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Bacteria-based household cleaning products — Specification

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In order to match with technological development and to keep continuous progress in industries, standards are subject to periodic review. Users shall ascertain that they are in possession of the latest edition

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Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 396 was prepared by Technical Committee RSB/TC 042, *Surface Active Agents*.

The assistance derived from the above source is hereby acknowledged with thanks.

Committee membership

The following organizations were represented on the Technical Committee on Surface Active agents (RSB/TC 042) in the preparation of this standard.

University of Rwanda/College of Science and Technology (UR/CST)

J&K

MORIJA Cosmetics/Morija Supply Ltd

Beauty Makers Association (BMA)

KAN-HAN Ltd

GAKO Organic Farming Training Center (GOFTC/Rwanda All Green Investment Ltd

MINAGRI/RALIS

Rwanda Standards Board (RSB) – Secretariat

Introduction

Microorganisms (such as bacteria and fungi) are naturally occurring, ubiquitous (found everywhere), and necessary in order for our environment to function. The vast majority of these microorganisms are fundamentally harmless to humans, animals, and the environment. Clearly, there are several potentially harmful bacteria that do present a public health risk (e.g., *Staphylococcus*, *E. coli, Salmonella* and so forth), but it is easy to forget that most microorganisms are beneficial and necessary for our healthy existence and survival.

Specialty chemicals and cleaning products comprised of microorganisms have been used successfully and safely for many years in a wide spectrum of industrial and household/consumer applications. These products work because the microorganisms can break down, degrade, and eventually consume a great variety of soil and other materials via the respective enzymes and metabolic pathways they utilize. At the same time, we know these microorganisms to be low risk because, traditionally, only non-pathogenic (i.e., non-disease causing) organisms are used in cleaning product applications.

The microorganisms commonly used in cleaning products are all well-known, non-pathogenic and non-toxigenic microorganisms that meet the criteria for classification as WHO Risk Group1, that is, safe for people and the environment.

Bacteria-based household cleaning products — Specification

1 Scope

This Draft Rwanda Standard specifies requirements, sampling and test methods for bacteria-based household cleaning products.

This Document covers products based on viable microorganisms for the treatment of septic systems, sanitary sewage pipelines for wastewater and for other sites with the aim of degrading organic matter and reducing odors.

It does not cover the cleaning products to be used in hospitals and other establishments related to health.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

RS EAS 814, *Determination of biodegradability of surfactants — Test method*

RS ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

RS ISO 18416, *Cosmetics — Microbiology — Detection of Candida albicans*

RS ISO 21150, *Cosmetics — Microbiology — Detection of Escherichia coli*

RS ISO 22717, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

RS ISO 22718, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

RS 278, *Cosmetics — Methods of sampling*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

bacteria-based products

products based on viable microorganisms that have the property of degrading organic matter and reducing odors from septic systems, sanitary sewage pipes and other similar systems.

3.2

viable microorganism

live and cultivable microorganism in culture media and under specific environmental conditions.

3.3

strain

genetic variant or subtype of a micro-organism.

3.4

spore

rounded resistant form adopted by a bacterial cell in adverse conditions.

3.5

wastewater

water from personal hygiene and hygiene of utensils and surfaces in domestic, commercial and industrial kitchens.

4 Requirements

4.1 General requirements

4.1.1 Selected strains of microorganisms in household cleaning products shall offer beneficial characteristics that include:

a) non-pathogenic to humans and animals

b) rapid degradation, consumption, and digestion of organic wastes

c) generation of safe, innocuous digestion by-products that do not produce malodors

d) grow and reproduce quickly and readily in the environments in which these products are used.

e) the incorporation of bacteria into cleaning products is commonly done with bacteria in spore form.

NOTE Spores are a metabolically inactive state in the life of the cell. Spores are highly resilient due to their resistance to unfavorable environmental conditions (high heat, acidic/alkaline pH, low water content, little or no nutrients) and harsh antimicrobial chemicals (toxic chemical agents, radiation, and desiccation).

f) the vegetative cell then begins to degrade and break down complex material, including organic material comprised of proteins, carbohydrates, fats, oils, greases, sugars, cellulose, starch, and so forth, via the cells enzymatic activity. Enzymatic degradation of these complex organic substrates results in smaller, simpler compounds and molecules which can be utilized by bacteria for metabolization and food source purposes. There are no free enzymes resulting from the microorganism spore in the final product.

4.1.2 The micro-organisms for bacterial-based products for use in the home shall be classified as WHO Risk Group 1 or equivalent bio-safety designation (Annex A). For strains that do not appear on any international bio-safety designation lists, alternative means may be acceptable; consultation with the Authority shall be required.

4.1.3 Genetically modified micro-organisms shall not be accepted in formulations;

4.1.4 The supplier of the microorganisms shall present the certificate or declaration that ensures the non-pathogenicity of the above product;

4.1.5 Complementary formulation components;

4.1.5.1 Only the ingredients listed in annex B shall be allowed;

4.1.5.2 The use of flavorings, coloring agents and other substances which may confuse the product with food, cosmetics or medicines shall not be allowed;

4.1.6 The permitted forms of presentation of the products based on bacteria shall be: liquid, solid, paste and gel.

4.1.7 For the record, the data and tests mentioned in annex C shall be presented.

4.2 Specific requirements

The product shall comply with the requirements given in Table 1, when tested in accordance with the methods described therein.

