Proposed Registration Decision PRD2012-15

Ammonia (Present as Ammonium Sulphate)

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Overview

Proposed Registration Decision for Ammonia (Present as Ammonium Sulphate)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of BCMW Technical and Busan 1215 Liquid Microbicide, containing the technical grade active ingredient ammonia (present as ammonium sulphate), to control algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of BCMW Technical and Busan 1215 Liquid Microbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on ammonia (present as ammonium sulphate), the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on ammonia (present as ammonium sulphate), which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Ammonia (Present as Ammonium Sulphate)?

Ammonium sulphate is an inorganic salt providing a source of ammonia (NH_3). The active ingredient resulting from Busan 1215 Liquid Microbicide treatment is monochloramine (NH_2Cl), which is being generated *in situ* when the ammonia from the ammonium sulphate reacts with the sodium hypochlorite. This reaction occurs through a chemical feed skid mixing sodium hypochlorite and Busan 1215 Liquid Microbiocide. Monochloramine is known to kill cells by oxidation reactions with membrane-bound enzymes.

Health Considerations

Can Approved Uses of Ammonia (present as Ammonium Sulfate) Affect Human Health?

Ammonia (present as Ammonium Sulfate) is unlikely to affect human health when used according to label instructions.

Exposure to ammonia (present as ammonium sulfate) may occur when handling the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Ammonia (present as ammonium sulfate) is of low toxicity by the oral, dermal and inhalation routes, minimally irritating to the eyes, slightly irritating to the skin, and is not a dermal sensitizer. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects. The precautionary label statement indicating that contact with skin, eyes, and clothing must be avoided, and the personal protective equipment statement that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear are effective mitigative measures to reduce the risk associated with the use of this product.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use of Busan 1215 Liquid Microbicide is for treatment of process waters in the production of non-food contact paper. Dietary intake is not anticipated.

No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Busan 1215 Liquid Microbicide

Occupational exposure to individuals loading Busan 1215 Liquid Microbicide is not expected to result in unacceptable risk when the product is handled according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Ammonia (Present as Ammonium Sulphate) Is Introduced Into the Environment?

BCMW Technical and the associated end-use product Busan 1215 Liquid Microbicide are to be used in industrial process water systems for the control of slime. The product is applied in conjunction with sodium hypochlorite to form monochloramine, a slow acting oxidizing microbicide. Monochloramine, which is the primary chemical of environmental concern with the use of Busan 1215, could potentially enter the environment through industrial effluent discharge. Discharges can be to both freshwater and marine water bodies, as industrial facilities where this product is to be used can be located near both types of aquatic environments. Levels of monochloramine discharged to the environment through effluent is expected to be low; however, the chemical is toxic to aquatic organisms, and label statements referring to dechlorination of effluent to undetectable levels will be required prior to discharge, where applicable.

Value Considerations

What Is the Value of Busan 1215 Liquid Microbicide?

Busan 1215 Liquid Microbicide is used for the control of bacterial, fungal and biofilm growth in recirculating cooling water systems, evaporative condensers, airwashers, reverse osmosis systems, influent water systems and industrial fresh water systems such as holding ponds used for cooling purposes, and in process water systems used for the manufacture of paper and paperboard products.

Busan 1215 Liquid Microbicide will provide a source of ammonia to be mixed with sodium hypochlorite to generate monochloramine. Because of its specific chemical properties, this new active ingredient provides an alternative for the treatment of free floating bacteria, fungi and biofilms in fouled industrial systems. Monochloramines are less corrosive for the system and less reactive with organic matter than stronger oxidizers. As a consequence, the product is not expected to have an impact on chemical additives (for example, optical brightening agents) used in pulp treatment.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Busan 1215 Liquid Microbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because ammonia (present as ammonium sulfate) is used for formulating a commercial product, the statement on the technical label: “prevent access by unauthorized personnel” in the precaution section of the technical label will help mitigate the inappropriate use of the product, and help avoid accidental exposure. Other precautionary statements on the technical and end-use product labels, such as: “Avoid breathing vapor. Avoid contact with eyes, skin, clothing, and the contamination of food. Wear coveralls over long sleeved shirt and long pants, goggles or face shield, chemical-resistant gloves, socks and chemical-resistant footwear during mixing, loading, application, clean-up and repair activities.” should be effective in minimizing the potential for exposure.

