000 mg/kg with only slight or negligible toxic effects.

Sodium cyanurate was administered to rats and mice in drinking water at concentrations up to 5375 ppm, the daily compound consumption was 500-700 mg/kg for rats and 2000-2200 mg/kg for mice. In a few male rats and mice on the highest dose, bladder calculi and accompanying hyperplasia were noted.

In a 2 year study on rats, the no-effect level during the first 12 months of sodium cyanurate administration in the drinking water was 2400 ppm (average daily compound consumption 145 mg.kg (males) 266 mg/kg (females). During the last 12 months, the no effect level was 5375 ppm (371 mg/kg (males) 634 mg/kg (females)).

6.1.2 Dermal

In undiluted form, sodium dichloroisocyanurate is corrosive to moist skin and eyes and causes severe irritation. Undiluted sodium dichloroisocyanurate dihydrate is also a severe irritant to rabbit eyes. Sodium dichloroisocyanurate diluted to 5% in water did not cause skin irritation or sensitisation to humans. A 2% solution applied to rabbit eyes caused moderate irritation.

6.1.3 Inhalation

Sodium dichloroisocyanurate is moderately toxic when inhaled, delayed death resulting in 4 out of 10 rats inhaling 200 mg/1 of fine powder for 1 hour, thought similar nose-only exposure to coarse powder caused no deaths. A 4-week inhalation study in which rats inhaled the sodium salt at 32.8 mg/m^3 for 6 hours/day, 5 days/week produced no remarkable pathology. Reduction in body weight gain was the only significant finding .

Several inhalation studies have been conducted with rats exposed to chlorinated isocyanurate dust . In these studies, groups of 10 male and female CD rats were exposed separately to dichloroisocyanurate dust an analytical exposure levels of approximately 3, 10 and 30 mg/m^3 for 6hr/day, 5 days/week for a total of 4 weeks.

No mortality occurred in test animals in these studies. Adverse reactions were observed in mid and particularly high dose animals during the exposure period and included moist rales, nasal discharge, excess salivation, lacrimation and laboured breathing.

The lower exposure concentration of 3mg/m^3 was considered a no-effect level. This dose was calculated by assuming that total volume of air inspired by a rat over a 6 hour exposure period is 0.086m^3. The comparable dose administered to a man (total volume of air inspired over 8 hours is 10.4m^3) exposed to 0.5mg/m^3 of chlorinated isocyanurate dust (a nonimitating level based on Monsanto workplace experience) can be estimated to be about 0.07 mg/kg. This level is lower by a factor 08 than the no-effect exposure level in the rat (34).

6.2 Irritability of the skin and eyes

Data collected in the Sax's Dangerous properties of Industrial Material (35) shows the following results:

		Skin Irritation
Skin Rabbit:	500mg/34 hours	well defined erythema and slight edema.
Skin Rabbit	500mg/72 hours	severe erythema (beet redness) to slight eschar formation (injuries in dept) and severe edema (raised more than 1 mm and extending beyond area of exposure).
Eye Rabbit	10mg/34 hours	severe.

Sodium dichlorocyanurate in the dry form is not appreciably irritating to dry skin. However, when moist, the concentrated material is irritating to skin and also may cause severe eye irritation.

Cyanuric acid at concentrations of up to 8% in water did not cause skin or eye irritation (34) and no cases of dermatitis have been reported among exposed workers.

Rabbits were unaffected by 5ml of 0.8% aqueous suspension dermally on 5 days/week for 3 months; higher concentrations caused slight kidney damage.

6.3 Dermal Sensitivity

Not applicable.

6.4 Information regarding absorption by the skin.

Not applicable.

Available toxicological details regarding the inactive substances.

Adipic Acid

GENERAL STATEMENT

In the USA, adipic acid is classified "Generally Recognised as Safe" by the Food and Drug Administration and finds use in food starches and jellies.

