



29 April 2016

(16-2411)

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Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Notifying Member: <u>MEXICO</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: <i>Secretaría de Salud</i> (Ministry of Health) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: <i>Comité Consultivo Nacional de Normalización de Regulación y Fomento Sanitario</i> (National Advisory Committee on Standardization for the Regulation and Promotion of Health) Oklahoma número 14, planta baja, Colonia Nápoles 03810, México, D.F. Tel.: 5080 5200, Ext. 1333 Email: rfs@cofepris.gob.mx
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Denatured ethyl alcohol (tariff heading: 22072001)
5.	Title, number of pages and language(s) of the notified document: <i>Proyecto de norma oficial mexicana PROY-NOM-138-SSA1-2015, que establece las especificaciones sanitarias del alcohol etílico desnaturalizado, utilizado como material de curación, así como para el alcohol etílico de 96°g.l. sin desnaturalizar, utilizado como materia prima para la elaboración y/o envasado de alcohol etílico desnaturalizado como material de curación</i> (Draft Mexican Official Standard PROY-NOM-138-SSA1-2015 establishing the sanitary specifications for denatured ethyl alcohol, used as a wound dressing material, for undenatured 96° G.L. ethyl alcohol, used as a raw material in the production of denatured ethyl alcohol as a wound dressing material, and for packaging establishments) (11 pages, in Spanish)
6.	Description of content: Ethyl alcohol, or ethanol, is one of the most widely used wound dressing materials, due to its antiseptic properties. However, given that ethyl alcohol can be easily obtained by the general population and is an addictive substance, it may be used inappropriately (ingested), and its consumption may lead to public health problems. Denaturing substances are therefore added to ethyl alcohol, such as denatonium benzoate, sucrose octaacetate and acetone, which give it an unpleasant taste. Nevertheless, it is necessary to issue provisions on the control and processing of this wound dressing material, in order to prevent it from being used for purposes other than those for which it is marketed, namely, to dress wounds.

7.	<p>Objective and rationale, including the nature of urgent problems where applicable: The notified draft Standard establishes the sanitary specifications for denatured alcohol, used as a wound dressing material, for denatured 96° G.L. ethyl alcohol used as raw material in the production of denatured ethyl alcohol as a wound dressing material, and for packaging establishments.</p>
8.	<p>Relevant documents:</p> <ul style="list-style-type: none"> • <i>Norma Oficial Mexicana NOM-241-SSA1-2012, Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de dispositivos médicos</i> (Mexican Official Standard NOM-241-SSA1-2012: Good manufacturing practices for establishments engaged in the manufacture of medical devices) • <i>Norma Oficial Mexicana NOM-008-SCFI-2002, Sistema General de Unidades de Medida</i> (Mexican Official Standard NOM-008-SCFI-2002: General system of units of measurement) • <i>Norma Oficial Mexicana NOM-002-SCFI-2011, Productos preenvasados - Contenido neto - Tolerancias y métodos de verificación</i> (Mexican Official Standard NOM-002-SCFI-2011: Pre-packaged products - Net content - Tolerances and verification methods) • <i>Norma Oficial Mexicana NOM-030-SCFI-2006, Información comercial - Declaración de cantidad en la etiqueta.- Especificaciones</i> (Mexican Official Standard NOM-030-SCFI-2006: Trade information - Quantity declarations on labels - Specifications) • <i>Norma Oficial Mexicana NOM-137- SSA1-2008, Etiquetado de dispositivos médicos</i> (Mexican Official Standard NOM-137- SSA1-2008: Labelling of medical devices) • <i>Norma Oficial Mexicana NOM-005-STPS-1998, Relativa a las condiciones de seguridad e higiene en los centros de trabajo para el manejo, transporte y almacenamiento de sustancias químicas peligrosas</i> (Mexican Official Standard NOM-005-STPS-1998 on occupational health and safety requirements governing the handling, transport and storage of hazardous chemical substances) • <i>Norma Oficial Mexicana NOM-002-STPS-2010, Condiciones de seguridad - Prevención y protección contra incendios en los centros de trabajo</i> (Mexican Official Standard NOM-002-STPS-2010: Safety requirements - Prevention of and protection against fire in the workplace) • <i>Norma Oficial Mexicana NOM-018-STPS-2015, Sistema armonizado para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo</i> (Mexican Official Standard NOM-018-STPS-2015: Harmonized system for the identification and communication of dangers and risks associated with hazardous chemical substances in the workplace)
9.	<p>Proposed date of adoption: The notified draft Mexican Official Standard will be adopted upon its publication in the Official Journal as a final standard.</p> <p>Proposed date of entry into force: This Standard will enter into force, on a mandatory basis, 60 calendar days after its publication in the Official Journal.</p>
10.	<p>Final date for comments: 60 days after its notification to the WTO.</p>
11.	<p>Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Secretaría de Economía Subsecretaría de Competitividad y Normatividad Dirección General de Normas Tel.: (+52) 55 52 29 61 00, Ext. 43244 Fax: (+52) 55 5520 9715 Website: http://www.economia-noms.gob.mx/?P=144 Email: normasomc@economia.gob.mx and/or sofia.pacheco@economia.gob.mx</p> <p>Text available online at: http://www.dof.gob.mx/nota_detalle.php?codigo=5434785&fecha=27/04/2016 http://members.wto.org/crnattachments/2016/TBT/MEX/16_1719_00_s.pdf</p>