Table 1 – Specific requirements

S/N	Parameters	Requirements	Test methods
(i)	Solubility in water	Completely soluble	Annex C
(ii)	Rinsing properties	To pass the test	Annex D
(iii)	pH	5.5 – 6.5	Annex E
(iv)	Biodegradability test	To pass the test	RS EAS 814
(v)	Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould), CFU/g, max.	1×10^2	RS ISO 21149
(vi)	Escherchia coli in 1g or 1ml	absent	RS ISO 21150
(vii)	Candida albicans in 1g or 1ml	absent	RS ISO 18416
(viii)	Pseudomonas aeruginosa in 1g or 1ml	absent	RS ISO 22717
(ix)	Staphylococcus aureus in 1g or 1ml	absent	RS ISO 22718

5 Packaging and labelling

5.1 Packaging

The packages shall be resistant and compatible with the product, minimizing the direct contact of the operator with the product.

5.2 Labelling

5.2.1 The following information shall appear in legible and indelible marking on each container or on a label securely attached to each container:

a) name of the product as “Bacteria-based household cleaner”;

b) the manufacturer's name, trade name or trademark and full address;

c) net content;

d) list of ingredients: Mention the microorganisms by the scientific name, and the other components of toxicological interest by the technical name;

e) batch number;

f) manufacture and expiry dates;

g) instruction for use; and

h) country of origin

5.2.2 In addition to 5.2.1, the following additional information shall appear on the label:

i. a declaration that the product contains microorganisms;

ii. information on disposal of the product and the packaging;

iii. the statements: “WATCH OUT! DANGEROUS IF SWALLOWED, CONTAINS LIVE MICROORGANISMS”, "BEFORE USE READ THE LABEL INSTRUCTIONS”;

iv. do not apply on food, cooking utensils, aquariums and food handling surfaces;

v. do not reuse empty containers;

vi. keep the product in its original container;

vii. wear gloves to apply the product;

viii. in case of direct contact with the product, wash the part with soap and water;

ix. in case of contact with eyes, rinse with plenty of running water and consult the nearest Health Service, taking the container or the product label;

x. keep the product out of reach of children and pets (in bold and capitalized); and

xi. in case of aspiration or inhalation, move person to ventilated place (when appropriate).

5.2.3 When applicable, the following information shall be added:

A. on the procedures to be adopted in case of accidental spillage of the product; and

B. on incompatibilities and restrictions of use of the product, when applicable.

6 Sampling

Sampling shall be done in accordance with RS 278.

Annex A
(normative)

Risk Group and Bio-safety Level Definitions

A.1 European Economic Community (Directive 93/88/EEC, Oct. 1993)

Group 1, biological agent means one that is unlikely to cause human disease;

Group 2, biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;

Group 3, biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;

Group 4, biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

A.2 NIH Guidelines on Recombinant DNA (April 2002)

Risk Group 1 (RG1), agents are not associated with disease in healthy adult humans.

Risk Group 2 (RG2), agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 3 (RG3), agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

Risk Group 4 (RG4), agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

A.3 Canadian Laboratory Bio-safety Guidelines (2nd ed. 1996)

Risk Group 1 (low individual and community risk), this group includes those microorganisms, bacteria, fungi, viruses and parasites, which are unlikely to cause disease in healthy workers or animals.

Risk Group 2 (moderate individual risk, limited community risk), a pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 3 (high individual risk, low community risk), a pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another, or that can be treated by antimicrobial or anti-parasitic agents.

Risk Group 4 (high individual risk, high community risk), a pathogen that usually produces very serious human animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or casual contact.

A.4 CDC/NIH Bio-safety in microbiological and Biomedical Laboratories (4th Edition, 1999)

BIOSAFETY LEVEL 1 is suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.

BIOSAFETY LEVEL 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.

BIOSAFETY LEVEL 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

BIOSAFETY LEVEL 4 is required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.

Annex B
(normative)

Complementary components of formulation

Lactic acid

Linear ethoxylated alcohol

Amylase

Beta Gluconase

Sodium bicarbonate

Sodium carbonate

Cellulase

Sodium, Potassium, Magnesium, Calcium, Ammonium and Ferrous Chlorides

Dipropylene glycol monoethyl ether

Hexylic, octyl and decyl ethers

Disodium phosphate

Phosphate mono and dibasic potassium

Monosodium phosphate

Tricalcium phosphate

Glucose

Hemicellulose

Protein hydrolyzate

Hydroxyethyl cellulose

Lipase

Sodium molybdate

Monoethanolamine

Sorbitan mono oleate

Pectinase

Protease

Magnesium sulphate

Anionic and non-ionic surfactants

Annex C
(normative)

Required information for the quality control of household use of bacteria based products

C.1 General information

1) Name of the applicant company;
2) Full address of the applicant company;
3) Copy of the authorization / authorization of the operation of the company issued by the Competent Health Authority;
4) Name and signature of the legal representative before the Competent Sanitary Authority;
5) Data and signature of the technical manager;
6) Label text.
7) In the case of imported products in addition to the items mentioned above include:
   a) Copy of the certificate of free sale issued by the Competent Sanitary Authority of the country of origin duly legalized;
   b) Copy of the certificate of registration issued by the Competent Sanitary Authority of the country of origin, duly legalized, in the corresponding cases;
   c) Original label and corresponding translation, if applicable;
   d) Copy of the document containing the quali-quantitative formula issued by the manufacturer in the country of origin.

