DJS 351: 202(X)
ICS 71.100.40

Draft Jamaican Standard Specification

for

Instant hand sanitizers

BUREAU OF STANDARDS JAMAICA

DEADLINE FOR COMMENTS: MAY 3, 2020

IMPORTANT NOTICE

Jamaican standards are subjected to periodic review. The next amendment will be sent without charge if you cut along the dotted line and return the self-addressed label. If we do not receive this label we have no record that you wish to be kept up-to-date. Our address:

Bureau of Standards Jamaica
6 Winchester Road
P.O. Box 113
Kingston 10
Jamaica W.I.

----------(✂cut along the line)----------

DJS 351: 202X

NAME OR
DESIGNATION……

ADDRESS……

……

……

JBS CERTIFICATION MARK PROGRAMME

The general policies of the JBS Certification Mark Programme are as follows:

- The JBS provides certification services for manufacturers participating in the programme and licensed to use the gazetted JBS Certification Marks to indicate conformity with Jamaican Standards.
- Where feasible, programmes will be developed to meet special requirements of the submittor.
- JBS certification is provided in the interest of maintaining agreed-upon standard requirements. Where applicable, certification may form the basis for acceptance by inspection authorities responsible for enforcement of regulations.
- In performing its functions in accordance with its policies, JBS does not assume or undertake to discharge any responsibility of the manufacturer or any other party.

Participants in the programme should note that in the event of failure to resolve an issue arising from interpretation of requirements, there is a formal appeal procedure.

Further information concerning the details of JBS Certification Mark Programme may be obtained from the Jamaica Bureau of Standards, 6 Winchester Road, Kingston 10.

CERTIFICATION MARKS

Product Certification Marks

Plant Certification Mark

Certification of Agricultural Produce (CAP) Mark

Jamaica-Made Mark

Draft Jamaican Standard Specification

for

Instant hand sanitizers

Bureau of Standards Jamaica
6 Winchester Road
P.O. Box 113
Kingston 10
JAMAICA, W. I.
Tel: (876) 926 -3140-5/ 618 – 1534 / 632- 4275
Fax: (876) 929 -4736
Website: www.bsj.org.jm
E-mail: info@bsj.org.jm

Month 201

ISBN XXX XXX XXX XXX X
Declared by the Bureau of Standards to be a standard specification pursuant to section 7 of the Standards Act 1968.

First published Month 201X

This standard was circulated in the draft form for comment under the reference DJS 351: 20XX
Jamaican Standards establish requirements in relation to commodities, processes and practices, but do not purport to include all the necessary provisions of a contract.

The attention of those using this standard specification is called to the necessity of complying with any relevant legislation.

Amendments

No.	Date of Issue	Remarks	Entered by and date

Contents

Foreword

The use of alcohol-based hand sanitizer products is widespread. It is therefore important to ensure that these products are safe and suitable for the intended use.

The safety and efficacy of the product is dependent on its composition and the manufacturing process therefore its physical, chemical and microbiological properties must be specified and controlled. All manufacturers, importers, distributors and other entities engaged in the production and/or trade of alcohol-based hand sanitizers shall comply with the requirements of this standard.

This Standard is intended to be compulsory.

Related Documents

This Standard makes reference to the following:

a) *World Health Organization (WHO) 2009 Recommended hand rub formulation*
b) *JS 170 Jamaican standard specification for Cosmetics Part 1: General requirements*
c) *JS 170 Jamaican standard specification for Cosmetics Part 2: Water used in the preparation of cosmetics*
d) *CRS 55-1: 2016 Labelling of goods — Part 1: General requirements*
e) *CRS 55-1: 2016 Labelling of goods — Part 2: Specific requirements for prepackaged goods*

Instant Hand Sanitizer - Specification

1. Scope

This Jamaican standard prescribes the requirements for alcohol-based instant hand sanitizers. The standard does not include requirements for non-alcohol-based hand sanitizers.

2. Definition

For the purpose of this standard the following definition applies:

2.1. hand sanitizer. An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth.

NOTE Such preparations may contain one or more types of alcohol, other active ingredients with excipients, and humectants.

3. General Requirements

3.1 Product Description

3.1.1 The hand sanitizer shall be in the form of liquid, foam or gel.

3.1.2 The hand sanitizer shall also comply with the requirements outlined in Table 1 when tested with the appropriate methods.

