

SAFETY DATA SHEET

Product Name: Aquatabs 8.5mg
Revision date: 30.10.2018
Supersedes:

Revision: 0

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance/preparation

Product Name : Aquatabs 8.5mg Effervescent NaDCC Tablet.
Synonyms : None

1.2 Use of the substance/preparation

Aquatabs 8.5mg Tablets are used for disinfection of drinking water for human consumption.

1.3 Company/undertaking identification

Manufacturer : Medentech, Clonard Road, Wexford, Ireland
Tel: +353 53 9117900
Fax: +353 53 9141271
e-mail: msds@medentech.com

Ireland: Poisons Information for medical professionals: Telephone 01 809 2566 (8.00am – 10.00pm).

2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture according to regulation (EC) No. 1272/2008 (CLP/GHS):

Eye Irritant: Category 2 – causes serious eye irritation.

Target Organ Toxicity (single exposure): Category 3 – May cause respiratory tract irritation.

Hazardous to Aquatic Environment - Acute Hazard: Category 1 - Very toxic to aquatic life.

Hazardous to Aquatic Environment - Chronic Hazard: Category 1 - Very toxic to aquatic life with long lasting effects.

Additional Information:

EUH031 – Contact with acids liberates toxic gases.

2.2 Label Elements

Labelling in accordance with regulation (EC) No. 1272/2008 (CLP/GHS):



Signal Word: WARNING

Health Hazard Statement(s)

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Environmental Hazard Statement(s)

H410 - Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statement

EUH031- Contact with acids liberates toxic gas.

Precautionary Statement(s) - Prevention

P261 - Avoid breathing dust/fumes.

P273 - Avoid release to the environment.

P280 -Wear protective gloves/ eye protection.

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Precautionary Statement(s) - Response

P305 + P351 + P338 - IF IN EYES - Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical attention.

P312 - Call a POISON CENTER or doctor if you feel unwell.

P391 - Collect spillage.

Precautionary Statement(s) - Storage

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

Precautionary Statement(s) - Disposal

P501 - Dispose of contents and container in accordance with applicable local, regional, national, and/or international regulations.

2.3 Other Hazard Information

Short-Term Exposure (Acute)

Inhalation: This material contained in this tablet in solid form is not expected to produce respiratory effects. Particles of respirable size are generally not encountered. The respirable fraction for the tablet active ingredient is typically less than 0.1% by weight for the granular and extra granular grades. If it is ground or otherwise in a powdered form, effects similar to a corrosive substance may occur. May cause severe irritation of the respiratory tract with coughing, choking, pain and possibly burns of the mucous membranes. If significant or prolonged exposure occurs, pulmonary oedema may develop, either immediately or more often within a period of 5-72 hours. The symptoms may include tightness in the chest, dyspnea, frothy sputum, cyanosis, and dizziness. Physical findings may include moist rales, low blood pressure and high pulse pressure. Severe cases may be fatal.

Eyes: This material is irritating to the eye. Direct contact may cause severe irritation, pain and burns, possibly severe, and permanent damage including blindness. The degree of injury depends on the concentration and duration of contact.

Skin: Direct contact with wet material or moist skin may cause severe irritation, pain, and possibly burns. Dry material is less irritating than wet material. This material is not a skin sensitiser based on studies with guinea pigs.

Ingestion: Not a likely route of exposure. Harmful if swallowed. Ingestion may cause immediate pain and severe burns of the mucous membranes. There may be discoloration of the tissues. Swallowing and speech may be difficult at first and then almost impossible. The effects on the oesophagus and gastrointestinal tract may range from irritation to severe corrosion. Oedema of the epiglottis and shock may occur.

Repeated Exposure (Chronic)

Based on animal studies, exposure to concentrations of monosodium cyanurate at the solubility limit may cause cardiovascular, kidney and urinary bladder effects.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: eye disorders, respiratory disorders, skin disorders and allergies.

TARGET ORGANS: cardiovascular system, kidneys, bladder.

PBT: The substances contained in this preparation are not identified as PBT substances.

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3. COMPOSITION/INFORMATION ON INGREDIENTS.