Environment

Label statements necessitating dechlorination of effluent to non-detectable levels when monochloramine residuals (measured as chlorine, Cl_2) are detected prior to discharge will be required.

Next Steps

Before making a final registration decision on ammonia (present as ammonium sulphate), the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

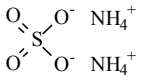
When the PMRA makes its registration decision, it will publish a Registration Decision on ammonia (present as ammonium sulphate) (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ammonia (Present as Ammonium Sulphate)

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ammonia (present as ammonium sulfate)
Function	Slimicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Ammonia (present as diammonium sulfate)
2. Chemical Abstracts Service (CAS)	Ammonia (present as ammonium sulfate)
CAS number	7783-20-2
Molecular formula	$(NH_4)_2SO_4$
Molecular weight	132.1
Structural formula	
Purity of the active ingredient	7.59% ammonia (present as ammonium sulfate)

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—BCMW Technical

Property	Result
Colour and physical state	Colourless liquid
Odour	Ammoniacal Odour
Melting range	N/A
Boiling point or range	100.3°C
Density	1.15 g/cm^3
Vapour pressure at 20°C	~ 2.3 kPa

Property	Result
Ultraviolet (UV)-visible spectrum	No absorbance expected at $\lambda > 300$ nm
Solubility in water	Completely soluble in water.
Solubility in organic solvents	The product is expected to be soluble in polar solvents and insoluble in non-polar solvents.
n-Octanol-water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	Ammonia (aq.) $pK_a = 9.25$ at 25°C
Stability (temperature, metal)	The product is stable for 28 days at 50°C. The product is corrosive to yellow metals such as bronze (moderate effect on titanium) but compatible with stainless steel.

End-use Product—Busan 1215 Liquid Microbicide

Property	Result
Colour	Colourless
Odour	Ammoniacal odour
Physical state	Liquid
Formulation type	Solution
Guarantee	7.59% ammonia (present as ammonium sulfate)
Container material and description	High-density polyethylene (HDPE) screw-cap containers
Density	1.15 g/cm^3
pH of 1% dispersion in water	9.0-9.5
Oxidizing or reducing action	Weak oxidizer and reducer
Storage stability	The product is stable for one year when stored in commercial HDPE containers at ambient temperature; stable for 28 days when stored in HDPE at 50°C.
Corrosion characteristics	The product is non-corrosive to the packaging material (HDPE). The product is corrosive to yellow metals such as bronze (moderate effect on titanium) but compatible with stainless steel. Containers made from acetal, natural rubber, polycarbonate, polyurethane and viton are not recommended and softening, loss of strength and swelling may occur in materials made of LDPE (minor effects on PVC).
Explodability	No explosive potential

1.3 Directions for Use

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, ammonia to sodium hypochlorite.

When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of 0.5-5 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand (for example, 0.5-1 ppm). The product may be added to the system continuously or intermittently to any area of the system where uniform mixing can be obtained.

Mix 9 ml of Busan 1215 to 30 ml of 10% wt/wt sodium hypochlorite OR mix 15 ml of Busan 1215 to 30 ml of 15% wt/wt sodium hypochlorite.

For intermittent treatment
1 to 2 ppm total chlorine residual in excess of the system oxidant demand for 5 to 60 minutes every 1 to 6 hours.

For continuous treatment
0.5 to 1 ppm total chlorine residual in excess of system oxidant demand on a continuous basis.