Adipic acid is listed in the US Food Chemicals Codex as a Food Acidulant. Adipic acid dust can irritate eyes, mucous membranes and skin, the latter especially in the presence of moisture e.g. perspiration. Prolonged contact with dust, vapour or aqueous solutions (especially when hot) should be avoided.

Adipic acid has not undergone an assessment of either skin or eye irritancy according to OECD protocol and the only information available is derived from sources in the public domain.

Specifically, adipic acid is reputed to produce severe eye irritation in rabbits following the administration of 20mg over a 24 hour period. This reference is cited in the Registry of Toxic Effects of Chemical Substances, NIOSH 1978.

It is appropriate to note that adipic acid is identified as an eye irritant in the context of the EEC Dangerous Substances Directive 67/548 and is listed in annex 1 of the Directive with risk phrase R36 "irritating to the eyes".

SPECIFIC TOXICITY

Experience on humans: prolonged contact can lead to a drying out of the skin.
LD_{50} oral (rat): ca. 5700mg/kg
LC_{50} inhalation (rat): > 7.7mg/1/4 hour

Primary skin irritation (rabbit): non-irritant
Primary mucous membrane irritation (rabbit eye): irritant.

Acute inhalation hazard (rat): test results dependent on toxicity and volatility): no deaths occurred after 8 hours exposure to an atmosphere saturated with the substance at 20°C.

<u>Sodium Bicarbonate</u>

GENERAL STATEMENT
Sodium bicarbonate is a substance of low toxicity widely used in food and medicine. It should be treated as a low toxicity dust. (Recommended occupational exposure limit (unlisted HSE) 10mg/m^3 – 8 hour TWA total dust, 5mg/m^3 8 hour TWA respirable dust).

SPECIFIC TOXICITY
Ingestion: practically non-harmful. Oral rat LD_{50} 4220 mg/kg.
Skin and eye irritation: sodium bicarbonate is not regarded as constituting a hazard to the skin or eyes. The information that has been referenced in support of this judgement was reported by Laberco Laboratories in 1972, Hudson Laboratories in 1972 and Murphy et al in

1982. The responses observed in these studies included slight conjunctivitis that persisted for up to seven days without any iridial or conrneal involvement. All three investigators concluded that sodium bicarbonate was non-irritant to the eyes.

Two studies have been reported assessing the skin irritation potential of sodium bicarbonate. The method used in these studies was that of Draize et al (1944) which employs a 24 hour contact with abraded and intact rabbit skin. Although this method does not comply completely with current EEC requirements, it may be regarded as being more stringent than the EEC test method. By this method, Laberco Laboratories and Hudson Laboratories found that sodium bicarbonate was not irritant to the skin.

Information regarding the exposure of man and of the user to the biocidal product

The absence of significant cyanurate-induced effects via a variety of studies designed to measure different toxic endpoints, indicates that there is a substantial margin of safety for human exposure to cyanurate in our recommended **JAVEL® AQUA** applications.

1. From the published literature, (e.g. A review of Toxicology Studies on Cyanurate & Its Chlorinated Derivatives. Hammond et al **Environmental Health Perspectives** vol 69 pp. 287-292, 1986), there are many findings from acute, subchronic, reproduction, matabolism, mutagenicity and chlronic/carcinogenicity tests on cyanurate.

2. Cyanuric acid is practically non toxic when administered as a single oral or dermal dose (Rat oral LD_{50} > 10,000 mg/Kg: Rabbit dermal LD_{50} > 7940 mg/Kg).

3. In a series of metabolic studies, cyanurate has been shown to be readily eliminated from the body unchanged.

   (Barbee et al}Toxicologist 3:80 1983;}Inokuchi et al Eisei Kagaku 24: 49-59 1978}Toxicologist 4: 92 1984}

   The findings appeared to be applicable to humans, since cyanurate was found to be rapidly and quantitatively eliminated unchanged in urine following oral ingestion by volunteers (Allen et al Drug. Metab. Rev. 13: 499-516 1982)

4. From Teratology studies it was concluded that sodium cyanurate was not foetotoxic or teratogenic (FMC studies & Cascieri et al Toxicologist 3: 65 1983).