Ingredient	Weight in Product (% w/w)	EC (EINECS) No.	EU Classification	CLP Classification
Trosclosene Sodium / 1,3,5 - Triazine - 2,4,6 (1H, 3H, 5H) - trione, 1, 3 - dichloro-, sodium salt CAS No. 2893-78-9	10-62.5%	220-767-7	O; X _n ; N R8, R22, R31, R36/37, R50/53	Danger Oxidizing Solid – Cat. 2; Eyes irritant – Cat.2; Harmful if swallowed – Cat.4; May cause respiratory tract irritation – Cat.3; Very toxic to aquatic life Cat.1; H302; H319; H335; H272; H410; EUH031
Adipic Acid CAS No. 124-04-9	10-40%	204-673-3	X _i , R36,	Warning Eyes irritant Cat.2; H 319
Sodium Carbonate CAS No. 497-19-8	4-15%	207-838-8	X _i , R36	Warning Eyes irritant Cat.2; H 319

Important Note: the classification descriptions given in this section relate to the components in their pure form and do not correspond to the classification of this preparation (see section 16 for full description of R phrases)
The classification of this tablet as supplied is given in Section 15.

4. FIRST AID MEASURES.

Inhalation: Move person to fresh air. Keep at rest in a position comfortable for breathing. If breathing is difficult have trained person administer oxygen. If respiration stops, have a trained person administer artificial respiration. Get medical attention immediately.

Skin contact: Immediately brush off excess chemical and flush with plenty of soap and water. Remove contaminated clothing. Wash clothing before reuse. If signs of irritation or discomfort, seek medical attention.

Eye contact: Immediately flush eyes with a directed stream of water for at least 15 minutes, forcibly holding eyelids apart to ensure complete irrigation of all eye and tissue. Remove contact lens, if present, after first 5 minutes, then continue rinsing eye. Obtain medical advice.

Ingestion: Never give anything by mouth to an unconscious person. If swallowed do not induce vomiting. Give large quantities of water. (If available give several glasses of milk) If vomiting occurs spontaneously keep airway clear and give more water. Get medical attention if there are signs of discomfort or ill health.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

5. FIRE-FIGHTING MEASURES.

Fire Hazard: Negligible fire hazard. If heated by outside source to temperatures above 240°C (464°F), this product will undergo decomposition with the evolution of noxious gases but no visible flame. Wet material may generate nitrogen trichloride, an explosion hazard.

Extinguishing Media

Do not attempt to extinguish the fire without a self-contained breathing apparatus. Do not let the fire burn. Flood with copious amounts of water. Do not use dry chemicals, carbon dioxide or halogenated extinguishers since there is potential for a violent reaction.

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Fire-Fighting Techniques/Comments

Fire-fighters should wear full protective clothing and a self contained breathing apparatus. Using a 10% solution of sodium carbonate, thoroughly decontaminate fire-fighting equipment including all fire fighting wearing apparel after the incident.

Hazardous Combustion Products

Thermal decomposition or combustion products: chlorine, nitrogen, nitrogen trichloride, cyanogens chloride, oxides of carbon, phosgene.

6. ACCIDENTAL RELEASE MEASURES.

Personal Precautions

Avoid contact with skin and eyes. Wear chemical safety goggles and chemical resistant gloves.
Handle product in a well-ventilated area.

Environmental Precautions

Do not release into the environment.
Prevent flow of material into water source and begin monitoring available chlorine and pH immediately.
Notify all downstream users of possible contamination.

Methods for Cleaning Up

Contain spilled material. Any spillage should be cleaned up as soon as possible. Do not add water to spilled material. Using clean dedicated equipment, sweep and scoop all spilled material, contaminated soil, and other contaminated material and place into clean, dry containers for disposal. Do not close drums containing wet or damp material. Do not transport wet or damp material.

7. HANDLING AND STORAGE.

7.1 Handling

Do not get in eyes, on skin or on clothing.
Avoid breathing airborne particulates; wear respiratory protection when exposure is possible.
Use only outdoors or in a well-ventilated area.
Wear goggles or face shield and rubber gloves when handling.
Wash hands thoroughly with soap and water after handling.
Wash contaminated clothing before use.
Vapour space in a closed container may contain a slight amount of chlorine gas and compounds from decomposition of the product.