Table 1 — Requirements for Instant Hand Sanitizer

The table shows a minimum and maximum range for alcohol content and pH. All other values within the table are maximum allowable limits.

Characteristics	Requirement
Alcohol content (ethanol and /or isopropanol) v/v	60-80%
Turbidity	10 (NTU)
Ph	6-8
Total hardness ($CaCO_3$)	5 mg/L
Total solids	10 mg/L
Chloride	0.5 mg/L
Sulphate	1 mg/L
Calcium	5 mg/L

Characteristics	Requirement
Heavy metals • Cadmium • Copper • Manganese • Mercury • Lead	 0.003 mg/L 2.0 mg/L 0.5 mg/L 0.001 mg/L 0.01 mg/L
Iron	1 mg/L
Non-volatile residue	5 mg/L
Specific conductance	10 µmho/cm
Bactericidal efficacy	to pass test

4. Requirements for establishments producing hand sanitizer

4.1 Buildings and facilities

4.1.1 Buildings used in the manufacture or storage of hand sanitizers shall be of suitable size, design and construction to permit unobstructed placement of equipment, orderly storage of materials and products, sanitary operation and adequate cleaning and maintenance.

4.1.2 Floors, walls and ceilings shall be constructed of smooth easily cleanable surfaces and shall be kept clean and in good repair.

4.1.3 Fixtures, ducts and pipes shall be installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment or finished products in bulk.

4.1.4 Lighting and ventilation shall be sufficient for the intended operation and comfort of personnel.

4.1.5 Water supply, washing and bathroom facilities, floor drainage and sewage system shall be adequate for sanitary operation and cleaning of facilities, equipment and utensils, as well as to satisfy employee needs and facilitate personal cleanliness.

4.2 Equipment

4.2.1 Equipment and utensils used in processing, handling, holding, transferring and filling shall be of appropriate design, material and workmanship to prevent corrosion, build-up of material, or adulteration with lubricants, dirt or sanitizing agents.

4.2.2 Utensils, transfer piping and contact surfaces of equipment shall be well maintained and cleaned and shall be sanitized at appropriate intervals.

4.2.3 Cleaned and sanitized portable equipment, utensils and contact surfaces shall either be covered and protected, or stored and located in a manner that protects them from dust, harmful micro-organisms or other contamination.

4.3 Personnel

4.3.1 The personnel supervising or performing the manufacture or control of the hand sanitizer shall have the education, training and/or experience to perform the assigned functions.

4.3.2 Persons coming into direct contact with materials used to make the hand sanitizer, finished products in bulk or contact surfaces, shall wear appropriate outer garments, gloves, hair restraints and other protective garments as necessary and shall maintain adequate personal cleanliness, to prevent adulteration of the hand sanitizer.

4.4 Raw materials

4.4.1 Raw materials and primary packaging materials shall be stored and handled in a manner which prevents their mixing, contamination with micro-organisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.

4.4.2 Containers of raw materials shall be closed and bagged or boxed. Raw materials shall be stored off the floor and away from walls.

4.4.3 Containers of raw materials shall be labelled and colour coded with respect to identity. They shall also be labelled with respect to lot identification and control status.

4.4.4 Raw materials shall be sampled and tested or examined in accordance with documented procedures assuring the absence of contamination with filth, micro-organisms or other extraneous substances to the extent necessary to prevent adulteration of finished products.

4.4.5 Materials not meeting acceptance specifications shall be properly identified and controlled to prevent their use in the manufacture of the hand sanitizers.

4.5 Production control

4.5.1 Manufacturing and control procedures shall be established and written instructions, that is, formulations, processing, transfer and filling instructions, in-process control methods among others shall be maintained.

4.5.2 The equipment used for processing, transfer and filling, and the utensils and the containers for holding raw and bulk materials, shall be clean, in good repair and in sanitary condition.

4.5.3 Samples shall be taken, as appropriate, during and/or after processing, transfer or filling, for testing for adequacy of mixing or other forms of processing, absence of hazardous micro-organisms or chemical contaminants and compliance with any other acceptance specifications.

4.5.4 Major equipment, transfer lines, containers and tanks used for processing, filling or holding the hand sanitizer shall be identified to indicate contents, batch designation, control status and other pertinent information.