1.4 Mode of Action

The ammonium sulphate in Busan 1215 Liquid Microbicide provides a source of ammonia to be mixed with sodium hypochlorite through a chemical feed skid. Ammonia and ammonium compounds will react *in situ* with sodium hypochlorite to form chloramines. The reaction is closely controlled in the skid in term of pH to form only monochloramine, which is known to kill cells by reacting with membrane-bound enzymes.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in BCMW Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Ion chromatography and titration methods were proposed for enforcement purposes. These are standard methods and therefore acceptable without validation. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA has conducted a detailed review of the submitted data for ammonia (present as ammonium sulfate). The submitted toxicity studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is adequate to qualitatively assess the toxicological hazards of this pest control product.

Submitted information for the technical grade active ingredient, ammonia (present as ammonium sulfate), and the end-use product, Busan 1215 Liquid Microbicide (7.59 % w/w ammonia (present as ammonium sulfate)), suggests that the active ingredient is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. Ammonia (present as ammonium sulfate) is mildly irritating to the skin, slightly irritating to the eyes, and is not a skin sensitizer.

Based on information for short-term toxicity, developmental toxicity (prenatal), and genotoxicity available for ammonia (present as ammonium sulfate) at the time of evaluation, coupled with a long history of safe use as a household cleaning agent, it appears unlikely that treatment-related effects will result from exposure to ammonia (present as ammonium sulfate).

3.1.1 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on Health Canada's website. Incidents from Canada were searched and reviewed for active ammonia (present as ammonium sulfate). As of March 15, 2012, there have been no human incident reports for products containing ammonia (present as ammonium sulfate) in Canada.

3.2 Food Residue Exposure Assessment

The slimicide, monochloramine, which results when combining Busan 1215 Liquid Microbicide with sodium hypochlorite, is used in the process of treating paperboard products which is intended for non-food uses. Dietary exposure to monochloramine or any unreacted Busan 1215 Liquid Microbicide is not expected.

3.3 Occupational and Residential Risk Assessment

3.3.1 Use Description / Exposure Scenario

Busan 1215 Liquid Microbicide, when mixed with sodium hypochlorite to produce the slimicide, monochloramine, is proposed to control algal, bacterial, and fungal deposits in influent water systems and all process water systems used in the manufacture of paper and paperboard products, as well as in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, industrial fresh water systems, airwashers, reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems.

3.3.2 Mixer, Loader and Applicator Exposure and Risk Assessment

Mixing Busan 1215 Liquid Microbicide with sodium hypochlorite to produce the slimicide, monochloramine, occurs in a closed system. The potential for skin and eye exposure to Busan 1215 Liquid Microbicide is limited to loading the product into the appropriate storage container, *i.e.* principally dermal exposure but there is the possibility of splash and thus the potential for ocular exposure exists. The potential for skin and eye exposure to monochloramine is primarily limited to obtaining treated industrial fluids for analysis. Exposure to individuals loading the pesticide, as well as those involved with clean-up and maintenance duties, is expected to be negligible when the product is used according to label directions.

3.3.3 Bystander Exposure and Risk Assessment

Bystander exposure is expected to be negligible when the product is used according to label directions.

3.3.4 Postapplication Exposure

Postapplication activities are typical, for example, sampling treated industrial fluid for analysis. A re-entry period is not necessary for monochloramine or Busan 1215 Liquid Microbicide for all proposed uses.

Observing the hygiene statements on the label is sufficient to limit individuals from unnecessary risk due to postapplication exposure.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Once formed, monochloramine will readily transform into multiple compounds (other inorganic chloramines, organic chloramines, ammonia, and free chlorine). Therefore, it is generally referred to as monochloramine residuals, which are measured in terms of mg Cl_2/L. The fate of monochloramine residuals once discharged into the environment is influenced by water-phase

processes, including dilution, mixing, advection, chemical demand, benthic demand, photodegradation, volatilization, sediment adsorption and reaction, and sediment associated transport, deposition, burial and resuspension. Considering all processes, available data suggest that monochoramines have a half-life of 2 to 41 days. As such, monochloramine residuals can be categorized as non-persistent to slightly persistent in aquatic systems.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations to which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which may take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicology endpoints in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level). If the generation of quantitative data is not practical for a particular active ingredient/product, a qualitative assessment may be more appropriate.

