INTERNATIONAL MARITIME ORGANIZATION

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MARINE ENVIRONMENT PROTECTION COMMITTEE
68th session
Agenda item 2

MEPC 68/2/6
27 October 2014
Original: ENGLISH

HARMFUL AQUATIC ORGANISMS IN BALLAST WATER

Application for Basic Approval of the VARUNA Ballast Water Treatment System

Submitted by Singapore

SUMMARY

Executive summary:	This document contains the non-confidential information related to the application for Basic Approval of the VARUNA Ballast Water Treatment System submitted in accordance with the *Procedure for approval of ballast water management systems that make use of Active Substances (G9)* adopted by resolution MEPC.169(57). The relevant documents and application dossier will be provided to the Marine Environment Division of the Organization for review by the GESAMP-Ballast Water Working Group. This document contains a summary for translation purposes.[1]
Strategic direction:	7.1
High-level action:	7.1.2
Planned output:	7.1.2.4
Action to be taken:	Paragraph 15
Related documents:	BWM/CONF/36; BWM.2/Circ.13/Rev.2; BWM.2/Circ.37 and BWM.2/Circ.53

INTRODUCTION

1 According to regulation D-3.2 of the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004, ballast water management systems that make use of Active Substances to comply with the Convention shall be approved by the Organization.

2 The Maritime and Port Authority of Singapore with this puts forward an application for Basic Approval in accordance with the *Procedure for approval of ballast water management systems that make use of Active Substances (G9)*. Procedure (G9) identifies

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1 This document is over 20 pages long and, in accordance with paragraph 6.11 of the Committees' Guidelines (MSC-MEPC.1/Circ.4/Rev.2), only the first four pages will be translated into the three working languages, with the annex in English only.

the required information (resolution MEPC.169(57), annex, paragraph 4.2.1) including provisions for risk characterization and analysis (resolution MEPC.169(57), annex, paragraph 5.3), which, according to section 6, should be evaluated by the Organization.

3 At its sixty-sixth session, MEPC endorsed the revised Methodology for information gathering and conduct of work of the GESAMP-BWWG, which has been disseminated as BWM.2/Circ.13/Rev.2. Furthermore, the non-confidential information presented here, is structured according to circular BWM.2/Circ.37 on information that should be made available in proposals for approval of ballast water management systems in accordance with the Procedure for approval of ballast water management systems that make use of Active Substances (G9).

4 On behalf of the Maritime and Port Authority of Singapore (MPA) a recognized organization (Lloyd's Register Asia), has verified this application dossier and the test protocols applied for all tests undertaken and believes it to satisfy the data requirements of Procedure (G9) adopted by resolution MEPC.169(57).

5 In accordance with circular BWM.2/Circ.53, Singapore submits the non-confidential part of the manufacturer's dossier, in the annex to this document, to the Organization for evaluation according to Procedure (G9). The complete application dossier will be made available to the experts of the GESAMP-BWWG with the understanding of confidential treatment.

SUMMARY

Technical description of the VARUNA Ballast Water Treatment System

6 The VARUNA Ballast Water Treatment System (VARUNA BWTS) is a once-through electrochemical treatment system with a combination of physical separation (filtration), electrochemical treatment and neutralization processes. The primary, secondary treatments are performed during ballasting operation and the tertiary treatment is carried out during deballasting operation. The entire treatment process is monitored by a control unit that optimizes the treatment process according to the treatment requirement.

Primary treatment

7 Primary treatment is carried out by a self-cleaning filter equipped with automatic backwash actuated by differential pressure (DP) switch/gauge/timer. The primary treatment aids in physical separation and removal of larger micro-organisms and particulate matter of size ≥ 40 μm and the separated particulate matter is removed by self-cleaning backwash cycles and discharged back to the source environment. This physical separation process, not only reduces the magnitude of the required electrochemical treatment, but also reduces the load of organic matter in the ballast tanks and the discharge water making the system environmentally friendly.

Secondary treatment

8 The ballast water filtered by the primary treatment process passes through the bipolar electrolyzer where the secondary treatment, i.e. electrochemical disinfection, occurs. The secondary treatment is performed by a bipolar electrolyzer that generates sodium hypochlorite (Active Substance) by partial electrolysis of the sodium chloride available in the ballast water. The sodium hypochlorite along with the other oxidants formed during the electrolysis of ballast water neutralizes the micro-organisms, thereby disinfecting the entire ballast water before storing in ballast tanks. The residual chlorine available in the form of

sodium hypochlorite and other oxidants maintains the sterility of the ballast water during storage, until discharge.

9 VARUNA BWTS is designed to produce a TRO level of 10 ± 1 mg/l (equivalent of chlorine). The tests of the VARUNA BWTS pilot plant conducted for Basic Approval showed that compliance with the D-2 standard can be achieved at 10 ± 1 mg/l.

Tertiary treatment

10 During discharge of ballast water, the residual oxidants (TRO), if any, could potentially harm the marine organisms and the ecosystem receiving the discharged ballast water. Hence, neutralizing the available TRO before discharging prevents the ensuing damage to the ecosystem. In the VARUNA BWTS, the residual TRO in the treated water is neutralized by the tertiary treatment process by dosing sodium thiosulphate (neutralizing agent) before discharge into the environment. Thus, the residual TRO (measured as chlorine) in the discharge water is neutralized before its discharge, to achieve the Maximum Allowable Discharge Concentration (MADC) of Active Substance of less than 0.2 mg/l (TRO) for its safe discharge into the environment.

11 Risk assessment was conducted for the Active Substance, Relevant Chemicals and Other Chemicals. The risk assessment showed that except for the handling of neutralization chemical carried onboard, there is no other means of exposure to chemicals from handling of chemicals on board as injection of the neutralization chemical is automated. It is recommended that usage of Personal Protective Equipment (PPE) will prevent any accidental contact with the chemical at the time of handling or preparation. However, the results on risk assessment to crew based on DNEL and DMEL shows that RCR is exceeding 1, for tribromomethane (based on DNEL), and for bromate ion, dibromochloromethane, dichlorobromomethane and tribromomethane (based on DMEL) and hence it indicates that unacceptable risk for the crew or inspecting officer, through exposure in the ballast tank, cannot be excluded. As the cause for the presence of these molecules above acceptable limits could not be identified with the available results, a second tier assessment considering specific risk control measures, such as aeration, ventilation of ballast tanks prior and during tank entry, respiratory protection, skin and eye protection will be carried out during the land based testing and the results with suitable mitigation measures will be submitted along with the application for final approval.

12 Predicted Environmental Concentration/Predicted No Effect Concentration (PEC/PNEC) ratios were estimated by using the Marine Antifoulant Model for Predicted Environmental Concentration for Ballast Water (MAMPEC-BW). The results of the environmental risk assessment for the water treated using VARUNA BWTS revealed that the PEC/PNEC ratio was found to exceed 1 for chronic exposure to monochloroacetonitrile in the harbour and for acute exposure to monochloroacetic acid near ship. The prediction indicates that unacceptable risk for aquatic environment cannot be excluded. This will be further examined during the land based testing to identify the cause and necessary mitigation measures will be included to control the formation of monochloroacetonitrile and monochloroacetic acid. The results along with mitigations measures, if any, will be submitted as part of the Application for Final Approval. However, the resulting RCR showed that a chronic effect to the general public from the uptake of chemicals, through inhalation, dermal uptake, swallowing seawater and oral uptake of seafood, from the discharged ballast water is unlikely.

13 The evaluation of environmental risks is based on persistence/bioaccumulation/toxicity (PBT) criteria, and was primarily done on the 12 relevant substances and the Active Substance of sodium hypochlorite. None of the substances were categorized as PBT substances.

Neutralization

14 VARUNA BWTS is equipped with a neutralization system to ensure a concentration compliant with the GESAMP-BWWG discharge criteria allowing discharge without a specified holding time.

ACTION REQUESTED OF THE COMMITTEE

15 The Committee is invited to consider the proposal for approval and decide as appropriate.

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ANNEX

**VARUNA BALLAST WATER TREATMENT SYSTEM
APPLICATION FOR BASIC APPROVAL**

**Checklist: BWM.2/Circ.13/Rev.2 and BWM.2/Circ.37
By Kadalneer Technologies Pte. Ltd.**

Section No. in BWMC.2/ Circ.13/ Rev.2	VARUNA BWTS Dossier section	Section No. in VARUNA BWTS dossier	Section No. in BWM.2/ Circ.37	Section No. in Procedure (G9)	Comments
1	**INTRODUCTION**	1	1	Not available	
2	**GENERAL**	1	2	Not available	
3	**APPLICATION DATA SET**	3	3	4	
3.1	General	3.1	Not available	4.1	
3.2	Identification of the Active Substance or Preparation	3.2	3.2	4.1	
3.2.1	Preparations	3.2.1	3.2.1	4.1.1	
3.2.2	Active Substances	3.2.1	3.2.2	4.1.1	
3.2.3	Relevant Chemicals	3.2.2	3.2.3	2.1.4 and 4.1.1	
3.2.4	Other Chemicals	3.2.3	3.2.4	Not available	
3.3	Data on effects on aquatic plants, invertebrates and fish, and other biota, including sensitive and representative organisms	3.3	3.3	4.2.1.1	

Section No. in BWMC.2/ Circ.13/ Rev.2	VARUNA BWTS Dossier section	Section No. in VARUNA BWTS dossier	Section No. in BWM.2/ Circ.37	Section No. in Procedure (G9)	Comments
3.3.1	General	3.3	Not available	4.2.1.1	
3.3.2	Acute aquatic toxicity	3.3	3.3.2	4.2.1.1	
3.3.3	Chronic aquatic toxicity	3.3	3.3.3	4.2.1.1	
3.3.4	Endocrine disruption	3.3	3.3.4	4.2.1.1	
3.3.5	Sediment toxicity	3.3	3.3.5	4.2.1.1	
3.3.6	Food web/ population effects	3.3	3.3.6	4.2.1.1	
3.4	Data on mammalian toxicity (Procedure (G9(, paragraph 4.2.1.2)	3.4	3.4	4.2.1.2	
3.4.1	General	3.4	3.4.1	4.2.1.2	
3.4.2	Acute toxicity	3.4	3.4.2	4.2.1.2	
3.4.3	Effects on skin and eye	3.4	3.4.3	4.2.1.2	
3.4.4	Repeated- dose toxicity	3.4	3.4.4	4.2.1.2	
3.4.5	Chronic toxicity	3.4	3.4.5	4.2.1.2	
3.4.6	Developmental and reproductive toxicity	3.4	3.4.6	4.2.1.2	
3.4.7	Carcinogenicity	3.4	3.4.7	4.2.1.2	
3.4.8	Mutagenicity / Genotoxicity	3.4	3.4.8	4.2.1.2	
3.4.9	Toxicokinetics	3.4	3.4.9	4.2.1.2	
3.5	Data on environmental fate and effect under aerobic and anaerobic conditions (Procedure (G9), paragraph 4.2.1.3)	3.5	3.5	4.2.1.3	

Section No. in BWMC.2/ Circ.13/ Rev.2	VARUNA BWTS Dossier section	Section No. in VARUNA BWTS dossier	Section No. in BWM.2/ Circ.37	Section No. in Procedure (G9)	Comments
3.5.1	General	3.5	Not available	4.2.1.3	
3.5.2	Modes of degradation (biotic; abiotic)	3.5	3.5.2	4.2.1.3	
3.5.3	Persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters)	3.5	3.5.3	4.2.1.3	
3.5.4	Bioaccumulation, partition coefficient, octanol/water partition coefficient	3.5	3.5.4	4.2.1.3	
3.5.5	Bioavailability/ biomagnificiation/ bioconcentration	3.5	3.5.5	4.2.1.3	
3.5.6	Reaction with organic matter	3.5	3.5.6	4.2.1.3	
3.5.7	Potential physical effects on wildlife and benthic habitats	3.5	3.5.7	4.2.1.3	
3.5.8	Potential residues in seafood	3.5	3.5.8	4.2.1.3	
3.5.9	Any known interactive effects	3.5	3.5.9	4.2.1.3	
3.6	Physical and chemical properties for the Active Substances and Preparations and treated ballast water, if applicable (Procedure (G9), paragraph 4.2.1.4)	3.6	3.6	4.2.1.4	
3.6.1-16	Physical and chemical properties for the Active Substances and Preparations and treated ballast water, if applicable (Procedure (G9), paragraph 4.2.1.4)	3.6	3.6.1-16	4.2.1.4	
3.6.17-20	pH, Salinity and TOC, DOC, % D25angelparticulate matter	3.6	3.6.17-20	4.2.1.4	