5. From reproductive studies, it was concluded that sodium cyanurate did not interfere with reproductive performance in the rat when administered throughout 3 consecutive generations (Wheeler et al Toxicologist 5: 189 1985).

6. In mutagenicity studies with sodium cyanurate, there was no evidence of cyanurate-induced chromosomal aberrations in rat bone marrow cells (Hammond et al Fundam Appl. Toxicol. 5 655-664 1985).

7. Subchronic toxicity studies of sodium cyanurate demonstrated that there was no evidence of compound-related clinical changes and gross or microscopic lesions in the tissues of high dosage rats and mice. (Industry ad hoc committee and National Toxicology Programme).

8. Chronic Toxicity/Carcinogenicity Studies using sodium cyanurate showed no treatment related mortality, no evidence of dose-related gross or microscopic pathological changes in test and sacrificed animals examined up to 18 months. (Industry ad hoc Committee, Cascieri et al Toxicologist 5: 58 1985).

7. ECOTOXICOLIGICAL STUDIES

7.1 Possible routes of entry to the environment according to the foreseen manner of application or use.

General draining system.

7.2 Information on the ecotoxicology of the active ingredient

Cyanuric acid and derivatives which revert readily to cyanuric acid (e.g. chlorinated isocyanurates) biodegrade readily under a wide variety of natural conditions, and particularly well in systems of either low or zero dissolved-oxygen level, such as anaerobic activated sludge and sewage, soils, muds and muddy streams and river waters, as well as ordinary aerated activated sludge systems with typically low (1 to 3 ppm) dissolved-oxygen levels. Degradation also proceeds in 3.5% sodium chloride solution. Consequently, there are degradation pathways widely available for breaking down cyanuric acid discharged in domestic effluents. The overal degradation reaction is merely a hydrolysis; CO_2 and ammonia are the initial hydrolytic breakdown products. Since no net oxidation occurs during this breakdown, biodegradation of cyanuric acid exerts no primary biological oxygen demand. However, eventual nitrification of the ammonia released will exert its usual biological oxygen demand. Biodegradation of cyanuric acid also takes place in systems of considerable salinity (36)

Studies carried out by the Department of Agricultural Microbiology in Poland (37) have shown that cyanuric acid was not toxic for soil microorganisms examined and was even observed to stimulate the growth of Azotobacter in chernozem. Some isolated fungi were capable of cleaving the ring of cyanuric acid. With the use of ^{15}N-labeled cyanuric acid it was found that the nitrogen taken from this compound by Aspergillus minutus and Pseudogymnoascus sp. was incorporated into their proteins. About 70-90% of ^{15}N derived from cyanuric acid was

detected in the biomass of the examined fungi. The ability of soil microorganisms to cleave the triazine ring is of importance in the detoxication of soils treated with triazine herbicides.

7.3 Available information concerning the ecotoxicity of the active ingredients

Refer to 7.2

8. MEASURES WHICH MUST BE TAKEN FOR THE PROTECTION OF MAN, ANIMALS AND ENVIRONMENT

9. CLASSIFICATION, PACKAGING AND LABELLING

See Material Safety Data Sheet drawn up according to the Regulation of the European Community 1907/2006 (REACH) and 453/2010 available in the company JAVEL POLSKA-www.javel.pl or being an annex to the documentation.

10. SUMMARY

JAVEL® AQUA Effervescent Chlorine Tablets

These small, white tablets are based on dry chlorine donor, sodium dichloroisocyanurate (NaDCC) which is blended with effervescent components before being compressed into tablet form. The result is a fast-dissolving, highly convenient, safer and more accurate alternative to liquid bleach.