The risk assessment for Busan 1215 Liquid Microbicide is quantitative (screening level risk assessment) and qualitative (refined risk assessment).

4.2.1 Risk to Terrestrial Organisms

Limited risk to non-target terrestrial species is expected from the use of Busan 1215 Liquid Microbicide and any resulting monochloramine input into the environment. The use pattern of this product would not result in terrestrial exposure.

4.2.2 Risk to Aquatic Organisms

The amount of monochloramine discharged into the aquatic environment through the use of the product Busan 1215 Liquid Microbicide is expected to be at, or lower than, the limit of detection (0.01 to 0.02 mg/L, depending on the analytical method). However, even at very low levels monochloramine residuals can be toxic to aquatic organisms. It is expected that any discharge of the chemicals will be subject to dilution and normal transformation, and present a low risk to aquatic organisms. As a precaution, label statements requiring the dechlorination of effluent, where applicable, will be necessary.

Non-target aquatic organisms are at most risk due to potential exposure through effluent discharge. A screening level risk assessment indicated some risk to non-target aquatic organisms. A subsequent qualitative refined risk assessment was conducted. The refined assessment indicated that, under the current use pattern, the low levels of monochloramine residual expected to be discharged into the environment would likely be subject to dilution and degradation, and present minimal toxicity. As a precaution to mitigate any unforeseen risk to aquatic organisms, label statements requiring dechlorination (to non-detect levels) of industrial process water prior to discharge into the environment will be necessary.

5.0 Value

5.1 Effectiveness Against Pests

Data from published literature was provided, as well as three reports from the operational use of the biocide. The field data were obtained from a cooling tower, a pulp and paper mill and a liner board machine. Monitoring of various parameters such as monochloramine levels, adenosine triphosphate (ATP) levels, bacteria, moulds and slime growth were followed over significant periods of time (for example, several months). These field reports and published literature demonstrated the capacity of Busan 1215 Liquid Microbicide to control bacteria, moulds and biofilm in industrial process fluids in various conditions.

5.1.1 Acceptable Efficacy Claims

The acceptable claims for Busan 1215 Liquid Microbicide is to control bacteria, moulds and biofilm growth in influent water systems, in all process water systems used for the manufacture of paper and paperboard products, in industrial cooling towers, in recirculating cooling water systems, in ponds used for cooling purposes, in evaporative condensers, in airwashers equipped with mist eliminating systems and in reverse osmosis systems.

5.2 Economics

No information provided.

5.3 Sustainability

5.3.1 Survey of Alternatives

More than 60 active ingredients, combination of active ingredients or devices are registered for uses in this use in industrial process fluids.

5.3.2 Information on the Occurrence or Possible Occurrence of the Development of Resistance

At the time of publication, no resistant bacteria have been observed by the company when using Busan 1215 Liquid Microbicide treatments. The proposed treatment is not set up to treat process waters or industrial systems to sterility, and it is acceptable that a certain level of microorganisms remains in the process fluids. If organisms proliferate that show increased resistance to the treatment and that have a negative impact on the efficacy of the treatment program, several options are possible, such as using the highest treatment dosage allowed, changing the treatment program (for example, from continuous to intermittent, using variations on length and intensity of dosing shocks, etc.), and introduce an alternating treatment program of a different type, (for example, alternate a Busan 1215 Liquid Microbicide program with a non-oxidizing biocide).