C.2 Technical information

1) Product description
2) Name or brand of the product;
3) Qualitative quantitative composition of the product, specifying microorganisms by their scientific name and microbial strains, their origin, number of viable microorganisms expressed in colony forming units per milliliter or per gram (cfu / ml) or (cfu / g) and other components expressed by their technical names or common names, where applicable, and in units of the metric system;
4) Physical and chemical data of the product (color, state, miscibility, pH, specific gravity, viscosity, water solubility and other data when necessary);
5) Description of the primary and secondary packaging, if any;
6) Description of the lot or consignment identification system;
7) Form of presentation;
8) Microbiological test data indicating:
   a) The scoring of viable microorganisms for each microbial strain in cfu / ml or cfu / g;
   b) Absence of pathogenic microorganisms of the genera Salmonella, Shigella and Escherichia coli;
   c) Absence of Pseudomonas aeruginosa;
   d) Absence of microorganisms Saprophytes mainly Stenotrophomonas maltophilia with resistance outside the patterns defined in the literature through the presentation of data "in vitro" susceptibility to the recommended antimicrobial susceptibility;
   e) Biochemical identification data of the microorganisms used;
   f) Total count of viable microorganisms in cfu / ml or cfu / g.
9) Stability test data including the total counts of viable microorganisms of the prepared product and at the end of the intended period of validity.
10) Term of validity.
11) Information on incompatibilities, where appropriate.

12) Efficacy data using methods recognized by the scientific community.
13) Methods of deactivation and disposal of the product and its packaging taking care to avoid risks to human health and the environment.
14) Data on the conservation of the product.

Annex D
(normative)

Test for solubility

D.1 Preparation of synthetic hard water

Weigh to the nearest 0.001 g, about 0.264 g of $CaCl_2.2H_2O$ and 0.295 g of $MgSO_4.2H_2O$. Transfer quantitatively to a 1-L volumetric flask; dissolve in a small portion of distilled water and make up to the mark with distilled water.

The resulting solution will have a concentration of 8.1 millimole per litre calcium hardness.

D.2 Procedure

Using a pipette, transfer 5.0 mL of the detergent into a test tube and add sufficient synthetic hard water prepared in A.1 to give a volume of 50 mL. Stir vigorously for 5 min, and observe for solubility.

Annex E
(normative)

Test for rinsing properties

Dissolve 2.0 mL of the product as completely as possible in 98 mL of synthetic hard water (see A.1) at ambient temperature, in a clean 250-mL Erlenmeyer flask. Stopper the flask and stir vigorously for 1 min. Pour out the solution. Rinse the flask by the same procedure, using three 75 mL portions of synthetic hard water alone. Invert the flask, allow to dry and examine for any residue not rinsed from the interior. The flask shall contain no more residues after being dried than a similar allowed drying after rinsing with synthetic hard water alone.

Annex F
(normative)

Determination of pH

F.1 General

pH determination should be made in an acid free atmosphere.

F.2 Apparatus

F.2.1 Any standard pH meter, equipped with a low sodium error glass electrode. The instrument shall be calibrated and standardized with standard buffer solutions (see E.3.2) before use.

F.2.2 Volumetric flask, 1000 mL capacity

F.2.3 Beakers, 1000 mL

F.3 Reagents

F.3.1 Distilled water shall be boiled thoroughly or purged with carbon dioxide-free air to remove carbon dioxide and shall be protected with soda lime or soda asbestos while cooling and in storage. The pH of this water shall be protected with soda lime or soda asbestos while cooling and in storage. The pH of this water shall be between 6.2 and 7.2 at 27 °C. The residue on evaporation when heated at 105 °C for one hour shall not exceed 0.5 mL per litre.

F.3.2 Standard buffer solutions with the pH range of 9 to 11 at 27 ºC for calibrating the pH meter.

F.4 Procedure

Weigh to the nearest milligram approximately 10 g of the material and transfer to a 1-L volumetric flask. Partially fill the flask with distilled water and agitate until the sample is completely dissolved. Adjust the temperature of the solution and the distilled water to 27 °C ± 2 °C and fill to the calibration mark with distilled water, stopper the flask mix thoroughly and allow the solution to stand at a temperature of 27 °C ± 2 °C for two hours prior to measuring the pH. Measure the pH of the solution at 27 °C ± 2 °C using a glass electrode.

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