Section No. in BWMC.2/ Circ.13/ Rev.2	**VARUNA BWTS Dossier section**	**Section No. in VARUNA BWTS dossier**	**Section No. in BWM.2/ Circ.37**	**Section No. in Procedure (G9)**	**Comments**
3.7	Analytical methods at environmentally relevant concentrations	3.7	3.7	4.2.1.5	
4	**USE OF ACTIVE SUBSTANCE OR PREPARATION**	4	4	4	
4.1	The manner of application	4.1 & 4.2	4.1	4.2.6 & 4.2.7	
5	**RISK CHARARACTERIZATION - HUMAN HEALTH**	5	6	5	
6	**RISK CHARARACTERIZATION - ENVIRONMENT**	6	6	5	
6.1	Screening for persistence, bioaccumulation and toxicity (Procedure (G9), paragraph 5.1)	6.1	6.1	5.1	
6.1.1	Persistence (G9:5.1.1.1)	6.1	6.1	5.1.1.1	
6.1.2	Bioaccumulation (G9: 5.1.1.2)	6.1	6.1	5.1.1.2	
6.1.3	Toxicity tests (G9: 5.1.1.3)	6.1	6.1	5.1.1.3	
6.1.4	Does the Active Substance and/or Preparation meet all three criteria for PBT?	6.1	6.1	6.4.1	
6.2	Evaluation of the treated ballast water	6.2 and 6.3	6.2	5.2	
6.2.1	General	6.2 and 6.3	Not available	5.2.1	
6.2.2	Basic Approval	6.2 and 6.3	6.2	5.2.1.1	
6.2.3	Final Approval	Not applicable	Not available	5.2.1.2	

Section No. in BWMC.2/ Circ.13/ Rev.2	VARUNA BWTS Dossier section	Section No. in VARUNA BWTS dossier	Section No. in BWM.2/ Circ.37	Section No. in Procedure (G9)	Comments
6.2.4	Comparison of effect assessment with discharge toxicity	6.2 and 6.3	6.2	5.2.2 - 5.2.6	
6.2.5	Determination of holding time	6.3	6.2.3	5.2.7	
6.3	Risk characterization and analysis	6.3	6.3	5.3	
6.3.1	Prediction of discharge and environmental concentrations	6.3	6.3.1	6.4.4	
6.3.2	Effects assessment	6.2	6.3.2	5.3.9	
6.3.3	Effects on aquatic organisms	6.2	6.3.3	5.3.9 - 5.3.11	
6.3.4	Comparison of effect assessment with discharge toxicity	6.4 and 7.3	6.3.4	5.3.14	
7	RISK ASSESSMENT	7	7	6	
7.1	Risk to safety of ship	7.1	7.1	6.3	
7.2	Risks to human health	7.2	7.2	6.3	
7.2.1	General	7.2.1	7.2	6.3.1	
7.2.2	Health effects in humans	7.2.2	7.2.2	5.3.12 & 6.3.2	
7.2.3	Human exposure scenario	7.2.3	7.2.3	6.3.3	
7.3	Risks to the aquatic environment	7.3	7.3	6.4.1 - 6.4.3	
8	ASSESSMENT REPORT	8	8	4.3	
9	MODIFICATION TO THE APPLICATION	Not applicable	Not available	8.4	
10	FINAL APPROVAL	Not applicable	Not available	8.2	

Preface

This document concerns the annex for the proposal for Basic Approval of the VARUNA Ballast Water Treatment System, with the exclusion of confidential parts.

The contents of this document are based on the annex of BWM.2/Circ.13/Rev.2 (15 April 2014) revised Methodology for information gathering and conduct of work of the GESAMP-BWWG", endorsed by MEPC 66 on 4 April 2014.

Sections 1 (Introduction) and 2 (General) are replaced by a section 1 on company information and a section 2 on system description, as required for the annex on the non-confidential dossier.

This annex needs to be preceded by the formal application for Basic Approval of the VARUNA BWTS which is added here in front part of the report as prepared by IMARES.

1 INTRODUCTION

KADALNEER TECHNOLOGIES PTE. LTD. approached the consortium including NIOZ, GoConsult and IMARES Wageningen UR for support in the achievement of the IMO type approval of the VARUNA Ballast Water Treatment Systems (BWTS) that applies sodium hypochlorite, produced by electrochemical process, as Active Substance.

A necessary first step towards this type approval is the Basic Approval. Basic Approval is granted by MEPC after evaluation of the Basic Approval dossier by the GESAMP-Ballast Water Working Group (GESAMP-BWWG). For this the toxicity of sodium hypochlorite treatment and potentially related disinfection by-products must be assessed and the potential human and environmental risks must be addressed.

The aim of this document is to collect available data on the toxicity of sodium hypochlorite treatments, and to perform the risk analyses conform the requirements of the GESAMP-BWWG, in order to obtain Basic Approval for the VARUNA BWTS. In case it is concluded that the available existing data is not sufficient for an adequate risk assessment, recommendations will be formulated how these data gaps can be filled.

1.1 Company information

KADALNEER TECHNOLOGIES PTE. LTD. was incorporated on 2 April 2014 (Singapore Registration No. 201409684W). The Company is in the business of ballast water management systems which is a regulatory driven equipment to be fitted onboard all seagoing maritime vessels in accordance to the BWM Convention.

The vision of KADALNEER TECHNOLOGIES PTE. LTD. is to achieve excellence in cost effective ballast water management systems.

Its mission is to actively partner its customers to provide innovative and sustainable technical solutions.

The Company develops ballast water management systems, gets it certified and approved by governing bodies before marketing it to the maritime industry.

The VARUNA BWTS described in this dossier has not been submitted before, and therefore no evaluations are available from previous applications.

An operating and maintenance manual of the pilot ballast water management system is annexed to the confidential Basic Approval application.

2 DESCRIPTION OF THE SYSTEM

2.1 Method

The VARUNA BWTS is a once-through electrochemical treatment system with a combination of physical separation (filtration), electrochemical treatment and neutralization processes.

2.2 Generic process details of VARUNA BWTS

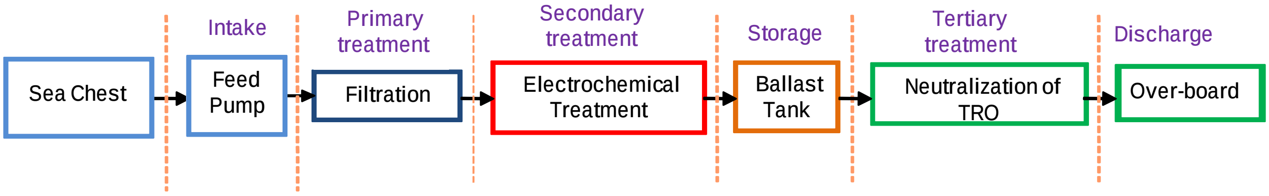


Figure 1: Generic process flow of VARUNA Ballast Water Treatment System

VARUNA BWTS comprises a three stage treatment process, wherein the primary and secondary treatment are performed during ballasting operation and the tertiary treatment is carried out during deballasting operation. The entire treatment process is monitored by a control unit that optimizes the treatment process according to the treatment requirement. The following are the processes performed during various treatment stages.

Primary treatment (ballasting operation)

Primary treatment is carried out by a self-cleaning filter equipped with automatic backwash actuated by differential pressure (DP) switch / gauge / timer. The primary treatment aids in physical separation and removal of larger micro-organisms and particulate matter and the separated particulate matter is removed by self-cleaning backwash cycles. As ballast water carrying particulate matter and organisms passes through the filter, the filter retains the particles and water borne organisms of size ≥ 40 µm within the chamber. The retained particles accumulate on the filter resulting in build-up of pressure inside the chamber. This change in differential pressure actuates the feedback mechanism that in turn initiates the backwash process whereby the accumulated particles and organisms are siphoned out and discharged back to the source environment. The filter is also equipped with a timer for actuating the self-cleaning process on a pre-set timely manner. Thus filtration process aids in containment and redirection of a major portion of the particulate matter and the organisms back in to the source environment. This physical separation process, not only reduces the magnitude of the required electrochemical treatment, but also reduces the load of organic matter in the ballast tanks and the discharge water making the system environmentally-friendly.

Secondary treatment (ballasting operation)

The ballast water filtered by the primary treatment process passes through the bipolar electrolyzer where the secondary treatment, i.e. electrochemical disinfection, occurs. The secondary treatment is performed by a bipolar electrolyzer that generates sodium hypochlorite (Active Substance) by partial electrolysis of the sodium chloride available in the ballast water. The sodium hypochlorite along with the other oxidants formed during the electrolysis of ballast water neutralizes the micro-organisms, thereby disinfecting the entire ballast water before storing in ballast tanks.

In the bipolar electrolyzer, as the ballast water passes through an array of direct current energised anode and cathode elements several electrochemical reactions are initiated that result in dissociation of salts and water molecules present in the ballast water. The dissociated ions further react and form the disinfection agents. For example, as the sodium chloride (NaCl) is the major component present in the seawater, the electrolytic process results in its dissociation resulting in sodium (Na^+) and chloride (Cl^-) ions. Simultaneously, hydrogen and hydroxyl ions are formed by dissociation of water (H_2O) molecules.

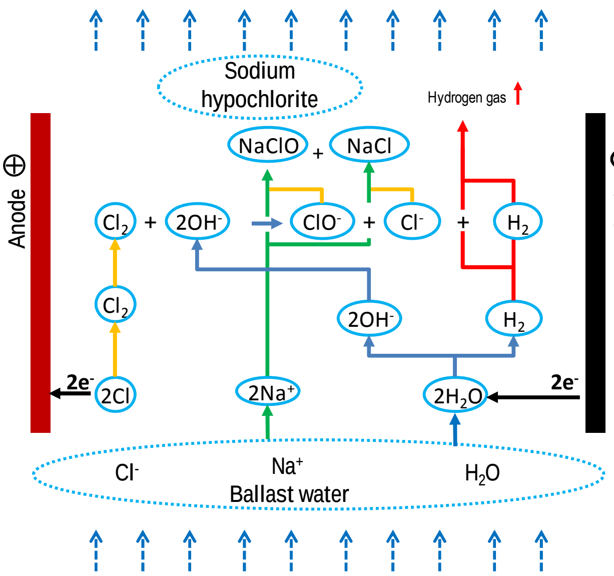


Figure 2: Electrochemical reaction

Electrode reaction:

Anode reaction: $2Cl^- \rightarrow Cl_2 + 2e^-$
Cathode reaction: $2H_2O + 2Na^+ + 2e^- \rightarrow 2Na^+ + 2OH^- + H_2$ (g)

In solution, the ions migrate from cathode to anode and vice versa and in the presence of water react with each other resulting in the formation of sodium hydroxide (NaOH) molecules, chlorine (Cl_2) and hydrogen (H_2).

$$2\ NaCl\ (aq) + 2H_2O \rightarrow 2\ NaOH + Cl_2\ (g) + H_2\ (g) \qquad (1)$$

The chlorine generated in reaction (1) further reacts with the sodium hydroxide, a co-product of the reaction, to form sodium hypochlorite (NaOCl) along with sodium chloride (NaCl) and water (H_2O) molecules.

$$Cl_2 + 2NaOH \leftrightharpoons NaCl + NaOCl + H_2O \qquad (2)$$

The sodium hypochlorite solution reacts in an equilibrium reaction, resulting in hypochlorous acid, an efficient disinfectant.

$$NaOCl + H_2O \leftrightharpoons NaOH + HOCl \qquad (3)$$

Simultaneously, several other reactions occur during the electrochemical process resulting in generation of oxidants such as, hydroxyl radical (OH^-), hydrogen peroxide (H_2O_2), hypochlorite ion (OCl^-), hypobromite ion (OBr^-) etc.

These mixed oxidants (TRO or Total Residual Oxidants), produced at a concentration of 10 ± 1 mg/l during the electrolysis of ballast water, react spontaneously with the microorganisms and the organic matter available in the ballast water through oxidation-reduction reactions neutralizing the microscopic organisms ensuring complete sterilization of the ballast water. The residual chlorine available in the form of sodium hypochlorite and other oxidants maintains the sterility of the ballast water during storage, until discharge. The small amount of hydrogen gas formed as by-product during the electrochemical process is vented out safely from the ballast tanks through the vent.

Tertiary treatment (deballasting operation)

During discharge of ballast water, the residual oxidants (TRO), if any, could potentially harm the marine organisms and the ecosystem receiving the discharged ballast water. Hence, neutralizing the available TRO before discharging prevents the ensuing damage to the ecosystem. In the VARUNA BWTS, the residual TRO in the treated water is neutralized by the tertiary treatment process by dosing sodium thiosulphate (neutralizing agent) before discharge in to the environment.