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, BCMW, and reaction chemicals including monochloramine, were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- BCMW does not meet all Track 1 criteria, and is not considered a Track 1 substance.
- Transformation products of BCMW (reaction) do not meet the Track 1 criteria.

[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade BCMW and the end-use product Busan 1215 Liquid Microbicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

A potential for concern for fresh water and marine organisms was identified during the risk assessment. To minimize toxic levels of monochloramine residuals present in effluent discharged to the environment, a label statement directing facilities to conduct dechlorination of process water when detectable levels of total chlorines are measured will be required. Standard environmental label statements for products than can be released into aquatic environment will also be used. With these mitigative measures, the product is expected to pose a minimal risk to non-target organisms.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *PMRA Formulants Policy*.

7.1 Human Health and Safety

The available information for ammonia (present as ammonium sulfate) is adequate to identify the toxicological hazards that may result from human exposure to ammonia (present as ammonium sulfate). Submitted information suggests that ammonia (present as ammonium sulfate) is of low acute toxicity irrespective of the route of exposure, minimally irritating to the eyes, slightly irritating to the skin, and not a skin sensitizer.

Although occupational exposure is possible, the precautionary statements on the product labels are sufficient to minimize any risk due to exposure of workers and bystanders.

Exposure to ammonia (present as ammonium sulfate) or monochloramine from the diet or drinking water is not expected.

7.2 Environmental Risk

The chemicals of concern, monochloramine and residuals, are not expected to build-up in the environment under the current use pattern, and exposure to non-target organisms is expected to be low, risk to the environment through this use will be minimal, and is acceptable.

7.3 Value

The data submitted in support of Busan 1215 Liquid Microbicide were adequate to demonstrate its efficacy for use against free floating bacteria and fungi and as a slimicide. Busan 1215 Liquid Microbicide is less corrosive, has a less reactive mode of action, and is not expected to negatively impact other chemicals used in the process of producing paper and paperboard products. Busan 1215 Liquid Microbicide provides an alternative for the treatment of fouled systems.

7.4 Unsupported Uses

The use of Busan 1215 Liquid Microbicide against algae, in paint spray booth sumps, non-fish containing decorative fountains, sewage and wastewater systems and against molluscs in both seawater and freshwater influent systems could not be supported with the data provided. These uses were withdrawn from the label at the applicant's request.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of BCMW Technical and Busan 1215 Liquid Microbicide, containing the technical grade active ingredient ammonia (present as ammonium sulphate), to control algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

ATP	Adenosine triphosphate
CAS	Chemical Abstracts Service
CEPA	Canadian Envrironmental Protection Act
DNA	deoxyribonucleic acid
EP	end-use product
EPA	Environmental Protection Agency
FDA	Food and Drugs Act
GRAS	generally regarded as safe
HDPE	High-density polyethylene
hr	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
LC50	lethal concentration 50%
LD50	lethal dose 50%
LDPE	low density polyethylene
LOAEL	lowest observed adverse effect level
MAS	mean average score
MAS	maximum average score for 24, 48 and 72 hours
MIS	maximum irritation score
MRL	maximum residue level
NA	nutrient agar
NOAEL	no observed adverse effect level
PCPA	*Pest Control Product Act*
PHED	Pesticide Handlers Exposure Database
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PVC	Polyvinyl chloride
SC	soluble concentrate
TGAI	technical grade active ingredient
TSMP	toxic substances management policy
UV	Ultraviolet

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Biota	N/A	Ammonia and ammonium ions	Kjeldahl titration	N/A	1914762, 2031100
		Nitrate ions	Ion chromatography		
Sediment	N/A	Ammonia and ammonium ions	Kjeldahl titration	N/A	1914762, 2031100
		Nitrate ions	Ion chromatography		
Soil	N/A	The method for sediment was extended to soil.			
Water	N/A	Ammonia and ammonium ions	Kjeldahl titration	N/A	1914762, 2031100
		Nitrate ions	Ion chromatography		
		Chlorine and chloramines	Titration		1914698, 2031098