7.2 Storage

Store in original container and in a cool dry area where temperatures do not exceed 25°C. Keep container tightly closed and store away from incompatible materials (refer to section 10 for list of incompatible materials).
Contact with acid liberates toxic gases.
Do not allow water to get into the container. Keep out of reach of children.
Store locked up.

7.3 Handling Instructions for Specific Uses

Mix only with water. Use clean dry utensils. Do not mix this product with remnants of any other products. Such uses may cause a violent reaction leading to fire or explosion.
Contamination with moisture, organic matter or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion.
Vapour space in a closed container may contain a slight amount of chlorine gas and other chlorine containing compounds from decomposition of the product. Exposure to chlorine gas may cause burning of the eyes, burning of

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the nose and mouth and irritation of the linings of the respiratory tract with coughing, a choking sensation, substernal pain, vomiting, nausea, headache, dizziness and fainting.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION.

The information below relates to Sodium Dichloroisocyanurate in its pure form.

This preparation contains 1,3,5 - Triazine - 2,4,6 (1H, 3H, 5H) - trione, 1, 3 - dichloro-, sodium salt (sodium dichloroisocyanuric acid).

Weight of Sodium Dichloroisocyanurate acid in this preparation product (% w/w): 10-65%

Regulatory Exposure limit(s): None

Derived No Effects Level (DNEL): Workers

Acute Exposures: Systemic Effects - N/A - the substance is corrosive. Risk mitigation measures (RMM) apply to prevent exposure.

Acute Exposures: Inhalation - N/A - the substance is corrosive. Risk mitigation measures (RMM) apply to prevent exposure.

Long-Term Exposure (Systemic Effects): Dermal - 2.3 mg/kg bw/day

Long-Term Exposure (Systemic Effects): Inhalation - 8.11 mg/m³

Derived No Effects Level (DNEL): Population

Acute Exposure: Systemic Effects - Dermal and Inhalation: N/A - the substance is corrosive. **Oral:** the acute oral DNEL is covered by the long term oral DNEL.

Acute Exposure: Dermal - The acute dermal DNEL for local effects is not determined as the test material is corrosive on skin contact.

Acute Exposure: Inhalation - The acute inhalation DNEL for local effects is not determined as the test material is corrosive.

Long-Term Exposure (Systemic Effects): Dermal - 1.15 mg/kg bw/day

Long-Term Exposure (Systemic Effects): Oral - 1.15 mg/kg bw/day

Long-Term Exposure (Systemic Effects): Inhalation - 1.99 mg/m³

Predicted No Effect Concentration (PNEC): Environment

PNEC: Aquatic –

- PNEC aqua (freshwater): 0.00017 mg/L
- PNEC aqua (marine water): 1.52 mg/L
- PNEC aqua (intermittent releases): 0.00017 mg/L

PNEC: Soil –

- PNEC sediment (freshwater): 7.56 mg/kg sediment dw
- PNEC soil: 0.756 mg/kg soil dw

PNEC: Sewage Treatment Plant –

- PNEC STP: 0.59 mg/L

PNEC Mammals (oral) –

- There is no concern for secondary poisoning from the substance or the degradant.

Additional Advice: Chlorine and chlorine compounds may be found in slight amounts in the head space of containers of Products.

Risk management measures (RMM):

RMM: Health

- The use of a half-face respirator with chlorine cartridges (EN140) is required during opening of drums and filling of containers.
- An IOEL of 1.5 mg/m³ chlorine is applicable.
- The substance is corrosive so risk mitigation measures (wearing PPE consisting of gloves (nitrile), coverall and safety glasses) while handling the raw material and where exposure may be possible, would apply.
- Local exhaust ventilation should be used where opening of drums and filling of containers occurs.

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RMM: Environment

• Engineering controls should be used to eliminate emissions of dust and chlorinated fumes as appropriate. All gas emissions should be filtered for dust and treated with sodium hydroxide to remove chlorine and other volatile chlorinated species. Dry solid residues from air filtration systems are collected and either recycled or disposed of. The waste dust from formulation or tableting is sent to an external waste treatment site for disposal.