In VARUNA BWTS, the tertiary treatment is carried out by the neutralization system comprising, in sequence, a TRO analyzer (controller) (higher range: 1 to ≥ 10 mg/l), a dosing pump (connected to a control unit and storage tank), storage tank, a control unit, a static mixer and a TRO monitor (lower range: 0 – 5 mg/l). The first (higher range) TRO analyzer measures the concentration of available TRO (as chlorine) and based on the available concentration the control unit controls the dosing pump to dose the required quantity of sodium thiosulphate into the discharge line. The static mixer located after the dosing pump aids in proper mixing of sodium thiosulphate in the ballast water to complete the neutralization process. Finally, a second TRO-sensor (lower range – 0 to 5 mg/l) monitors the residual chlorine levels in the discharge water. A residual TRO concentration of less than 0.2 mg/l (equivalent of chlorine) is proposed to be maintained in the discharge water. The following typical reaction illustrates the residual chlorine neutralization process and the products formed:

When mixed with chlorine-containing water, sodium thiosulphate reacts with the chlorine according to the following equation:

$$Na_2S_2O_3 + Cl_2 + H_2O \rightarrow Na_2SO_4 + S + 2HCl \quad (4)$$

Sodium thiosulphate also reacts with hydrochloric acid (produced in reaction 4) to form breakdown products such as sulphur, sodium chloride, sulphur dioxide and water:

$$Na_2S_2O_3 + 2HCl \rightarrow 2NaCl + H_2O + S + SO_2 \quad (5)$$

Thus, the residual TRO (measured as chlorine) in the discharge water is neutralized before its discharge, to achieve the Maximum Allowable Discharge Concentration (MADC) of Active Substance of less than 0.2 mg/l (TRO) for its safe discharge in to the environment.

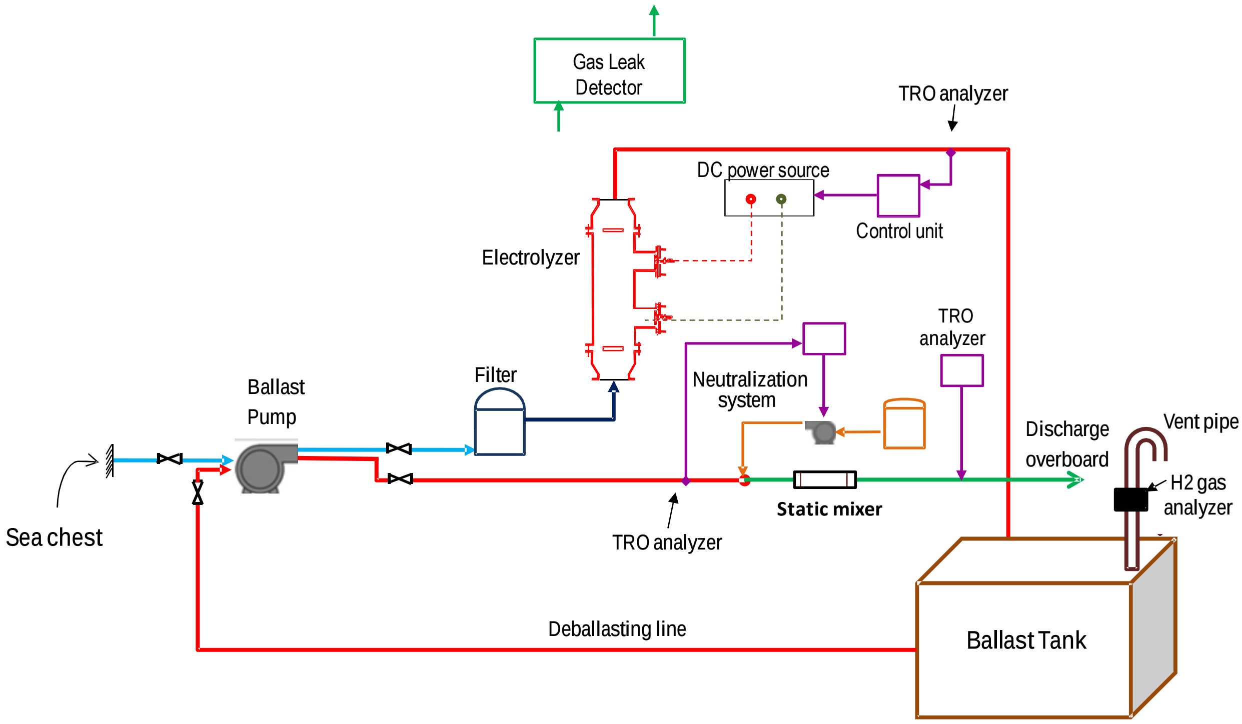


Figure 3: Generic process flow diagram of VARUNA Ballast Water Treatment System

2.3 Chemicals associated with the system

2.3.1 Identification of chemicals associated with the ballast water management system

Active Substances

The VARUNA BWTS generates sodium hypochlorite (Active Substance), by electrochemical process.

Relevant Chemicals

Relevant Chemicals were measured in the prototype test facility of the pilot VARUNA BWTS by use of standardized methods, and with detection limits as presented in table 1. During both the brackish water test and the marine test, environmental water quality parameters were within acceptable limits as stated by the IMO Guidelines (G8) minimum requirement for challenge water quality. Data are presented in table 2. Samples were stored in thermo boxes from the collection time and during transport until samples were handled in the laboratory for analyses.

As the result of the theoretical analysis of the reaction of Active Substance (sodium hypochlorite) generated from electrolysis of ballast water, 43 substances were identified as Relevant Chemicals by the Relevant Chemicals generation test with the prototype test facility (17 m^3) of the VARUNA Pilot BWT System.

Table 3 below shows the results of chemical analyses in the Relevant Chemical generation test.

Table 1: Applied methods of analyses and detection limits of Relevant Chemicals

Test	Detection Limit	Reference Method
Total Trihalomethanes (TTHM) μg/L	1	USEPA 8260C
Trichloromethane μg/L	1	USEPA 8260C
Dichlorobromomethane μg/L	1	USEPA 8260C
Dibromochloromethane μg/L	1	USEPA 8260C
Tribromomethane μg/L	1	USEPA 8260C
2,4,6 - Tribromophenol ug/L	1	USEPA 8270D
Halogenated Acetic Acids (HAA) μg/L	1	USEPA 552
Monochloroacetic Acids (MCAA) μg/L	10	USEPA 552
Dichloroacetic Acids (DCAA) μg/L	2	USEPA 552
Trichloroacetic Acids (TCAA) μg/L	2	USEPA 552
Monobromoacetic Acids (MBAA) μg/L	2	USEPA 552
Dibromoacetic Acids (DBAA) μg/L	2	USEPA 552
Tribromoacetic Acids (TBAA) μg/L	5	USEPA 552
Bromochloroacetic acids (BCAA) μg/L	2	USEPA 552
Dibromochloroacetic acids (DBCAA) μg/L	5	USEPA 552
Dichlorobromoacetic Acids (DCBAA) μg/L	5	USEPA 552
Dalapon μg/L	5	USEPA 552
Dichloroacetonitrile μg/L	1	USEPA 551
Dibromoacetonitrile μg/L	1	USEPA 551
Bromochloroacetonitrile μg/L	1	USEPA 551
Monobromoacetonitrile μg/L	1	USEPA 551
Monochloroacetonitrile μg/L	1	USEPA 551

Table 2: Environmental water quality parameters taken during intake (challenge/test water) for brackish water test (left) and marine water test. G8 = intake requirement, target = targeted concentration for testing, achieved concentration = concentration during intake of test water

	Brackish water range (intake)			High salinity range (intake)		
Parameter	**G8**	**Target**	**Achieved concentration**	**G8**	**Target**	**Achieved concentration**
Salinity, PSU	3-32	22	20.93 ± 0.05	> 32	33	33.58 ± 0.12
Total suspend solids (TSS), mg/l	> 50	70	61.87 ± 1.76	> 1	10	18.07 ± 2.12
Dissolved organic carbon (DOC), mg/l	> 5	7	7.99 ± 0.56	> 1	2.5	3.95 ± 0.26
Particulate organic carbon (POC), mg/l	> 5	7	5.24 ± 0.30	> 1	2.5	4.78 ± 0.99
pH	-		7.81 ± 0.07			8.22 ± 0.01
Temperature, °C	-		29.3 ± 0.1			30.9 ± 1.2
Dissolved oxygen, mg/l	-		6.50 ± 0.06			5.27 ± 0.06
Turbidity, NTU	-		13.57 ± 2.78			5.87 ± 1.06

Table 3: Chemical analysis of treated ballast water in different salinities as reported by the applicant

Chemical	**Detection limit**	**Brackish water**			**Seawater**		
	(µg/L)	During treatment (µg/L)	After 24 h (µg/L)	After 48 h (µg/L)	During treatment (µg/L)	After 24 h (µg/L)	After 48 h (µg/L)
Acetaldehyde	1	ND	ND	ND	ND	ND	ND
Bromate ion	5	ND	ND	ND	32	45	ND
Bromochloroacetic acid	2	7	5	ND	ND	6	ND
Bromochloroacetonitrile	1	2	2	2	2	3	ND
Chloral hydrate	1	ND	ND	ND	ND	ND	ND
Chloropicrin	1	3	2	ND	5	2	ND
Dalapon	5	ND	ND	ND	ND	ND	ND
1,2-dibromo-3-chloropropane	1	ND	ND	ND	ND	ND	ND
Dibromoacetic acid	2	34	13	8	ND	24	13
Dibromoacetonitrile	1	4	ND	ND	2	21	ND
Dibromochloroacetic acid	5	5	13	12	ND	18	15
Dibromochloromethane	1	6	12	17	13	41	42
1,1-dichloroethane	1	ND	ND	ND	ND	ND	ND
1,1-dibromoethane	1	ND	ND	ND	ND	ND	ND
Dibromomethane	1	ND	ND	ND	ND	ND	ND

Chemical	**Detection limit**	**Brackish water**			**Seawater**		
	(µg/L)	During treatment (µg/L)	After 24 h (µg/L)	After 48 h (µg/L)	During treatment (µg/L)	After 24 h (µg/L)	After 48 h (µg/L)
Dichloroacetic acid	2	ND	ND	ND	ND	ND	ND
Dichloroacetonitrile	1	ND	ND	ND	2	2	1
Dichlorobromoacetic acid	5	ND	ND	ND	ND	ND	ND
Dichlorobromomethane	1	ND	3	3	3	10	8
1,2-dichloroethane	1	ND	ND	ND	ND	ND	ND
Dichloromethane	1	ND	ND	ND	ND	ND	ND
1,2-dichloropropane	1	ND	ND	ND	ND	ND	ND
Formaldehyde	1	ND	ND	ND	ND	ND	ND
Monobromoacetic acid	2	11	ND	5	ND	7	6
Monobromoacetonitrile	1	ND	ND	ND	ND	ND	ND
Monochloroacetic acid	10	ND	ND	ND	ND	30	14
Monochloroacetonitrile	1	ND	ND	ND	ND	4	7
Monochloroamine	100	ND	ND	ND	ND	ND	ND
Potassium bromate	5	ND	ND	ND	ND	ND	ND
Sodium bromate	5	ND	ND	ND	37	52	ND
Sodium hypochlorite	100	ND	ND	ND	ND	ND	ND
Sodium thiosulphate	1000	ND	ND	ND	ND	ND	ND
Tetrachloromethane	1	ND	ND	ND	ND	ND	ND
Tribromoacetic acid	5	30	147	129	ND	144	108
Tribromomethane	1	236	720	652	235	1076	1099
2,4,6-tribromophenol	1	ND	ND	ND	ND	ND	ND
Trichloroacetic acid	2	ND	ND	ND	ND	ND	ND
Trichloroacetonitrile	1	ND	ND	ND	ND	ND	ND
Trichloroethene	1	ND	ND	ND	ND	ND	ND
1,1,1-trichloroethane	1	ND	ND	ND	ND	ND	ND
1,1,2-trichloroethane	1	ND	ND	ND	ND	ND	ND
Trichloromethane	1	ND	ND	ND	ND	ND	ND
Trichloropropane	1	ND	ND	ND	ND	ND	ND

Each value in table is the maximum of three samples.
N.D.: Not Detected.
Limit of detection: Not Limit of quantification (LOQ).

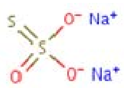
Maximum concentration measured of those chemicals present in the test system above detection limit are presented in table 4. These Relevant Chemicals were further applied for the risk assessments performed in the following sections.