Table 2 Toxicity Profile of Ammonia (present as Ammonium Sulfate) and Its Associated End-use Product (Busan 1215 Liquid Microbicide)

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS	REFERENCE (PMRA #)
ACUTE STUDIES - TECHNICAL [Ammonia (present as Ammonium Sulfate)]				
Acute oral toxicity	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			
Acute dermal toxicity	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			
Acute inhalation toxicity	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			
Dermal irritation	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			
Eye irritation	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS	REFERENCE (PMRA #)
Dermal sensitization	The end-use product, Busan 1215 Liquid Microbicide, is a repack of the TGAI. The studies were performed on the EP. The toxicological findings are the same for both the TGAI and the EP.			
ACUTE STUDIES – END-USE PRODUCT [Busan 1215 Liquid Microbicide]				
Acute oral toxicity	Sprague-Dawley rats (♀) Dose: 175, 550, 1750, or 5000 mg/kg bw	LD_{50} > 5000 mg/kg bw	Up and down procedure **Low toxicity**	1914844
Acute dermal toxicity	Albino Sprague-Dawley rats Dose: 2000 mg/kg bw	LD_{50} > 2000 mg/kg bw	Limit test **Low toxicity**	1914846
Acute inhalation toxicity	Albino Sprague-Dawley rats Dose: 2.08 mg/L	$_{4\ hr}$ LC_{50} > 2.08 mg/L	Limit test **Low toxicity**	1914848
Eye irritation	New Zealand White rabbits Dose: 0.1 ml undiluted	MIS 5.33/110 (1 hr after treatment) MAS 0.67/110 (24, 48, & 72 hours after treatment)	Conjunctivitis noted in all animals 1 hour post-exposure. Completely resolved by 48 hours. **Minimally Irritating**	1914849
Dermal irritation	New Zealand White rabbits Dose: 0.5 ml undiluted	MIS 1.00/8 (1 and 24 hrs after treatment) MAS 0.33/8 (24, 48, & 72 hours after treatment)	Mild transient erythema in all animals at 1 and 24 hours post-exposure. Completely resolved by 48 hours. **Slightly Irritating**	1914852

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS	REFERENCE (PMRA #)
Dermal sensitization	Albino Hartley guinea pigs Dose: 0.4 ml undiluted for both induction and challenge testing	Significant reaction was not noted 24 and 48 hours after administration of the challenge dose (0.4 ml of undiluted test substance)	Buehler Method. Only females tested. **Not a Dermal Sensitizer**	1914853

Table 3 Short-term Toxicity, Prenatal Development Toxicity, and Genotoxicity of Technical Ammonia (present as Ammonium Sulfate)

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS	REFERENCE (PMRA #)
SHORT-TERM TOXICITY				
90-day dietary	Albino rats (♀) Dose: 0, 100, 250, & 500 mg/kg bw/day	LOAEL: 500 mg/kg bw/day NOAEL: 250 mg/kg bw/day	Administered ammonium sulfamate dissolved in water. ↓ body weight at days 60 and 90 for the high dose group. No other treatment-related effects noted.	1914733
REPRODUCTION AND DEVELOPMENTAL TOXICITY				
Prenatal developmental toxicity	Sufficient information was available, as well as a history of use in household cleaning solutions, to suggest that treatment-related effects would not be anticipated.			

GENOTOXICITY			
STUDY	**SPECIES and STRAIN or CELL TYPE**	**RESULTS**	**REFERENCE (PMRA #)**
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 1535, TA 1537, and TA 1538; *Saccharomyces cereviscae*	Negative	1914738
Gene mutations in mammalian cells *in vitro*	Sufficient information was available, as well as a history of use in household cleaning solutions, to suggest that treatment-related effects would not be anticipated.		