Chlorine is regarded by many, including the Health Service and the Governments, as the most effective disinfectant in the fight against disease. That is why it is recommended by the world's major authorities for use against HIV (AIDS) and Hepatitis B viruses and why almost all of the world's piped water supplies are treated with chlorine.

Disinfecting solutions prepared from **JAVEL® AQUA** Effervescent Chlorine Tablets containing NaDCC are fast acting and have a complete spectrum of biocidal activity. Bacteria, bacterial spores, algae, fungi, protozoa and viruses are all sensitive to their effects.

Solutions remaining after the use of **JAVEL® AQUA** contain cyanuric acid or its salts. Within the environment, cyanurate is readily degraded by micro-organisms.

The problem of corrosion associated with liquid bleach has often resulted in the use of more expensive and less effective alternatives. It has been demonstrated that chlorine solutions produced using NaDCC tablets are in general significantly less corrosive.

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DRINKING WATER INSPECTORATE
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Mr B M Brigden
Technical Manager
Hydrachem Ltd
Gillmans Industrial Estate
Billingshurst
West Sussex
RH14 9EZ

Our Ref: DWI 56.4.200
Date: 31 October 1995

Dear Sir

WATER INDUSTRY ACT 1991: SECTION 69
WATER SUPPLY (WATER QUALITY) REGULATIONS 1989
WATER SUPPLY (WATER QUALITY) (AMENDMENT) REGULATIONS 1991

Oasis, Oasis Plus, Oasis 1000 and Oasis 3000
Effervescent chlorine tablets for use as disinfectants for waterworks apparatus, distribution pipes and service reservoirs

1 I am directed by the Secretary of State for the Environment to refer to the application dated 17th May 1995 which you made to the Committee on Chemicals and Materials of Construction for use in Public Water Supplies and Swimming Pools in respect of the use of **Oasis, Oasis Plus, Oasis 1000 and Oasis 3000** in contact with water for public supply. Under Regulation 25(1) of the above-mentioned regulations, the application or introduction by a water undertaker of any substance or product into water which is to be supplied for drinking, washing, cooking or food production purposes is now a matter for the Secretary of State (unless any of the sub paragraphs (b) to (d) apply).

2. With your consent, the Secretary of State has treated your application as one for his approval under Regulation 25(1)(a). He has taken into account the information that you gave to the Committee as to the nature of the product, its method of manufacture and its composition.

3. On the understanding that the material used, its source and the method of manufacture are not now substantially different from those notified to the Committee, and on condition that:

- the dose is such that the final concentration in the water used to wash installations does not exceed 100 mgl^{-1} of free available chlorine;

- Permission or consent is obtained for disposal of any wastewater to a sewer or water course from the relevant water undertaker or from the National Rivers Authority, as appropriate in England and Wales (in Scotland permission or

consent must be obtained from either the relevant water undertaker or River Purification Board depending on the disposal method);

- the products are used in accordance with the documents "Oasis and Oasis Plus Water purification tablets. Accurate, economical chlorine tablets for purification of water" or "Oasis 1000 and Oasis 3000 Water purification tablets. Accurate, economical chlorine tablets for disinfection of water, water tanks and water systems"

The Secretary of State hereby approves the use of **Oasis, Oasis Plus, Oasis 1000 and Oasis 3000** in contact with water which is to be supplied for drinking, washing, cooking or food production purposes.

4. Your attention is drawn to Regulation 25(6) of the Regulations, which enables the Secretary of State to revoke or modify this approval.

5. The Secretary of State will, as required by Regulation 25(8), issue by the end of this year a list containing the above product, the fact of its approval, and any conditions referred to in paragraph 3. However, you may publish this letter, if you wish.

6. This approval is given solely for the purposes of Regulation 25 and should not be taken to imply any recommendation as to the technical merits of **Oasis, Oasis Plus, Oasis 1000 or Oasis 3000** in contact with water for public supply.

Yours faithfully

A. Lloyd

A Lloyd
Chairman of the Committee