Table 4: Relevant chemicals selected for assessment in the Basic Approval dossier

Chemical	**Max. tank conc. (µg/L)**	**Max. tank conc. after 48 h (µg/L)**
Bromate ion	45	ND
Bromochloroacetic acid	7	ND
Bromochloroacetonitrile	3	2
Chloropicrin	5	ND
Dibromoacetic acid	34	13
Dibromoacetonitrile	21	ND
Dibromochloroacetic acid	18	15
Dibromochloromethane	41	42
Dichloroacetonitrile	2	1
Dichlorobromomethane	10	8
Monobromoacetic acid	11	6
Monochloroacetic acid	30	14
Monochloroacetonitrile	4	7
Sodium bromate	52	ND
Tribromoacetic acid	147	129
Tribromomethane	1076	1099

Other Chemicals

As a neutralizer, sodium thiosulphate will be applied to the treated ballast water before discharge.

1	Chemical (IUPAC) name	**Disodium thiosulphate**
2	CAS number	7772-98-7
3	Molecular mass	158.097
4	Empirical formula	$Na_2O_3S_2$
5	Structural formula	
6	Classification in accordance with the UN GHS system	Not classified
7	Particle size distribution	Not relevant

3 HAZARD PROFILE DATA AND EXPOSURE OF CHEMICALS ASSOCIATED WITH THE BWMS

3.1 General

The data-set presented in this application for the Basic Approval is based upon the Methodology as presented in the annex of BWM.2/Circ.13/Rev.2, endorsed by MEPC 66 on 4 April 2014.

Use is made of the electronic version of the GESAMP-BWWG Database, as described in document MEPC 67/INF.17. This version of the database includes several improvements and refinement of the data. In addition the list of chemicals has been reduced by two (as the GESAMP-BWWG recommends that bromate ion is reported instead of potassium bromate and sodium bromate, see MEPC 67/2/4, annex, paragraph 4.1.4).

3.2 Identification of the substances

3.2.1 Active Substances

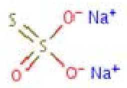
The active substance in the VARUNA BWTS is sodium hypochlorite, generated by electrochemical process. Sodium hypochlorite is taken up in the electronic version of the GESAMP-BWWG Database. No additional data were used in the assessments.

3.2.2 Relevant Chemicals (G9: 2.1.4)

Relevant Chemicals for electrolysis of seawater are listed in table 4. These are all included in the electronic version of the GESAMP-BWWG Database, and therefore "no additional properties on physico-chemistry, ecotoxicology and toxicology have to be submitted" (BWM.2/Circ.13/Rev.2, appendix 3, paragraph 5.3). No additional data were used in the assessments. Only the Relevant Chemicals of which concentrations above the detection limit were present in the Relevant Chemicals generation test (table 4) will be subjected to further risk analysis.

3.2.3 Other Chemical

As a neutralizer, sodium thiosulphate will be applied to the treated ballast water before discharge.

1	Chemical (IUPAC) name	**Disodium thiosulphate**
2	CAS number	7772-98-7
3	Molecular mass	158.097
4	Empirical formula	$Na_2O_3S_2$
5	Structural formula	
6	Classification in accordance with the UN GHS system	Not classified
7	Particle size distribution	Not relevant

3.3 Data on effects on aquatic plants, invertebrates and fish, and other biota, including sensitive and representative organisms (G9: 4.2.1.1)

For those chemicals that are subjected to further risk analysis, information is available from the electronic version of the GESAMP-BWWG Database, presented in document MEPC 67/INF.17. The Database contains information on:

- acute aquatic toxicity
- chronic aquatic toxicity
- endocrine disruption
- sediment toxicity
- food web/population effects

3.4 Data on mammalian toxicity (G9: 4.2.1.2)

For those chemicals that are subjected to further risk analysis, information is collected from the electronic version of the GESAMP-BWWG Database, presented in document MEPC 67/INF.17. The Database contains information on:

- acute toxicity
- effects on skin and eye
- repeated-dose toxicity
- chronic toxicity
- developmental and reproductive toxicity
- carcinogenicity
- mutagenicity/genotoxicity
- toxicokinetics

3.5 Data on environmental fate and effect under aerobic and anaerobic conditions (G9: 4.2.1.3)

For those chemicals that are subjected to further risk analysis, information is collected from the electronic version of the GESAMP-BWWG Database, presented in document MEPC 67/INF.17. The database contains information on:

- modes of degradation (biotic and abiotic)
- persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters)
- bioaccumulation, partition coefficient, octanol/water partition coefficient
- bioavailability/biomagniification/bioconcentration
- reaction with organic matter
- potential physical effects on wildlife and benthic habitats
- potential residues in seafood
- any known interactive effects

3.6 Physical and chemical properties (G9: 4.2.1.4)

For those chemicals that are subjected to further risk analysis, information is collected from the electronic version of the GESAMP-BWWG Database, presented in document MEPC 67/INF.17. The Database contains information on:

- melting Point
- boiling Point
- flammability (flash point)

- density (relative density)
- vapour Pressure,vapour Density
- water Solubility/dissociation constant
- oxidation/reduction potential
- corrosivity and chemical influence on the materials or equipment of normal ship construction
- auto-ignition temperature
- explosive properties
- oxidizing properties
- surface tension
- viscosity
- thermal stability and identity of relavant breakdown products
- pH
- salinity
- TOC, DOC, percentage of particulate matter
- other known relevant physical or chemical hazards

3.7 Analytical methods for measuring the concentration at environmentally relevant concentrations (G9: 4.2.1.5)

The Active Substance, sodium hypochlorite (TRO as Cl_2), is automatically monitored by a TRO meter unit in the VARUNA BWTS.

4 USE OF THE ACTIVE SUBSTANCE OR THE PREPARATION

4.1 The manner of application (G9: 4.2.6 and 7)

The VARUNA BWTS is a once-through electrochemical treatment system with a combination of Physical separation (filtration), electrochemical treatment and neutralization processes. An overview of equipment being applied in the Pilot BWT System is provided in the confidential Basic Approval dossier. During the electrochemical treatment the NaCl available in the ballast water is partially dissociated to form sodium hypochlorite (Active Substance) and other oxidants that aid in disinfection of the ballast water. Before discharge, the residual TRO available in the ballast water is neutralized using sodium thiosulphate for safe discharge in to the environment.

The VARUNA BWTS is a once-through electrochemical treatment system, hence, the whole flow of ballast water passes through the bipolar electrolyzer to produce a sodium hypochlorite concentration of 10 ± 1 mg/l. Hydrogen (H_2) gas is formed as a by-product of ballast water electrolysis, as illustrated by the following reaction:

$$NaCl + H_2O \rightarrow NaOCl + H_2 \uparrow$$

During the electrochemical treatment of ballast water, hydrogen is formed in low quantities, as a by-product at the cathode. For an average sodium hypochlorite production of 10 mg/l designed in the VARUNA BWT System, the calculated concentration of hydrogen gas produced in the electrolyzer would be at the rate of about 0.28 mg/l which would be much less than 1% of LEL. It is planned to vent out the hydrogen gas from the ballast tanks through the vent, to the air outside the ship.

Quantitative monitoring of hydrogen gas generation has been planned to be carried out during both land-based and shipboard testing of the VARUNA BWTS to verify the theoretical calculations. Detailed description of the gas analyer and construction and integration mechanism with the control system will be submitted as part of the application for Final Approval.

Nevertheless, the safety features in the VARUNA BWTS as well as the physical properties of hydrogen gas imply that it is unlikely to accumulate to levels of concern (e.g. above the LEL). Therefore, hydrogen gas is not considered relevant for the assessment of human health risks. As it is a low density atmospheric gas it will not be present in the discharge water, hence it is not considered for evaluation of its aquatic toxicity.

4.2 TRO dosage and monitoring

An online TRO analyzer measures the concentration of the TRO production and controls the transformer-rectifier through a feedback loop to maintain a steady production rate of 10 mg/l TRO (measured as Cl_2). The TRO production level aimed at is 10 ± 1 mg/l, which means the system is designed to operate and produce a TRO concentration of minimum 9 mg/l and a maximum of 11 mg/l. The TRO production concentration of less than or equal to 9 mg/l gives out a low production alarm and activates the control system and increases the generation of TRO by feeding more Direct Current (DC) and a concentration of greater than or equal to 11 mg/l gives out a high production alarm and reduces the DC current supply to the electrolyzer thereby decreasing the TRO production.

4.3 Neutralizing unit and monitoring at discharge

Since residual TRO if discharged into the marine environment may harm marine organisms and the environment, the VARUNA BWTS is designed to neutralize the TRO by dosing sodium thiosulphate prior to the discharge of ballast water.

The residual TRO is measured online and is neutralized using sodium thiosulphate, to achieve a discharge concentration of less than 0.1 mg/l TRO as Cl_2, in order not to exceed the MADC of 0.2 mg/l Cl_2. The system is designed to neutralize a TRO concentration of 0.02 mg/l or above and is designed to maintain a maximum discharge concentration of less than 0.2 mg/l.

In the VARUNA BWTS the neutralization system functions in synchrony with the deballasting process thereby neutralizing the TRO even if the concentration is maintained at the production levels (10 ± 1 mg/l). Hence, ballast water discharge can be carried out immediately after the treatment process without any retention time.

In VARUNA BWTS it is planned to design the neutralization system comprising, in sequence, a TRO-sensor (higher range – 0 to ≥ 10 mg/l) and a dosing pump connected to the discharge pipeline wherein a control unit aids in controlling the dosage of neutralizing agent, stored in a tank, required to neutralize the excess oxidants. A static mixer is provided after the dosing point to aid in proper mixing of the neutralizing agent with the discharge water. Finally, a second TRO-sensor (lower range – 0 to 5 mg/l) monitors the residual chlorine levels in the discharge water.

4.4 Safety issues

The VARUNA BWTS will be designed and constructed with a view to address the emergency situations and the safety of the ship and its crew. A detailed "Operation Manual" incorporating all safety procedures will be submitted along with the application for Final Approval.

Ship and personnel safety

The VARUNA BWTS is a once-through ballast water management system that electrolyzes the ballast water and produces the Active Substance in situ. The system does not involve storage or handling of the Active Substance during normal operating conditions.

The only chemical which needs to be stored is sodium thiosulphate for neutralization of residual TRO during the deballasting process. Crystalline form of sodium thiosulphate is to be stored in air tight polyethylene or polypropylene container in a cool, dry and ventilated environment. It is recommended that the ship's crew in charge of the operation reads the operation instruction and follows all the precautionary safety measure while handling the chemical. It is recommended that usage of Personal Protective Equipment (PPE), such as wearing protective clothing, mask, rubber or PVC gloves, safety glasses and a respirator will prevent any accidental contact with the chemical at the time of handling or preparation. The personnel handling the chemical should follow good industrial safety practice and hygiene principles for handling and storing.

Sodium thiosulphate is not a flammable material. In the event of contact with fire, noxious or toxic vapours including hydrogen sulphide and oxides of sulphur may be released. Hence, fire fighters should wear self-contained breathing apparatus during fire extinguishing operations.

For small fires it is recommended to use a fire extinguishing media, such as, dry chemical, carbon dioxide or water spray and for large fires, dry chemical or carbon dioxide is recommended. In the event of any spillage of the chemical, suitable safety handling methods may be used to collect the spill to prevent the release of the chemical into the sea.

Fire and explosion

The VARUNA BWTS is designed and is constructed with fire retardant material that are resistant to fire and does not evolve any toxic gases.

The hydrogen gas generated during the electrolytic process has been identified as one of the by-products of formed during the disinfection process which is non-toxic while it can act as an asphyxiant gas by reducing or displacing oxygen from the air in the surrounding area. Effects of reduced oxygen in the surrounding atmosphere may lead to diminished mental alertness, impaired muscular coordination, faulty judgement, depression of all sensations etc.

In the VARUNA BWTS the entire volume of pumped ballast water is treated by the electrolyzer, hence the accumulation of hydrogen into the ballast tanks could be avoided. Quantitative monitoring of hydrogen gas at the ballast water tank vent has been planned to be carried out both during land-based and shipboard testing of the VARUNA BWTS to measure quantitatively.

In addition to this, it is planned to install a multi gas leak detector in the VARUNA BWTS. The system is designed to receive the signals from the, gas leak detectors and in the incidence of any abnormal gas detection, the system gives alarm for the operator to switch off the system.

During the Pilot BWTS testing at DHI, Singapore for Basic approval a hydrogen and chlorine gas leak detector (see description in section 0) was installed inside the VARUNA BWTS pilot plant skid to detect for any hydrogen of chlorine gas leak from the system. The gas detector did not detect any leak from the system during the testing operation.

Detailed description of the hydrogen and chlorine gas sensors or analyzers and construction and integration mechanism with the control system will be submitted as part of the application for Final Approval.