4.5.5 The equipment for processing, holding, transferring and filling of each batch shall be labelled regarding identity, batch identification and control status.

4.6 Laboratory control

4.6.1 Raw materials, in-process samples and finished products shall be tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties and microbial contamination, as well as for hazardous or other unwanted chemical contaminants normally associated with the raw material.

4.6.2 Reference samples of approved lots or batches of raw materials and finished products shall be retained for a specified time period, shall be stored under conditions that protect them against contamination or deterioration, and shall be retested for continued compliance with established acceptance specifications.

4.6.3 The water supply, particularly the water used as a hand sanitizer ingredient, shall be tested regularly for its conformity with chemical, analytical and microbiological specifications.

4.7 Records

4.7.1 Control records shall be maintained for raw materials, primary packaging materials, batch manufacturing and distribution purposes.

4.7.2 Documentation of the handling, storage, laboratory control and use of raw materials and primary packaging materials, as well as disposal of rejected material shall be maintained.

4.7.3 During the manufacture of batches, the following shall be documented:

(a) names, lot numbers and quantities of raw materials used;

(b) names of personnel performing different duties

(c) processing, handling, transferring, holding and filling;

(c) sampling, controlling, adjusting and reworking; and

(d) code marks of batches and finished products.

4.7.4 Details of sampling, individual laboratory controls test results and control status of the finished products shall be recorded.

4.7.5 For distribution and traceability purposes, records of initial shipment, code marks and consignees shall be kept.

5. Packaging and Labelling

5.1 Packaging

5.1.1 The sanitizer shall be supplied in suitable sealed containers/packages.

5.1.2 The containers/packages (including the closures) shall not interact chemically or physically with the sanitizer and shall be strong enough to protect the sanitizer adequately during normal handling, transportation and storage.

5.1.3 Only containers/packages of the same size and bearing the same batch identification shall be packed together in a bulk container.

5.2 Labeling

5.2.1 General Requirements

5.2.1.1 A label affixed to, or marked on any product, or its external packing or referring to any product, shall conform to the following requirements:

a) It shall provide the common name of the product 'hand sanitizer', a description of the product and adequate information to a potential purchaser to enable the purchaser or consumer to select the product best suited to their needs. This information shall include the weight, net weight, volume, net volume, measurement, specification, or size as applicable and shall give an accurate description of components of the product as is necessary.

b) The name and strength of the active ingredient(s).

c) It shall provide a purchaser or consumer with appropriate safety instructions, and precautions for use where:

1) There is a risk to the health and safety of a consumer;

EXAMPLE The inclusion of Health warnings or allergy risks

2) Any significant deterioration of the quality, performance or life durability which may result if the product is not properly stored;

d) The name and identifiable address, the principal place of business or registered office of the manufacturer, agent, distributor, seller, re-filler, packer, importer or organization responsible for the product and the name of the country of origin. It shall be preceded by the words "manufactured by ....", "packed by.....", "distributed by....", "imported by.....", as applicable, and the following words as appropriate:

1) "made in (name of territory)";
2) "product of (name of territory)";
3) "packaged in (name of territory)";
4) "manufactured in (name of territory);
5) "assembled in (name of territory).

e) It shall be legible and durable up to the point-of-sale to the ultimate consumer. For legibility, the information appearing on a label shall be in a minimum type size in accordance Table 2 below.

f) The minimum type size shall be the smallest type size that is permitted based on space available for labelling. The height of the type shall be determined by measuring the height of the lower case 'o' or its equivalent when mixed upper and lower case letters are used, or the height of the upper case letters when only upper case letters are used. Minimum type sizes shall be as outlined in Table 2 below:

Table 2 — Minimum type size

Minimum type size	Area of principal display panel
1.6 mm (1/16 in)	32 cm^2 (5 in^2) or less
3.2 mm (1/8 in)	more than 32 cm^2 (5 in^2)

g) The label shall not be false**,** misleading or deceptive.

h) The label shall provide information regarding any specific dangers which might be related to the use of the product and shall provide first aid instructions where necessary.

i) The label shall not contain any information by words, pictorial or other devices which refer to, or are suggestive, either directly or indirectly, of another product with which such a product might be confused, or in such a manner as to lead the purchaser, or consumer to assume that the product is connected with such other products.