Table 4 Alternative Active Ingredients in USC 17

PMRA Active code	Accepted name (released to the public registry)
AAB	N-COCO-ALKYLTRIMETHYLENE DIAMINES PRESENT AS MONOBENZOATE SALT
AAD	ALKYL-1,3-PROPYLENE DIAMINE ACETATES
AAD,QDO	ALKYL-1,3-PROPYLENE DIAMINE ACETATES and OXYDIETHYLENE BIS(ALKYL DIMETHYL AMMONIUM CHLORIDE)
AAM	1-ALKYL-1,3-AMINOPROPANE
ACL	ACROLEIN
AMM	AMMONIUM BROMIDE
BBG	1,2-DIBROMO-2,4-DICYANOBUTANE
BBG,ISL,IST	1,2-DIBROMO-2,4-DICYANOBUTANE and 2-METHYL-4-ISOTHIAZOLIN-3-ONE and 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE
BCC,BCH	AVAILABLE CHLORINE PRESENT AS 1-BROMO-3-CHLORO-5,5-DIMETHYLHYDANTOIN AND RELATED HYDANTOINS and AVAILABLE BROMINE PRESENT AS 1-BROMO-3-CHLORO-5,5-DIMETHYLHYDANTOIN AND RELATED HYDANTOINS
BCD	1-BROMO-3-CHLORO-5,5-DIMETHYLHYDANTOIN AND RELATED HYDANTOINS
BCD,DDH,DDM	1-BROMO-3-CHLORO-5,5-DIMETHYLHYDANTOIN AND RELATED HYDANTOINS and 1,3-DICHLORO-5,5-DIMETHYLHYDANTOIN and 1,3-DICHLORO-5-ETHYL-5 METHYLHYDANTOIN
BHA	2-BROMO-4'-HYDROXYACETOPHENONE
BHA,TCM	2-BROMO-4'-HYDROXYACETOPHENONE and 2-(THIOCYANOMETHYLTHIO)BENZOTHIAZOLE
BIS	1,4-BIS(BROMOACETOXY)-2-BUTENE
BND	BRONOPOL

PMRA Active code	Accepted name (released to the public registry)
BND,ISL,IST	BRONOPOL and 2-METHYL-4-ISOTHIAZOLIN-3-ONE and 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE
BND,QAC	BRONOPOL and N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE
BRN	2,2-DIBROMO-3-NITRILOPROPIONAMIDE
BTS,MBC	BIS(TRICHLOROMETHYL)SULFONE and METHYLENE BIS(THIOCYANATE)
BTS,QAC	BIS(TRICHLOROMETHYL)SULFONE and N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE
CHC	CALCIUM HYPOCHLORITE
DAZ	DAZOMET
DCD,KMC	DISODIUM CYANODITHIOIMIDOCARBONATE and POTASSIUM N-METHYLDITHIOCARBAMATE
DDJ	AVAILABLE CHLORINE PRESENT AS 1,3-DICHLORO-5,5-DIMETHYLHYDANTOIN AND 1,3- DICHLORO-5-ETHYL-5-METHYLHYDANTOIN
DLE	DIODOFON
DMY,MMY	1,3-DIMETHYLOL-5,5-DIMETHYLHYDANTOIN and 1- OR 3-MONOMETHYLOL-5,5-DIMETHYLHYDANTOIN
DUW,MBC	DODECYLGUANIDINE HYDROCHLORIDE and METHYLENE BIS(THIOCYANATE)
DUW,QAC	DODECYLGUANIDINE HYDROCHLORIDE and N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE
GLT	GLUTARALDEHYDE
GLT,ISL,IST	GLUTARALDEHYDE and 2-METHYL-4-ISOTHIAZOLIN-3-ONE and 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE
GLT,QAC	GLUTARALDEHYDE and N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE
GLT,QDO	GLUTARALDEHYDE and OXYDIETHYLENE BIS(ALKYL DIMETHYL AMMONIUM CHLORIDE)
HHT	HEXAHYDRO-1,3,5-TRIS(2-HYDROXYETHYL)-S-TRIAZINE
HPS	TETRAKISHYDROXYMETHYL PHOSPHONIUM SULPHATE
HPX,PCA	HYDROGEN PEROXIDE and PEROXYACETIC ACID
ISL,IST	2-METHYL-4-ISOTHIAZOLIN-3-ONE and 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE
ISZ	4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE
KDD	POTASSIUM DIMETHYLDITHIOCARBAMATE
MBC	METHYLENE BIS(THIOCYANATE)
MBC,TCM	METHYLENE BIS(THIOCYANATE) and 2-(THIOCYANOMETHYLTHIO)BENZOTHIAZOLE
NAB,SDD	NABAM and SODIUM DIMETHYLDITHIOCARBAMATE
OPP	2-PHENYLPHENOL