Emergency measures in case of an accident

In the event of untoward or abnormal operating conditions such as, increase in the temperature within the system, increase in the pressure or accidental leakage of treated ballast water, the control system will give out warning alarm through a suitable device such as a siren and emergency warning light. In the event of increase in temperature, the feedback mechanism will shutdown the transformer rectifier, if no manual intervention takes place. The system will be provided with facilities along with operating procedure to aid in manual intervention by the trained ship crew to shut down the system safely, as a precautionary measure before the automatic shutdown or in the event the control system does not carry out auto shutdown in time. The manufacturer of VARUNA BWTS recommends that only trained personnel operate the system to avoid any unpleasant situations.

Possibility of destruction or decontamination following emergency release in the marine environment

The ballast water treated by the VARUNA BWTS produces the Active Substance through electrolysis of ballast water and produces a TRO of 10 ± 1 mg/l. The system is designed to carry out the neutralization process even if the total quantum of TRO produced is available in the treated water. In the worst case scenario, the neutralization unit could be operated along with the deballasting pump to dose the sodium thiosulphate at a preset concentration (for example 20 mg/l) for the discharge water flow rate maintained same as for the ballasting operation.

5 RISK CHARACTERIZATION – HUMAN HEALTH

The applied risk characterization followed the procedure for human risk assessment of ballast water chemicals in appendix 4 of BWM.2/Circ.13/Rev. 2.

In risk characterization for human health the exposure levels to which the target groups are exposed or likely to be exposed are compared with those levels at which no toxic effects from the chemicals are expected to occur.

A quantitative risk assessment is performed following four steps:

.1 **Hazard identification** – to characterize the substances of concern and their effects;

.2 **Dose (concentration) – response (effect) relation** – to establish the relationship between the dose and the severity or the frequency of the effect;

.3 **Exposure assessment** – to determine the intensity, and the duration or frequency of exposure to an agent; and

.4 **Risk characterization** – to quantify the risk from the above data.

5.1 Hazard identification

The Active Substance and 16 Relevant Chemicals are considered for hazard identification. Hazard profile data are collected in section 3 and originate from the GESAMP-BWWG Database. For human health characterization the mammalian toxicity data are of special importance. This includes a screening on carcinogenic, mutagenic, reproductive toxic and endocrine disruptive properties. Based on the appropriate toxicological studies on carcinogenicity, mutagenicity and reproductive toxicity, the Relevant Chemicals are scored on these three items, using 1 (one) if the substance showed the hazard under consideration and 0 (zero) if the substance did not show the hazard under consideration. There are some Relevant Chemicals showing at least one of the hazards, carcinogenicity, mutagenicity or reproductive toxicity. For these chemicals exposure should be avoided or relevant risk mitigation measures should be proposed to minimize exposure to an acceptable level using appropriate extrapolation methods.

The screening results of these separate properties are provided in the GESAMP-BWWG Database and are listed in table 5. However the integrated CMR classification in positive or negative is not provided. In the current assessment a cautious approach is chosen by classifying CMR as positive in case at least one of the components is identified as positive.

Table 5: Carcinogenic, mutagenic, and reproductive toxic properties of the Relevant Chemicals (1 = positive; 0 = negative)

Relevant chemicals	Carcinogenic (C)	Mutagenic (M)	Reprotoxicity (R)	CMR
Sodium hypochlorite	0	0	0	0
Bromate ion	1	1	0	1
Bromochloroacetic acid	1	0	1	1
Bromochloroacetonitrile	0	0	0	0
Chloropicrin	0	0	0	0
Dibromoacetic acid	1	1	0	1
Dibromoacetonitrile	0	0	0	0
Dibromochloroacetic acid	0	0	0	0
Dibromochloromethane	1	0	0	1
Dichloroacetonitrile	0	0	0	0
Dichlorobromomethane	1	0	0	1

Relevant chemicals	Carcinogenic (C)	Mutagenic (M)	Reprotoxicity (R)	CMR
Monobromoacetic acid	0	0	0	0
Monochloroacetic acid	0	0	0	0
Monochloroacetonitrile	0	0	0	0
Tribromoacetic acid	0	0	0	0
Tribromomethane	0	0	0	0

Five of the Relevant Chemicals are identified as carcinogenic. These are bromate ion, bromochloroacetic acid, dibromoacetic acid, dibromochloromethane and dichlorobromomethane. Two of them are probably non-threshold carcinogens because they are mutagenic. These are bromate ion and dibromoacetic acid. Bromochloroacetic acid is considered reproductive toxic. For the five Relevant Chemicals identified as carcinogenic a Derived Minimal Effect Level (DMEL) or equivalent end-point was determined and incorporated in the GESAMP-BWWG Database (see Table 6). These DMEL values are also used in the human risk assessment (see Table 15). It should be noted that a DMEL is not available for dibromochloromethane. On the other a DMEL for tribromomethane (bromoform) is shown in the GESAMP-BWWG Database, whereas this chemical is not considered carcinogenic. Both issues should be elucidated.

The assessment of the carcinogenicity, mutagenicity and reproductive toxicity properties of the Active Substance and the Relevant Chemicals can also be seen as relevant for the PBT assessment which is carried out in section 6.1 of this document.

5.2 Dose-response relation and Derived No Effect Level

In assessing the acceptable levels of the substances of concern, the procedure follows moving from animal experiments giving a No Observed Adverse Effect Level (NOAEL) to derive an exposure limit above, which humans should not be exposed to (Derived No Effect Level – DNELs). Taking into account the critical health effect that can be exerted by a threshold mode of action, the lowest DNEL for each exposure route is established by dividing the value of the critical dose descriptor, e.g. N(L)OAEL, by an assessment factor (AF) to allow for extrapolation from experimental data to real human exposure situations.

Two groups of potentially exposed persons are distinguished:

.1 workers (crew and port State control officers); and

.2 general public.

The proposed DNEL and/or DMEL of the 16 chemicals is based on the available toxicological data as provided by the GESAMP-BWWG Database, including the final assessment factor to establish the DNEL and/DMEL to be used in the human risk assessment. The DNEL and DMEL values are listed in table 6.

Table 6: DNEL and DMEL to be used in the risk assessment for humans

Chemical name	DNEL crew	DNEL general public	DMEL
	(µg/kg bw/d)	(µg/kg bw/d)	(µg/kg bw/d)
Sodium hypochlorite	275	138	
Bromate ion	22	11	0.11
Bromochloroacetic acid	1250	625	
Bromochloroacetonitrile	150	75	
Chloropicrin	2.04	1.02	
Dibromoacetic acid	72.4	36.2	0.13
Dibromoacetonitrile	164	82.1	
Dibromochloroacetic acid	297	148	
Dibromochloromethane	214	107	1.5

Chemical name	DNEL crew	DNEL general public	DMEL
	(µg/kg bw/d)	(µg/kg bw/d)	(µg/kg bw/d)
Dichloroacetonitrile	57.1	28.6	
Dichlorobromomethane	40	20	2.4
Monobromoacetic acid	70	35	
Monochloroacetic acid	70	35	
Monochloroacetonitrile	8.16	4.08	
Tribromoacetic acid	857	429	
Tribromomethane	179	89.3	7.7

5.3 Exposure assessment

The exposure assessment consists of two major steps. The first step is the measurement and/or assessment of the concentrations in the ballast water, the air above the ballast water, the harbour water and the air above harbour water. The second step consists of the assessment of the uptake by humans of the chemicals from water and air via different intake routes like inhalation, dermal uptake, and oral uptake. These are called human exposure scenarios and will be elaborated in section 7.2. The first step is elaborated in the present paragraph.

In order to perform a risk assessment related to both the environment and those people who may be exposed to any chemicals associated with the BWMS, the concentration of such chemicals is estimated in:

.1 the air space in the ship's ballast water tank;

.2 the atmosphere surrounding the ship;

.3 leakages and spills when operating the system; and

.4 in the harbour water.

The concentrations of the Relevant Chemicals in the ballast tank are measured immediately after treatment and 24 and 48 hours later. For each detected chemical the maximum values are selected for risk assessment calculations. For most of the detected chemicals the concentrations measured after 24 hours are somewhat higher than after 48 hours after treatment (see section 2.3). The concentrations in the harbour water are calculated with the most recently available version of the MAMPEC model. For details and results see section 6.3 and table 10.

The concentrations in the air above the ballast water tank and above the harbour water are calculated using Henry's Law Constant and a dilution factor of 10 (see appendix 4 in BWM.2/Circ.13/Rev.2). The resulting worst-case concentrations in water and air are calculated for application in the assessment of the exposure of humans (crew, port State control and the general public) to the Active Substance and the Relevant Chemicals due to the ballasting and deballasting processes (see table 7).

Table 7: Concentration of the Active Substance and Relevant Chemicals to be used in the risk assessment for humans

Relevant chemicals	Crew		General public	
	Concentration in tank water (µg/L)	**Concentration in tank air** (mg/m^3)	**Concentration in seawater (MAMPEC)** (µg/L)	**Concentration in air above sea** (mg/m^3)
Sodium hypochlorite	10000	4.2E-03	NA	NA
Bromate ion	97	4.1E-05	NA	NA
Bromochloroacetic acid	7	5.8E-07	NA	NA
Bromochloroacetonitrile	3	1.6E-05	0.044	2.3E-08
Chloropicrin	5	9.2E-03	NA	NA
Dibromoacetic acid	34	0.0E+00	0.420	0.0E+00
Dibromoacetonitrile	21	3.6E-05	NA	NA
Dibromochloroacetic acid	18	0.0E+00	0.404	0.0E+00
Dibromochloromethane	42	1.8E-01	0.281	1.2E-04
Dichloroacetonitrile	2	3.2E-05	0.025	4.0E-08
Dichlorobromomethane	10	8.9E-02	0.048	4.3E-05
Monobromoacetic acid	11	4.6E-07	0.124	5.2E-10
Monochloroacetic acid	30	1.3E-06	0.270	1.1E-09
Monochloroacetonitrile	7	3.2E-04	0.162	7.4E-07
Tribromoacetic acid	147	2.1E-06	2.73	3.9E-09
Tribromomethane	1099	2.5E+00	11.3	2.6E-03

5.4 Risk characterization

In the risk characterization, these estimates are combined with the results of the effects assessment and conclusions are drawn whether or not there is a concern for any scenarios assessed (Risk Characterization Ratio (RCR) = Exposure/DNEL). This risk characterization is elaborated in section 7.2.

In case the human risk assessment results in the conclusion that there is an unacceptable risk (RCR > 1), a second tier assessment should be performed by considering specific risk control measures in order to lower this risk to acceptable levels (protective clothing, respirators and self-contained breathing apparatus, crew training, good operational practices etc.).

6 RISK CHARACTERIZATION – ENVIRONMENT

The environmental risk assessment follows the procedure for environmental risk assessment of ballast water chemicals in the annex of BWMC.2/Circ.13/Rev. 2.

Four principles were followed:

1. **Hazard identification** – to identify the substances of concern and their effects;

2. **Dose (concentration) – response (effect) relation** – to characterize the relationship between the dose and the severity or the frequency of the effect;

3. **Exposure assessment** – to determine the intensity, and the duration or frequency of exposure to an agent; and

4. **Risk characterization –** to quantify the risk from the above data.

6.1 Hazard identification

Table 8 below summarizes the persistence (P), bioaccumulation (B) and toxicity (T) qualification of the Active Substance and the Relevant Chemicals generated by the VARUNA BWTS. These substances do not correspond to PBT criteria. In addition the neutralizer, sodium thiosulphate, is an inorganic compound decomposing quickly and also does not correspond to PBT criteria. The qualification as well as underlying data for PBT of these chemicals are contained in the GESAMP-BWWG Database. For persistence and degradation data, see section 3.5 of the current document. For bioaccumulation data, see sections 3.3 and 3.5 of this document. For ecotoxicity data, see section 3.3 of this document.

Table 1: Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T) of the Relevant Chemicals. Are the criteria met?

Chemical by-product	Persistence (P) (Yes/No)	Bioaccumulation (B) (Yes/No)	Toxicity (T) (Yes/No)	PBT (Yes/No)
Sodium hypochlorite	No	?	Yes	No
Bromate ion	?	No	No	No
Bromochloroacetic acid	?	No	No	No
Bromochloroacetonitrile	No	No	No	No
Chloropicrin	?	No	Yes	No
Dibromoacetic acid	No	No	No	No
Dibromoacetonitrile	?	No	No	No
Dibromochloroacetic acid	?	No	No	No
Dibromochloromethane	No	No	No	No
Dichloroacetonitrile	Yes	No	No	No
Dichlorobromomethane	No	No	No	No
Monobromoacetic acid	No	No	No	No
Monochloroacetic acid	No	No	Yes	No
Monochloroacetonitrile	?	No	No	No
Tribromoacetic acid	No	No	No	No
Tribromomethane	No	No	No	No

The assessment of the carcinogenicity, mutagenicity and reproductive toxicity properties of the Active Substance and the Relevant Chemicals can also be seen as relevant for the PBT assessment and is carried out in section 5.1 of this document.