Engineering controls:

Use only in well-ventilated areas. Provide local exhaust ventilation where dust or mist may be generated. Ensure compliance with applicable exposure limits.

Personal Protective Equipment:

Eye Protection: Wear chemical safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Skin and Body Protection: Wear protective clothing to minimize skin contact. When potential for contact with dry material exists, wear disposable coveralls suitable for dust exposure, such as Tyvek®. Contaminated clothing should be removed and laundered before reuse.

Hand Protection: Wear appropriate chemical resistant gloves.

Protective Material Types: Butyl rubber, Natural rubber, Neoprene, Nitrile, Polyvinyl chloride (PVC), Tyvek®

Respiratory Protection: An approved respirator with EN140 (chlorine) cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, or when symptoms have been observed that are indicative of overexposure. The added protection of a full face piece respirator is required when visible dusty conditions are encountered and eye irritation may occur. A respiratory protection program that meets applicable regulatory requirements must be followed whenever workplace conditions warrant use of a respirator.

9. Physical and Chemical Properties.

Appearance	:	White/off white tablet
Odour	:	Slight chlorine odour.
pH	:	5 – 6
Boiling point/boiling range	:	Not applicable (solid)
Flash point	:	Not applicable (solid)
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	Not applicable (not volatile)
Vapour density	:	Not applicable (not volatile)
Water solubility	:	Completely Soluble in Water
Partition coefficient: n-octanol/water	:	Log Kow = 0
Evaporation rate	:	Not applicable (solid)
Thermal Decomposition Temp	:	225 - 250°C

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10. STABILITY AND REACTIVITY.

Stability Data: Stable.

Incompatibility (Materials to avoid):

Strong acids and/or alkalines. Reducing agents. Combustible material. The active ingredient in this preparation is a strong oxidising agent. The preparation of concentrated solutions or slurries is not recommended. Avoid contact with water on concentrated material in the container. Also avoid contact with easily oxidisable organic material: ammonia, urea or similar nitrogen containing compounds; inorganic reducing compounds; floor sweeping compounds; calcium hypochlorite and alkalis.
Do not get water inside packaging.

Hazardous Decomposition Products: Chlorine, Nitrogen trichloride, Cyanogen chloride, Oxides of carbon, Phosgene.

Polymerisation - Avoid: Hazardous Polymerisation will not occur.

11. TOXICOLOGICAL INFORMATION.

Toxicity and Hazard Report was undertaken by the Russian Disinfection Research Institute on the Sodium Dichloroisocyanurate in an effervescent base (Reference Directive 67/548/EEC Annex VI, Point 2: Classification on the basis of physiochemical properties (adequate information to demonstrate in practice...). Based on this report an EU Competent Authority determined that product does not bear the symbol Harmful, with "Harmful if Swallowed". The Authority determined that the Irritant symbol (Xi) to be appropriate with the R36/37 phrases.

Skin and Eye Contact: Irritating to Eyes. (Note: the in-use solution is not irritating to eyes)

Not classified as Irritating to the skin. Not a Potential Sensitiser.

Ingestion: The Acute Oral LD₅₀ (rat) > 2000mg/kg for the product supplied.

Inhalation: Sodium Dichloroisocyanurate is irritating to the respiratory system.

The information below relates to Sodium Dichloroisocyanurate in its pure form.

This preparation contains 1,3,5 - Triazine - 2,4,6 (1H, 3H, 5H) - trione, 1, 3 - dichloro-, sodium salt (sodium dichloroisocyanuric acid) at levels that may produce a biological effect.

This ingredient is moderately toxic by ingestion. It is irritating to the eyes and respiratory system. No specific toxicological information is available for this preparation.