5.2.2 Prevention of deception

A label on the package of the product may contain other information, designs, symbols or pictorial matter, provided that no words, illustration, symbols, or other matter are used to:

a) give an erroneous impression of the net contents of the package;

b) give an erroneous impression of any ingredient or component of the product or that the product contains an ingredient or component that is does not contain;

c) refer to the nature, origin, type, quality, performance, function, or method of manufacture or production of the product that is likely to give an erroneous impression of the matter described or depicted;

d) give an erroneous impression of the country of origin of the product; and

e) give an erroneous impression of the price or unit price of the product.

5.2.3 Language to be used on labels of pre-packaged goods

5.2.3.1 All statements required shall be in the official language or languages of the country in which the product is being sold.

5.2.4 Presentation of Information

5.2.4.1 All labelling information required by this standard shall be clearly presented and readily discernible under normal conditions of sale.

5.2.4.2 Where the statements of common name, manufacturer's name, manufacturer's address or country of origin consist of more than one word, the statements required by (6.2.1.1 d) shall be in letters of identical size and style of print.

5.2.5 Date markings and expiry dates

5.2.5.1 Where the product is likely to deteriorate after the date of manufacture or packaging so that the quality, safety, hygiene or other desirable characteristics are not likely to be maintained, the expected shelf life shall be indicated with a date of minimum durability and it shall be placed on the product, label or package. Such a date mark shall not be defaced or removed from the product or from the label on the package before possession of the product by the purchaser.

5.2.5.2 The format for the date markings shall be as follows:

a) the day, month and the year for hand sanitizer produced for consumption within a period of not more than three months; and

b) the month and the year for hand sanitizer produced for consumption within a period longer than three months.

5.2.5.3 The month shall be declared using the first three letters, first four letters, full word or numerical format.

5.2.5.4 The year shall be declared as follows:

a) a two digit numerical representation is adequate when accompanied by the first three letters of the month; or

EXAMPLE JAN 08

b) a four digit numerical representation, such as 2008, when the two digit numerical representation of the month is used.

EXAMPLE 01 2008

5.2.5.5 The date of minimum durability shall be declared by the words "best before" or words expressing similar intent including "expiry" or "use by", "BB" or "EXP". The words used to express date of minimum durability shall be accompanied by:

a) either the date itself; or

b) a reference to where the date is given.

5.2.5.6 In addition to the date of minimum durability if there are any special conditions for storage of the good, it shall be declared on the label if the validity of the date depends on it.

The Council is appointed by the Minister in the manner provided for in the Standards Act, 1969. Using its powers in the Standards Act, the Council appoints committees for specified purposes.

The Standards Act, 1969 sets out the duties of the Council and the steps to be followed for the formulation of a standard.

Preparation of standards documents

The following is an outline of the procedure which must be followed in the preparation of documents:

1. The preparation of standards documents is undertaken upon the Standard Council's authorisation. This may arise out of representation from national organisations or existing Bureau of Standards' Committees of Bureau staff. If the project is approved it is referred to the appropriate sectional committee or if none exists a new committee is formed, or the project is allotted to the Bureau's staff.

2. If necessary, when the final draft of a standard is ready, the Council authorises an approach to the Minister in order to obtain the formal concurrence of any other Minister who may be responsible for any area which the standard may affect.

3. The draft document is made available to the general public for comments. All interested parties, by means of a notice in the Press, are invited to comment. In addition, copies are forwarded to those known, interested in the subject.

4. The Committee considers all the comments received and recommends a final document to the Standards Council

5. The Standards Council recommends the document to the Minister for publication.

6. The Minister approves the recommendation of the Standards Council.

7. The declaration of the standard is gazetted and copies placed on sale.

8. On the recommendation of the Standards Council the Minister may declare a standard compulsory.

9. Amendments to and revisions of standards normally require the same procedure as is applied to the preparation of the original standard.

Overseas standards documents

The Bureau of Standards Jamaica maintains a reference library which includes the standards of many overseas standards organisations. These standards can be inspected upon request.

The Bureau can supply on demand copies of standards produced by some national standards bodies and is the agency for the sale of standards produced by the International Organization for Standardization (ISO) members.

Application to use the reference library and to purchase Jamaican and other standards documents should be addressed to:

Bureau of Standards Jamaica
6 Winchester Road
P.O. Box 113,
Kingston 10
JAMAICA, W. I.