6.2 Dose-response relation and predicted no effect level

The effect assessment of the Active Substances and Relevant Chemical is initially based on a data-set of acute and/or chronic ecotoxicity data for aquatic organisms, being primary producers (e.g. algae), consumers (e.g. crustacea), and predators (e.g. fish). These ecotoxicity data are referred to in section 3.3 of this document and originate from the GESAMP-BWWG Database.

An effect assessment on secondary poisoning to mammalian and avian top-predators is not prepared because it is not relevant because the substances of concern demonstrate a lack of bioaccumulation potential (e.g. BCF < 500 L/kg wet weight for the whole organism at 5% fat).

It is not necessary to conduct an assessment of effects to sediment species because the potential of the substance of concern to partition into the sediment is low (K_{oc} < 500 L/kg).

Currently there is no compelling physiological or empirical proof that marine organisms are more sensitive than freshwater organisms or vice versa and therefore, an additional assessment factor is not applied.

For assessment of effects to the aquatic environment, appropriate Predicted No-Effect Concentrations (PNEC) are derived. PNEC values are normally derived from acute and/or chronic aquatic toxicity results for relevant aquatic species by dividing the lowest available effect concentration with an appropriate assessment factor. The GESAMP-BWWG Database contains the selected acute and/or chronic aquatic toxicity and the safety factors and the resulting PNEC values for the Relevant Chemicals. These PNEC values are listed in table 9.

For four chemicals, the $PNEC_{near\ ship}$ is substantially lower than the $PNEC_{harbour}$ due to insufficient availability of acute ecotoxicity data. In these cases, the $PNEC_{near\ ship}$ is set equal to the $PNEC_{harbour}$. This is still considered a worst-case PNEC.

Table 2: PNEC values of chemicals associated with the BWMS and included in the GESAMP-BWWG Database

Relevant chemicals	Harbour PNEC (µg/L)	Near ship PNEC (µg/L)
Bromochloroacetonitrile	0.69	6.9
Dibromoacetic acid	6.9	69
Dibromochloroacetic acid	60	60
Dibromochloromethane	6.3	270
Dichloroacetonitrile	24.35	244
Dichlorobromomethane	78	8
Monobromoacetic acid	16	16
Monochloroacetic acid	0.58	0.58
Monochloroacetonitrile	0.16	1.6
Tribromoacetic acid	60	60
Tribromomethane	96	290

6.3 Exposure assessment

The MAMPEC-BW model, latest available version, is used to calculate PEC values with its standard settings (see appendix 5 of BWM.2/Circ.13/Rev.2. MAMPEC-BW calculates the stationary concentration in the harbour after discharge of ballast water. To account for local effects, near the ship at discharge, the local concentration at near sea ship is estimated using the formulae suggested in Zipperle et al., 2011 (Zipperle, A., Gils J. van, Heise S., Hattum B. van, Guidance for a harmonized Emission Scenario Document (ESD) on Ballast Water discharge, 2011):

$$C_{max} = \frac{C_{BW} + (S-1) \cdot C_{mean}}{S}$$

where:

C_{max} = the maximum concentration due to near sea ship exposure (µg/L)
C_{BW} = the concentration found in the discharged ballast water (µg/L)
S = dilution factor based on sensitivity analysis with a higher tier model, default value = 5
C_{mean} = the mean concentration as output from MAMPEC-BW

The discharged ballast water volume is 100,000 m^3/day set as default emission in the GESAMP-BWWG Model Harbour of MAMPEC-BW 3.0. Therefore, total emission (g/day) of Relevant Chemicals is calculated by multiplying the above-mentioned discharging concentration of Relevant Chemicals by discharged ballast water volume 100,000 m^3/day. In the current environmental risk assessment for each Relevant Chemical the concentrations after the longest retention time in the ballast water tank (48 hours) (see table 3 and table 4) in brackish water and in seawater are taken into account because this complies with the concentrations to be discharged into the harbour. Subsequently the maximum concentration is selected from the brackish water and the seawater tests. These concentrations are listed in table 10 together with the PEC values in the harbour (maximum) and near ship resulting from the calculations.

Table 10: Predicted environmental concentrations (PEC) values from MAMPEC modelling results from the GESAMP-BWWG Model Harbour

Chemical	Max. discharge conc. (µg/L)	PEC (µg/L)	PEC (µg/L)
		Maximum	Near ship
Bromochloroacetonitrile	2	0.044	0.42
Dibromoacetic acid	13	0.420	2.72
Dibromochloroacetic acid	15	0.404	3.18
Dibromochloromethane	42	0.281	8.54
Dichloroacetonitrile	1	0.025	0.21
Dichlorobromomethane	8	0.048	1.62
Monobromoacetic acid	6	0.124	1.26
Monochloroacetic acid	14	0.270	2.91
Monochloroacetonitrile	7	0.162	1.47
Tribromoacetic acid	129	2.73	27.0
Tribromomethane	1099	11.3	225

In section 7.3, the concentration calculated with this formula is compared to acute toxicity data for the Relevant Chemicals to evaluate the short-term effects on aquatic organisms.

6.4 Risk characterization

The risk of the discharged chemicals for the aquatic environment can be determined by comparison of the predicted exposure concentrations (PEC) with the no effect concentrations (PNEC) after chronic exposure in the harbour and acute exposure near ship. This is worked out in section 7.3 on risk to the aquatic environment.

6.5 Evaluation of the treated ballast water

A series of acute and chronic toxicity studies have been conducted by DHI on the effluent of brackish and marine water treated by the VARUNA Ballast Water Treatment System, following Guidelines (G8). After a full test cycle of two days, water was sampled and filtered for further ecotoxicological testing. Initial TRO of the brackish pilot scale test was 0.17 mg/l Cl_2, and in the marine test the initial TRO was 0.13 mg/l as Cl_2.

According to the requirements, the aquatic toxicity tests of three different trophic levels for treated ballast water were performed:

- algal growth rate inhibition test. Use was made of *Tetraselmis suecica*, following ISO 10253;

- crustacean acute immobilisation test. Use was made of *Acartia tonsa*, following ISO 14669;

- fish acute toxicity. Use was made of *Chanos chanos*, following OECD 203;

- crustacean Chronic development test on *Acartia tonsa*, following ISO/CD 16778; and

- fish chronic test with *Cyprinodon variegatus*, following OECD 212.

Table 3: Results for brackish and marine Whole Effluent Toxicity tests, expressed as No observed Effect concentration (NOEC) and Effect Concentration having 50% impact, where concentration refers to the percentage dilution of the effluent

Toxicity tests			Brackish water		Marine water	
Trophic level	**Species**	**Endpoint**	**NOEC**	**EC50**	**NOEC**	**EC50**
Algae	*Tetraselmis suecica*	Growth rate	N/A	N/A	N/A	N/A
Crustacean	*Acartia tonsa*	Acute	N/A	N/A	N/A	N/A
	Acartia tonsa	Chronic	50	90.6	50	60.6
Fish	*Chanos chanos*	Acute	N/A	N/A	N/A	N/A
	Cyprinodon variegatus	Chronic	N/A	N/A	N/A	N/A

Results from the Whole Effluent Toxicity tests (see table 11) showed no acute impacts on the tested algae (growth), crustacean and fish (both mortality as endpoint). However, in the chronic development test with the crustacean *Acartia tonsa*, the marine effluent showed a negative response to survival, larval development and slightly to hatching success. In contrast, no chronic effects were observed on fish.

7 RISK ASSESSMENT

7.1 Risk to safety of ship

This issue is not considered in the proposal for Basic Approval because it will be considered in the proposal for Final Approval.

7.2 Risks to human health

7.2.1 General

The human health risk assessment follows generally accepted guidelines including acute/short-term and long-term exposure situations. The risk assessment entails hazard identification and, as appropriate, dose (concentration) – response (effect) assessment, exposure assessment and risk characterization as indicated in section 5.2 of this document. The population groups deemed to be at risk and examined here include crew, passengers and all personnel, including the public, in ports. Potential health risks connected to the exposure of consumers via seafood or persons at the coast (e.g. beach) after discharge are also evaluated.

7.2.2 Health effects in humans

The effect assessment of the Active Substances, Preparations and Relevant Chemicals includes a screening on carcinogenic, mutagenic and reproductive toxic properties. The screening results may give rise to concern and further effect assessment for some of the Relevant Chemicals (G9: 5.3.12). It should be noted that the chemicals considered in the current risk assessment only comprises chemicals on the list of the 43 chemicals of appendix 6 of BWM.2/Circ.13/Rev.2 for which sufficient information is collected and no additional supporting information needs to be submitted by applicants as mentioned by the GESAMP-BWWG.

7.2.3 Human Exposure Scenario

A Human Exposure Scenario is provided as part of the risk assessment procedure for ballast water management systems, using the guidance contained in appendix 4 of this document (G9: 6.3.3).

Two groups of potentially exposed persons are distinguished:

.1 workers (crew and port State control officers); and

.2 general public.

The first approach for assessment of exposure of humans to the Active Substance and the Relevant Chemicals is focussed at the unprotected worker. Therefore an assessment using "worst-case" assumptions is conducted. If this indicates a risk of no concern, the assessment needs no further refinement. On the other hand further refinement is required in case a potential risk cannot be excluded. Appendix 4 of BWM.2/Circ.13/Rev.2 provides the guidance that is followed.

Two types of human exposure scenarios are worked out. These scenarios are defined in appendix 4 of the Methodology for information gathering and the conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.2). Subsequently each of the two exposure scenarios is quantified and compared with the criteria from the human effect assessment and conclusions will be drawn whether or not there is a concern (Risk Characterization Ratio (RCR) = Exposure/DNEL).

Crew exposure scenarios

The table below summarizes the exposure scenarios for vessel crews.

Table 4: Crew exposure scenarios

Operation	Exposure	Frequency/duration/quantity
Delivery, loading, mixing or adding chemicals to the BWMS	Potential dermal and inhalation for leakage and spills. For closed or automated systems the exposure is assumed to be minimal	Solids: 100 mg/container handled Liquids: 0.1 mL/container handled
Ballast tank cleaning	Inhalation of air in the ballast water tank	8 hours/day, 5 days/week, 1 event/year (acute/short term exposure)
	Dermal exposure to the whole body	8 hours/day, 5 days/week, 1 event/year (acute/short term exposure)
Ballast tank inspection	Inhalation of air in the ballast water tank	3 hours/day, 1 day/month (acute exposure)
Ballast water sampling	Inhalation of air in the ballast water headspace	2 hours/day, 5 days/week (acute exposure) 45 weeks/year (chronic exposure)
	Dermal exposure to primarily hands	2 hours/day, 5 days/week (acute exposure) 45 weeks/year (chronic exposure)
On-deck activities by crew on BWMS	Inhalation of air released from vents	1 hour/day, 6 months (short term exposure)

The uptake of chemicals by crew can occur via three activities: sampling, cleaning and inspection and two exposure routes: inhalation and dermal uptake. The calculated uptake is shown in the two tables below.