Weight of Sodium Dichloroisocyanurate acid in this preparation product (% w/w): 10-65%

Toxicological Effect	Exposure Results
Primary Skin Irritation	Moderate Irritation (rabbit, 24hr)
Primary Eye Irritation	Severe Irritation, Corrosive (rabbit, 24 hr)
Acute Toxicity - Oral	1823mg/kg oral-rat LD ₅₀
Acute Toxicity - Inhalation	0.27-1.17 mg/L/4 hour(s) inhalation-rat LC ₅₀
Acute Toxicity - Dermal	>5000 mg/kg skin-rabbit LD ₅₀
Mutagenicity	Not mutagenic in 5 salmonella strains and 1 E. coli strain.
Carcinogenicity	Not classified by NTP, IARC or OSHA
Reproductive Toxicity	There are no known or recorded effects on reproductive function or foetal development
Sensitisation - Skin	No Reports Found
Sensitisation - Respiratory	No Reports Found
Repeated-Dose Toxicity	No Reports Found

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12. ECOLOGICAL INFORMATION.

The information below relates to Sodium Dichloroisocyanurate in its pure form.

This preparation contains 1,3,5 - Triazine - 2,4,6 (1H, 3H, 5H) - trione, 1, 3 - dichloro-, sodium salt (sodium dichloroisocyanuric acid) at levels that may produce a biological effect.

Ecotoxicity: This preparation is likely to be highly toxic to aquatic life. No specific ecotoxicological information is available for this preparation.

Weight of Sodium Dichloroisocyanurate acid in this preparation product (% w/w): 10-65%

Fish Toxicity	Sodium Dichloroisocyanurate acid
Bluegill Sunfish	0.25-1.0 mg/L 96 hours LC ₅₀
Rainbow Trout	0.13-0.36 mg/L 96 hours LC ₅₀
Inland Silverside	1.21 mg/L 96 hours LC ₅₀
Invertebrate Toxicity	Sodium Dichloroisocyanurate acid
Water flea	0.196 mg/L 48 hours LC ₅₀
Mysid Shrimp	1.65 mg/L 96 hours LC ₅₀

Other Toxicity	Sodium Dichloroisocyanurate acid
Mallard Duck	Oral LD ₅₀ : 1916mg/Kg
Mallard Duck	LC ₅₀ : >10,000ppm diet
Bobwhite Quail	Oral LD ₅₀ : 1732 mg/kg
Bobwhite Quail	LD ₅₀ 10000 ppm diet

Persistence & Biodegradability: The materials used in this preparation will not persist in the environment. The free available chlorine from Sodium dichloroisocyanurate is rapidly consumed by reaction with organic and inorganic materials to produce chloride ion. The stable degradation products are chloride ion and cyanuric acid. Sodium Dichloroisocyanurate is subject to hydrolysis. Cyanuric acid produced by hydrolysis is biodegradable.

Bioaccumulative Potential: Trichloroisocyanuric acid hydrolyses in water liberating chlorine and cyanuric acid. These products are not bioaccumulative.

PBT Assessment: The substances contained in this preparation are not identified as PBT substances.

13. DISPOSAL CONSIDERATIONS.

Product Disposal

Do not put product, spilled product, partially filled containers into the waste compactor. Contact with incompatible materials could cause a reaction and fire. Do not transport damp or wet material. Neutralise materials to a non-oxidising state for safe disposal.

Disposal of Packaging

Clean Container and dispose of according to local and national regulations.

14. TRANSPORT INFORMATION.

Not Classified as Dangerous Goods.

15. REGULATORY INFORMATION.

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

The active substance is listed in the following chemical inventories:

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- Australian Chemical Inventory (AICS) – Listed
- Canadian Chemical Inventory (DSL) – Listed
- China Chemical Inventory (IECS) – Listed
- European Union Inventory (EINECS) – No: 220 – 767 -7
- Japan Chemical Inventory (ENCS) – No. 5- 1043
- Korean Chemical Inventory (KECL) – No. KE10215
- New Zealand Chemical Inventory (NZIOC) – Listed
- Philippines Priority Chemical List (PICCS) – Listed
- US Inventory Status (TSCA) – Listed

The mixture is generally classified and registered as a disinfectant, biocide, or pesticide. As such, it is notified to the Pesticide Control Service, Department of Agriculture, Food and the Marine in Ireland under its appropriate trade name.

15.2 Chemical Safety Assessment

No data available.