PMRA Active code	Accepted name (released to the public registry)
POD	POLY[OXYETHYLENE(DIMETHYLIMINIO)ETHYLENE(DIMETHYLIMINIO)ETHYLENE DICHLORIDE]
QAC	N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE
QAC,QAK,QDE,QDF	N-ALKYL (40% C12, 50% C14, 10% C16) DIMETHYL BENZYL AMMONIUM CHLORIDE and DIDECYL DIMETHYL AMMONIUM CHLORIDE and DIOCTYL DIMETHYL AMMONIUM CHLORIDE and OCTYL DECYL DIMETHYL AMMONIUM CHLORIDE
QAF,QAL	N-ALKYL (68% C12, 32% C14) DIMETHYL ETHYLBENZYL AMMONIUM CHLORIDE and N-ALKYL (5% C12, 60% C14, 30% C16, 5% C18) DIMETHYL BENZYL AMMONIUM CHLORIDE
QAK	DIDECYL DIMETHYL AMMONIUM CHLORIDE
QAL	N-ALKYL (5% C12, 60% C14, 30% C16, 5% C18) DIMETHYL BENZYL AMMONIUM CHLORIDE
QAL,QDM	N-ALKYL (5% C12, 60% C14, 30% C16, 5% C18) DIMETHYL BENZYL AMMONIUM CHLORIDE and DIALKYL (5% C12, 60% C14, 30% C16, 5% C18) METHYL BENZYL AMMONIUM CHLORIDE
QAX	DECYL ISONONYL DIMETHYL AMMONIUM CHLORIDE
QDE	DIOCTYL DIMETHYL AMMONIUM CHLORIDE
QDO	OXYDIETHYLENE BIS(ALKYL DIMETHYL AMMONIUM CHLORIDE)
SBR	SODIUM BROMIDE
SBR,SDT	SODIUM BROMIDE and SODIUM DICHLORO-S-TRIAZINETRIONE
SBR,SHC	SODIUM BROMIDE and SODIUM HYPOCHLORITE
SBR,TSC	SODIUM BROMIDE and AVAILABLE CHLORINE, PRESENT AS TRICHLORO-S-TRIAZINETRIONE
SBR,TST	SODIUM BROMIDE and TRICHLORO-S-TRIAZINETRIONE
SCH	SODIUM HYPOCHLORITE
SCL	SODIUM CHLORATE
SDD	SODIUM DIMETHYLDITHIOCARBAMATE
SDT	SODIUM DICHLORO-S-TRIAZINETRIONE
SHC	SODIUM HYPOCHLORITE
SHL	AVAILABLE CHLORINE, PRESENT AS SODIUM HYPOCHLORITE
TCM	2-(THIOCYANOMETHYLTHIO)BENZOTHIAZOLE
TST	TRICHLORO-S-TRIAZINETRIONE
TUC	2-(HYDROXYMETHYL)-2-NITRO-1,3-PROPANEDIOL
ZZZ	DEVICE, NO GUARANTEE REQUIRED

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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