Table 5: Inhalation uptake in the crew exposure scenarios

Substance	Concentration in air (mg/m^3)	Exposure (mg/kg bw d)			
		Sampling	Cleaning	Inspection	Crew on deck
Sodium hypochlorite	4.2E-03	1.7E-04	7.0E-04	2.6E-04	8.7E-05
Bromate ion	4.1E-05	1.7E-06	6.8E-06	2.5E-06	8.4E-07
Bromochloroacetic acid	5.8E-07	2.4E-08	9.7E-08	3.7E-08	1.2E-08
Bromochloroacetonitrile	1.6E-05	6.6E-07	2.6E-06	9.9E-07	3.3E-07
Chloropicrin	9.2E-03	3.8E-04	1.5E-03	5.7E-04	1.9E-04
Dibromoacetic acid	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
Dibromoacetonitrile	3.6E-05	1.5E-06	6.0E-06	2.2E-06	7.5E-07
Dibromochloroacetic acid	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
Dibromochloromethane	1.8E-01	7.3E-03	2.9E-02	1.1E-02	3.7E-03
Dichloroacetonitrile	3.2E-05	1.3E-06	5.4E-06	2.0E-06	6.7E-07
Dichlorobromomethane	8.9E-02	3.7E-03	1.5E-02	5.6E-03	1.9E-03
Monobromoacetic acid	4.6E-07	1.9E-08	7.7E-08	2.9E-08	9.6E-09
Monochloroacetic acid	1.3E-06	5.2E-08	2.1E-07	7.8E-08	2.6E-08
Monochloroacetonitrile	3.2E-04	1.3E-05	5.4E-05	2.0E-05	6.7E-06
Tribromoacetic acid	2.1E-06	8.6E-08	3.5E-07	1.3E-07	4.3E-08
Tribromomethane	2.5E+00	1.0E-01	4.1E-01	1.6E-01	5.2E-02

Table 6: Dermal uptake in the crew exposure scenarios

Substance	Conc. in treated ballast water (mg/m^3)	Exposure (mg/kg bw d)	
		Sampling	Cleaning
Sodium hypochlorite	10000	1.4E-03	3.2E-02
Bromate ion	97	1.4E-05	3.1E-04
Bromochloroacetic acid	7	9.8E-07	2.3E-05
Bromochloroacetonitrile	3	4.2E-07	9.7E-06
Chloropicrin	5	7.0E-07	1.6E-05
Dibromoacetic acid	34	4.8E-06	1.1E-04
Dibromoacetonitrile	21	2.9E-06	6.8E-05
Dibromochloroacetic acid	18	2.5E-06	5.8E-05
Dibromochloromethane	42	5.9E-06	1.4E-04
Dichloroacetonitrile	2	2.8E-07	6.5E-06
Dichlorobromomethane	10	1.4E-06	3.2E-05
Monobromoacetic acid	11	1.5E-06	3.6E-05
Monochloroacetic acid	30	4.2E-06	9.7E-05
Monochloroacetonitrile	7	9.8E-07	2.3E-05
Tribromoacetic acid	147	2.1E-05	4.8E-04
Tribromomethane	1099	1.5E-04	3.6E-03

The table below shows a comparison of the estimated exposure and DNEL in chronic effect on a worker via the dermal and inhalational route, and the resulting risk characterization ratio (RCR).

Risk to the crew

Table 15: Risk assessment in the crew scenarios based on DNEL (upper table) and DMEL for the Relevant Chemicals (lower table)

Chemical	**Exposure scenario**		**Aggregated exposure**	**DNEL**	**RCR**
	Dermal (mg/kg bw/d)	**Inhalation** (mg/kg bw/d)	(mg/kg bw/d)	(mg/kg bw/d)	
Sodium hypochlorite	3.2E-02	7.0E-04	3.3E-02	0.275	0.12
Bromate ion	3.1E-04	6.8E-06	3.2E-04	0.022	0.015
Bromochloroacetic acid	2.3E-05	9.7E-08	2.3E-05	1.25	0.000018
Bromochloroacetonitrile	9.7E-06	2.6E-06	1.2E-05	0.15	0.000
Chloropicrin	1.6E-05	1.5E-03	1.5E-03	0.00204	0.757
Dibromoacetic acid	1.1E-04	0.0E+00	1.1E-04	0.0724	0.0015
Dibromoacetonitrile	6.8E-05	6.0E-06	7.4E-05	0.164	0.000
Dibromochloroacetic acid	5.8E-05	0.0E+00	5.8E-05	0.297	0.000
Dibromochloromethane	1.4E-04	2.9E-02	2.9E-02	0.214	0.138
Dichloroacetonitrile	6.5E-06	5.4E-06	1.2E-05	0.0571	0.000
Dichlorobromomethane	3.2E-05	1.5E-02	1.5E-02	0.04	0.373
Monobromoacetic acid	3.6E-05	7.7E-08	3.6E-05	0.07	0.00051
Monochloroacetic acid	9.7E-05	2.1E-07	9.7E-05	0.07	0.00139
Monochloroacetonitrile	2.3E-05	5.4E-05	7.6E-05	0.00816	0.00934
Tribromoacetic acid	4.8E-04	3.5E-07	4.8E-04	0.857	0.001
Tribromomethane	3.6E-03	4.1E-01	4.2E-01	0.179	**2.3**

Chemical	Exposure scenario		Aggregated exposure	DMEL	RCR
	Dermal (mg/kg bw/d)	**Inhalation** (mg/kg bw/d)	(mg/kg bw/d)	(mg/kg bw/d)	
Sodium hypochlorite	3.2E-02	7.0E-04	3.3E-02		NA
Bromate ion	3.1E-04	6.8E-06	3.2E-04	0.00011	**2.91**
Bromochloroacetic acid	2.3E-05	9.7E-08	2.3E-05		NA
Bromochloroacetonitrile	9.7E-06	2.6E-06	1.2E-05		NA
Chloropicrin	1.6E-05	1.5E-03	1.5E-03		NA
Dibromoacetic acid	1.1E-04	0.0E+00	1.1E-04	0.00013	0.846
Dibromoacetonitrile	6.8E-05	6.0E-06	7.4E-05		NA
Dibromochloroacetic acid	5.8E-05	0.0E+00	5.8E-05		NA
Dibromochloromethane	1.4E-04	2.9E-02	2.9E-02	0.0015	**19.6**
Dichloroacetonitrile	6.5E-06	5.4E-06	1.2E-05		NA
Dichlorobromomethane	3.2E-05	1.5E-02	1.5E-02	0.0024	**6.22**
Monobromoacetic acid	3.6E-05	7.7E-08	3.6E-05		NA
Monochloroacetic acid	9.7E-05	2.1E-07	9.7E-05		NA
Monochloroacetonitrile	2.3E-05	5.4E-05	7.6E-05		NA
Tribromoacetic acid	4.8E-04	3.5E-07	4.8E-04		NA
Tribromomethane	3.6E-03	4.1E-01	4.2E-01	0.0077	**54.2**

Cleaning exerts the highest uptake and is the only one shown in the summarizing table.
NA: no DMEL value in the GESAMP-BWWG Database.

The RCR based on the DNEL shows that chronic effect on the crew during tank cleaning, sampling, inspection and deck activities is unlikely for most chemicals. Only for for tribromomethane the exposure/DNEL ratio is exceeding 1 and therefore an unacceptable risk for the crew cannot be excluded. The applicant should provide scientific justification, which may include potential mitigation measures. It should be noted that the exposure to tribromomethane is much higher via inhalation than via dermal. In addition the exposure decreases in the order cleaning, followed by inspection and sampling.

In addition the RCR based on the available DMEL values is calculated. This RCR is exceeding 1 for tribromomethane, dibromochloromethane, bromate and dichlorobromomethane and therefore an unacceptable risk for the crew cannot be excluded.

The formation of disinfection by-products, especially bromate or its associated molecules in electrochemically treated water is influenced by several factors such as, but not limited to, the bromide content, pH, temperature, and the presence of dissolved organic compounds (DOC) in the water that is treated. In the present tests conducted on the VARUNA BWTS for Basic Approval the possible cause for the higher bromate ion or its associated molecules in the treated water could not be identified with the available results.

Hence, a second tier assessment considering specific risk control measures will be carried out during the land based testing to identify the cause and to control the formation of these DBPs in the discharge water.

In the application for Final Approval submitted by Norway for the OceanSaver® Ballast Water Management System, risk due to tribromomethane (bromoform) had been identified and the GESAMP-BWWG and MEPC had recommended for suitable risk mitigation measures to be put in place possibly through aeration, to minimize human exposure to this halogenated organic compound which may represent a genotoxic/carcinogenic health risk (MEPC 58/2/8, annex 4, dated 28 July 2008 – Report of the seventh meeting of the GESAMP-BWWG).

Similarly, in the application for Basic Approval submitted by Japan for the Ecomarine-EC Ballast Water Management System, identifying the risk to human due to dibromochloromethane, dichlorobromomethane and tribromomethane, the GESAMP-BWWG and MEPC recommended that appropriate procedures should be developed for tank entry to prevent unacceptable risks to the crew, including:

.1 emptying of a full ballast tank and thereby replacing the atmosphere in the tank;

.2 full ventilation of the ballast tank prior to personnel entry;

.3 continuous ventilation during tank entry;

.4 respiratory protection; and

.5 skin and eye protection.

Also, the GESAMP-BWWG recommended that adequate respiratory, skin and eye protective devices should be used during ballast water sampling to prevent unacceptable long-term risks to the port State control officers performing sampling (MEPC 66/2/7, annex 7, dated 9 December 2013 – Report of the twenty-sixth meeting of the GESAMP-BWWG).

Hence, mitigation measures in-line with the above recommendations would be taken up during land based testing and/or suggested as safety measure to reduce the risk to ship's crew. The results of the second tier tests and mitigation measures identified, if any, will be submitted along with the application for Final Approval.

It should be noted that a DMEL is not available for dibromochloromethane. On the other hand a DMEL is derived for tribromomethane (bromoform) whereas this chemical is not considered carcinogenic. Both issues should be elucidated.

General public exposure scenarios

The table below shows the assumed exposure scenarios for the general public as defined in appendix 4 of the Methodology for information gathering and the conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.2).

Table 16: General public exposure scenarios

Situation	Exposure	Duration/quantity
Recreational activities in the sea	Inhalation of chemicals partitioning into the air above the sea	5 hours/day for 14 days of the year
	Dermal exposure to chemicals whilst swimming in the sea	5 hours/day for 14 days of the year
	Swallowing of seawater contaminated with treated ballast water	5 hours/day for 14 days of the year
Intake of seafood exposed to the treated ballast water	Oral consumption	Once or twice /day equivalent to 0.188 kg/day
Aggregated exposure(through swimming for the general public		

The uptake of chemicals by the general public can occur via two activities: recreational activities and eating seafood exposed to treated ballast water and four exposure routes: inhalation, dermal uptake, swallowing seawater and oral uptake of seafood The calculated uptake is shown in the two tables below.

Table 7: Inhalation during swimming in the general public scenarios

Substance	Inhalation	Inhalation
	Conc. in air above sea (mg/m^3)	**Uptake** (µg/kg bw /d)
Bromochloroacetonitrile	2.3E-08	1.2E-06
Dibromoacetic acid	0.0E+00	0.0E+00
Dibromochloroacetic acid	0.0E+00	0.0E+00
Dibromochloromethane	1.2E-04	6.1E-03
Dichloroacetonitrile	4.0E-08	2.1E-06
Dichlorobromomethane	4.3E-05	2.2E-03
Monobromoacetic acid	5.2E-10	2.7E-08
Monochloroacetic acid	1.1E-09	5.9E-08
Monochloroacetonitrile	7.4E-07	3.9E-05
Tribromoacetic acid	3.9E-09	2.0E-07
Tribromomethane	2.6E-03	1.3E-01

Table 18: Dermal uptake during swimming in the general public scenarios

Substance	Conc. in seawater (mg/m³)	Dermal uptake (µg/kg bw /d)
Bromochloroacetonitrile	4.4E-02	1.9E-04
Dibromoacetic acid	4.2E-01	1.8E-03
Dibromochloroacetic acid	4.0E-01	1.7E-03
Dibromochloromethane	2.8E-01	1.2E-03
Dichloroacetonitrile	2.5E-02	1.1E-04
Dichlorobromomethane	4.8E-02	2.0E-04
Monobromoacetic acid	1.2E-01	5.3E-04
Monochloroacetic acid	2.7E-01	1.2E-03
Monochloroacetonitrile	1.6E-01	6.9E-04
Tribromoacetic acid	2.7E+00	1.2E-02
Tribromomethane	1.1E+01	4.9E-02

Table 8: Swallowing contaminated seawater during swimming in the general public scenarios

Substance	Conc. in seawater (mg/m³)	Swallowed uptake (µg/kg bw /d)
Bromochloroacetonitrile	4.4E-02	1.8E-04
Dibromoacetic acid	4.2E-01	1.7E-03
Dibromochloroacetic acid	4.0E-01	1.7E-03
Dibromochloromethane	2.8E-01	1.2E-03
Dichloroacetonitrile	2.5E-02	1.0E-04
Dichlorobromomethane	4.8E-02	2.0E-04
Monobromoacetic acid	1.2E-01	5.2E-04
Monochloroacetic acid	2.7E-01	1.1E-03
Monochloroacetonitrile	1.6E-01	6.7E-04
Tribromoacetic acid	2.7E+00	1.1E-02
Tribromomethane	1.1E+01	4.7E-02

Table 20: Eating seafood exposed to treated ballast water in the general public scenarios

Substance	Conc. in seawater (mg/m^3)	BCF (L/kg)	Seafood uptake (µg/kg bw /d)
Bromochloroacetonitrile	4.4E-02	0.2	2.8E-05
Dibromoacetic acid	4.2E-01	3.2	4.2E-03
Dibromochloroacetic acid	4.0E-01	3	3.8E-03
Dibromochloromethane	2.8E-01	8	7.0E-03
Dichloroacetonitrile	2.5E-02	0.2	1.6E-05
Dichlorobromomethane	4.8E-02	0.1	1.5E-05
Monobromoacetic acid	1.2E-01	3.16	1.2E-03
Monochloroacetic acid	2.7E-01	6.9	5.8E-03
Monochloroacetonitrile	1.6E-01	4.8	2.4E-03
Tribromoacetic acid	2.7E+00	0.1	8.6E-04
Tribromomethane	1.1E+01	2.5	8.9E-02

Risk to the general public

The table below summarizes the exposure aggregated from Table 7 to Table and the derived no-effect level (DNEL) in chronic effect on the general public and the resulting risk characterization ratio (RCR).