16. OTHER INFORMATION.

The above information is intended to give general guidance as to health and safety. Whilst it is correct to the best of our knowledge and belief, no warranty can be given or implied that it will be adequate or applicable for all cases nor that the product will be suitable for any particular purpose since conditions of use are outside our control.

R phrases and Symbols used in Section 3

O Oxidising	R8 Contact with Combustible Materials may cause fire.
Xn Harmful	R22 Harmful if swallowed.
	R31 Contact with acid liberates toxic gases.
Xi Irritant	R36/37 Irritating to Eyes and Respiratory System.
N Dangerous for the Environment	R50/53 Very toxic to Aquatic Organisms. May cause long term effects in the aquatic environment.

A UN 6(c) bonfire test conducted on plastic and fibreboard drums of Troclosene Sodium (CAS No. 2893-78-9) showed no evidence of explosive properties. Therefore, per Note T in the 30th ATP to Directive 67/548/EEC, this substance is not labeled as explosive when packaged in plastic or fibreboard containers or in bulk bags.

CLP Classification used in Section 3

Physical Hazard(s): Oxidizing Solid - Category 2

Contact Hazard - Eye: Category 2 - Causes serious eye irritation

Acute Toxicity - Oral: Category 4 - Harmful if swallowed

Target Organ Toxicity (Single Exposure): Category 3 - May cause respiratory tract irritation

Hazardous to Aquatic Environment - Acute Hazard: Category 1 - Very toxic to aquatic life

Hazardous to Aquatic Environment - Chronic Hazard: Category 1 - Very toxic to aquatic life with long lasting effects

Health Hazard Statement(s):	H302 - Harmful if swallowed.
	H319 - Causes serious eye irritation.
	H335 - May cause respiratory irritation.
Physical Hazard Statement(s):	H272 - May intensify fire; oxidizer.
Environmental Hazard Statement(s):	H410 - Very toxic to aquatic life with long lasting effects.
Supplemental Hazard Statement:	EUH031- Contact with acids liberates toxic gas.

The inclusion of these phrases in Section 3 is mandatory according to Directive EC 1907/2006.

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Previous EU Classification of the mixture:

Indication of Danger



Irritant (Xi)



Dangerous for
the environment (N)

Risk Phrases

R31 : Contact with acids liberates toxic gases.
R36/37 : Irritating to eye and respiratory system.
R50/53 : Very Toxic to Aquatic Organisms. May cause long term adverse effects in the aquatic environment.

Safety Phrases

S2 : Keep out of reach of children.
S8 : Keep container dry.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35 : This material and its container must be disposed of in a safe way.
S37 : Wear suitable gloves.
S41 : In case of fire or explosion, do not breathe fumes.
S46 : If tablets are swallowed, seek medical advice immediately and show this container.
S50 : Do not mix with other products.
S61 : Avoid release to the environment. Refer to special instructions/safety data sheet.

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REVISION HISTORY:

Revision No. 0 – Created due to request for individual SDS.

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CERTIFICATE OF ANALYSIS

18 January 2021

PRODUCT	: Aquatabs 8.5mg
BATCH NO	: P695
APPEARANCE	: White/off white, flat bevelled edge plain tablet
AVERAGE WEIGHT	: 49.2mg
WEIGHT UNIFORMITY	: 48.2– 50.2mg
DIAMETER	: 4.75mm
HARDNESS	: 24 – 31N
DISINTEGRATION	: 1 min 18 sec – 1 min 25 sec
FRIABILITY	: Complies
ASSAY	: Each tablet contains 8.69mg sodium dichloroisocyanurate (trolosene sodium) in an effervescent base
AVAILABLE CHLORINE	: 5.61mg/tablet
DATE MANUFACTURED	: 11/2020
EXPIRY DATE	: 11/2025

Compiled by: *G. Conway*
Analyst

Approved by: *P.P. Glen Crogan*
Laboratory Supervisor

**THIS BATCH HAS BEEN PREPARED IN ACCORDANCE WITH
STANDARD OPERATING PROCEDURES AND GOOD MANUFACTURING
PRACTICE**