Table 21: Risk assessment in the general public scenario based on DNEL (upper table) and DMEL (lower table)

Chemical	Exposure in scenarios (µg/kg bw/d)				Aggregated exposure (µg/kg bw/d)	DNEL (µg/kg bw/d)	RCR
	Swimming			Seafood			
	Oral	Dermal	Inhalation	Oral			
Bromochloroacetonitrile	1.8E-04	1.9E-04	1.2E-06	2.8E-05	4.0E-04	75	5.3E-06
Dibromoacetic acid	1.7E-03	1.8E-03	0.0E+00	4.2E-03	7.8E-03	36.2	2.1E-04
Dibromochloroacetic acid	1.7E-03	1.7E-03	0.0E+00	3.8E-03	7.2E-03	148	4.9E-05
Dibromochloromethane	1.2E-03	1.2E-03	6.1E-03	7.0E-03	1.6E-02	107	1.5E-04
Dichloroacetonitrile	1.0E-04	1.1E-04	2.1E-06	1.6E-05	2.3E-04	28.6	8.1E-06
Dichlorobromomethane	2.0E-04	2.0E-04	2.2E-03	1.5E-05	2.6E-03	20	1.3E-04
Monobromoacetic acid	5.2E-04	5.3E-04	2.7E-08	1.2E-03	2.3E-03	35	6.5E-05
Monochloroacetic acid	1.1E-03	1.2E-03	5.9E-08	5.8E-03	8.1E-03	35	2.3E-04
Monochloroacetonitrile	6.7E-04	6.9E-04	3.9E-05	2.4E-03	3.8E-03	4.08	9.4E-04
Tribromoacetic acid	1.1E-02	1.2E-02	2.0E-07	8.6E-04	2.4E-02	429	5.6E-05
Tribromomethane	4.7E-02	4.9E-02	1.3E-01	8.9E-02	3.2E-01	89.3	3.6E-03

Chemical	Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	RCR
Bromochloroacetonitrile	4.0E-04	NA	NA
Dibromoacetic acid	7.8E-03	0.13	6.0E-02
Dibromochloroacetic acid	7.2E-03	NA	NA
Dibromochloromethane	1.6E-02	1.5	1.0E-02
Dichloroacetonitrile	2.3E-04	NA	NA
Dichlorobromomethane	2.6E-03	2.4	1.1E-03
Monobromoacetic acid	2.3E-03	NA	NA
Monochloroacetic acid	8.1E-03	NA	NA
Monochloroacetonitrile	3.8E-03	NA	NA
Tribromoacetic acid	2.4E-02	NA	NA
Tribromomethane	3.2E-01	7.7	4.1E-02

NA: No DMEL value in the GESAMP-BWWG Database.

The resulting RCR shows that a chronic effect to the general public from the chemicals in the discharged ballast water into the sea is unlikely. The exposure/DNEL ratio is less than 1 and therefore there is no unacceptable risk for the general public. This conclusion applies to both the DNEL and the DMEL approach.

7.3 Risks to the aquatic environment

The evaluation of persistence/bioaccumulation/toxicity (PBT) criteria was primarily done on the 12 relevant substances and the Active Substance of sodium hypochlorite to confirm that none of the substances were categorized as PBT-substances (see section 6.1).

The predicted exposure concentrations (PEC) and no effect concentrations (PNEC) after chronic exposure in the harbour and acute exposure near ship were derived in section 6. The risk is calculated here by taking the PEC/PNEC ratios (see table 22).

Table 22: Risk assessment (PEC/PNEC ratios) for the aquatic environment

Relevant Chemicals	Ballast water conc. (µg/L)	Maximum/harbour			Near ship		
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC (-)	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC (-)
Bromochloroacetonitrile	2	0.044	0.69	0.06	0.42	6.9	0.06
Dibromoacetic acid	13	0.420	6.9	0.06	2.72	69	0.04
Dibromochloroacetic acid	15	0.404	60	0.01	3.18	60	0.05
Dibromochloromethane	42	0.281	6.3	0.04	8.54	270	0.03
Dichloroacetonitrile	1	0.025	24.35	0.00	0.21	244	0.00
Dichlorobromomethane	8	0.048	78	0.00	1.62	8	0.20
Monobromoacetic acid	6	0.124	16	0.01	1.26	16	0.08
Monochloroacetic acid	14	0.270	0.58	0.47	2.91	0.58	**5.02**
Monochloroacetonitrile	7	0.162	0.16	**1.01**	1.47	1.6	0.92
Tribromoacetic acid	129	2.73	60	0.05	27.0	60	0.45
Tribromomethane	1099	11.3	96	0.12	225	290	0.78

The PEC/PNEC ratio is exceeding 1 for chronic exposure to monochloroacetonitrile in the harbour and for acute exposure to monochloroacetic acid near ship.

The prediction indicates that unacceptable risk for aquatic environment cannot be excluded. This will be further examined during the land based testing to identify the cause and necessary mitigation measures will be included to control the formation of monochloroacetonitrile and monochloroacetic acid. The results along with mitigations measures, if any, will be submitted as part of the application for Final Approval.

8 ASSESSMENT REPORT

8.1 Test report and data quality

A test report for the ballast water management system has been generated by a reputable and accredited institute, being involved in testing with ballast water (IMARES, the Netherlands). External Quality Assurance was provided by the NIOZ (the Netherlands), that has been involved in testing previous ballast water management systems which have also received Basic and Final Approval.

A pilot scale testing of the ballast water management system was performed under the DHI Business Management System, being certified to comply with resolution MEPC 174(58) by Lloyds Register, and ISO 9001, ISO 14001 and OHSAS 18001. The testing study followed the principles of the Guidelines (G8) and Procedure (G9) successfully. All microbiological and water quality analyses were performed by accredited laboratories using internationally accepted methods.

8.2 Assessment of risks to human health and the environment

The human health risk assessment followed generally accepted guidelines including acute/short-term and long-term exposure situations. Two types of human exposure scenarios were worked out. These scenarios are defined in appendix 4 of the Methodology for information gathering and the conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.2).

The uptake of chemicals by **crew** can occur via three activities: sampling, cleaning and inspection and two exposure routes: inhalation and dermal uptake. The RCR based on the DNEL shows that chronic effect on the crew during tank cleaning, sampling, inspection and deck activities is unlikely for most chemicals. Only for tribromomethane the exposure/DNEL ratio is exceeding 1 and therefore an unacceptable risk for the crew cannot be excluded.

The uptake of chemicals by the **general public** can occur via two activities: recreational activities and eating seafood exposed to treated ballast water and four exposure routes: inhalation, dermal uptake, swallowing seawater and oral uptake of seafood. The resulting RCR shows that a chronic effect to the general public from the chemicals in the discharged ballast water into the sea is unlikely. The exposure/DNEL ratio is less than 1 and therefore there is no unacceptable risk for the general public. This conclusion applies to both the DNEL and the DMEL approach.

The evaluation of **environmental** risks is based on persistence/bioaccumulation/toxicity (PBT) criteria, and was primarily done on the 12 relevant substances and the Active Substance of sodium hypochlorite. None of the substances were categorized as PBT-substances.
The PEC/PNEC ratio was found to exceed 1 for chronic exposure to monochloroacetonitrile in the harbour and for acute exposure to monochloroacetic acid near ship. Therefore an unacceptable risk for the aquatic environment cannot be excluded.

8.3 Available data on environmental exposure

Since no monitoring information is available, use was made of the results from a pilot scale testing facility (17 m^3) of the ballast water management system. Results from these (brackish water and marine water) tests provided appropriate information on the concentrations of Relevant Chemicals, in addition to the efficacy of the ballast water management system.

All required information on the Relevant Chemicals were taken from the electronic version of the GESAMP-BWWG Database, presented in document MEPC 67/INF.17. The applied risk characterizations for human health, and the aquatic environment followed the procedures of ballast water chemicals in appendix 4 of BWM.2/Circ.13/Rev.2.

Four principles were followed:

.1 **Hazard identification** – to identify the substances of concern and their effects;

.2 **Dose (concentration) – response (effect) relation** – to characterize the relationship between the dose and the severity or the frequency of the effect;

.3 **Exposure assessment** – to determine the intensity, and the duration or frequency of exposure to an agent; and

.4 **Risk characterization** – to quantify the risk from the above data.

For the calculation of exposure data for human health and the aquatic environment, use was made of the most recent available version of the MAMPEC-BW model. This model has specifically been developed and applied to assess exposure scenarios resulting from ballast water management systems. Exposure concentrations from the MAPEC model were compared with effect concentrations derived from the GESAMP-BWWG Database to quantify the Risk Characterization Ratio.

8.4 Evaluation and uncertainty assessment

Use has been made of the best available information and methodology to assess the risks to human health and the environment, by applying the principles as laid down by the BWM Convention and its guidelines as adopted by the Marine Environment Protection Committee. Pilot scale testing proved the efficacy of the test system and provided relevant information on chemical concentrations before and during treatment, and at discharge.

The environmental risk assessment revealed that the PEC/PNEC ratio was found to exceed 1 for chronic exposure to monochloroacetonitrile in the harbour and for acute exposure to monochloroacetic acid near ship. Results from the Whole Effluent Toxicity tests showed no acute impacts on the tested algae (growth), crustacean and fish (both mortality as endpoint). However, in the chronic development test with the crustacean *Acartia tonsa*, the marine effluent showed a negative response to survival, larval development and slightly to hatching success. In contrast, no chronic effects were observed on fish.

9 QUALITY ASSURANCE

IMARES utilizes an ISO 9001:2008 certified quality management system (certificate number: 124296-2012-AQ-NLD-RvA). This certificate is valid until 15 December 2015. The organisation has been certified since 27 February 2001. The certification was issued by DNV Certification B.V. Furthermore, the chemical laboratory of the Fish Division has NEN-EN-ISO/IEC 17025:2005 accreditation for test laboratories with number L097. This accreditation is valid until 1th of April 2017 and was first issued on 27 March 1997. Accreditation was granted by the Council for Accreditation.

10 REFERENCES

DHI. Pilot Scale Testing of the VARUNA Ballast Water Tretament System (VARUNA BWTS). Final Report, October 2014.

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MEPC. Guidelines for approval of ballast water management systems (G8). Resolution MEPC.174(58). Adopted on 10 October 2008.

MEPC. Procedure for approval of ballast water management systems that make use of Active Substances (G9). Resolution MEPC.169(57). Adopted on 4 April 2008.

MEPC 58/2/8, annex 4, Report of the seventh meeting of the GESAMP-Ballast Water Working Group, 2008.

MEPC 66/2/7, annex 7, Report of the twenty-sixth meeting of the GESAMP-Ballast Water Working Group, 2013.

11 APPENDICES CONTAINED IN THE CONFIDENTIAL DOSSIER

Appendix 1	VARUNA Ballast Water Treatment System - Application for Basic Approval – Confidential Dossier
Appendix 2	VARUNA Pilot Ballast Water Treatment System – Operation and Maintenance Manual
Appendix 3	DHI QAPP and QMP
Appendix 4	DHI Final Report - Pilot Scale Testing of the VARUNA Ballast Water Treatment System
Appendix 5	DHI Whole Effluent Toxicity Testing Report – VARUNA Ballast Water Treatment System
Appendix 6	Corrosion Testing - Letter from Exova

APPENDIX 1

Justification

Document No.: TiTaN-R&D/BWDD/0001/2014/Rev.01

Project Number: KNTPL/BWDD/004/2014

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APPENDIX 2

NON-CONFIDENTIAL INFORMATION – DATA FROM THE GESAMP- BWWG DATABASE

Complete data set and (eco-) toxicological risk assessment for the Active Substance and the selected Relevant Chemicals:

Chemical
Sodium hypochlorite
Bromate ion
Bromochloroacetic acid
Bromochloroacetonitrile
Chloropicrin
Dibromoacetic acid
Dibromoacetonitrile
Dibromochloroacetic acid
Dibromochloromethane
Dichloroacetonitrile
Dichlorobromomethane
Monobromoacetic acid
Monochloroacetic acid
Monochloroacetonitrile
Tribromoacetic acid
Tribromomethane

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