

DECLARATORIA de vigencia de la Norma Mexicana NMX-R-16197-SCFI-2019.

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- ECONOMÍA.- Secretaría de Economía.- Dirección General de Normas.

DECLARATORIA DE VIGENCIA DE LA NORMA MEXICANA NMX-R-16197-SCFI-2019, COMPILACIÓN Y DESCRIPCIÓN DE MÉTODOS DE DETECCIÓN TOXICOLÓGICA PARA NANOMATERIALES MANUFACTURADOS.

La Secretaría de Economía, por conducto de la Dirección General de Normas, con fundamento en lo dispuesto por los artículos 34, fracciones II, XIII y XXXIII de la Ley Orgánica de la Administración Pública Federal; 3, fracción X, 51-A, 51-B y 54 de la Ley Federal sobre Metrología y Normalización; 45 y 46 del Reglamento de la Ley Federal sobre Metrología y Normalización; y, 36, fracciones I, IX y XII del Reglamento Interior de la Secretaría de Economía, publica la Declaratoria de Vigencia de la Norma Mexicana que se enuncia a continuación, misma que ha sido elaborada y aprobada por el Comité Técnico de Normalización Nacional de Nanotecnologías.

El texto completo de la Norma Mexicana que se indica puede ser adquirido en el Centro Nacional de Metrología (CENAM) ubicado en Kilómetro 4.5 carretera a los Cues, Código Postal 76246, municipio El Marqués, Querétaro, teléfono (442) 211 0500 y/o al correo electrónico: rlazos@cenam.mx, o consultarlo gratuitamente en la Dirección General de Normas de la Secretaría de Economía, ubicada en Pachuca número 189, Colonia Condesa, Código Postal 06140, Demarcación Territorial Cuauhtémoc, Ciudad de México.

La presente Norma Mexicana entrará en vigor a los 60 días naturales contados a partir del día natural inmediato siguiente al día de la publicación de su declaratoria de vigencia en el Diario Oficial de la Federación. SINEC-20200219142059955.

| CLAVE O CÓDIGO | TÍTULO DE LA NORMA MEXICANA |
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| NMX-R-16197-SCFI-2019 | COMPILACIÓN Y DESCRIPCIÓN DE MÉTODOS DE DETECCIÓN TOXICOLÓGICA PARA NANOMATERIALES MANUFACTURADOS. |
| <p style="text-align: center;">Objetivo y campo de aplicación</p> <p>Esta Norma Mexicana ofrece una recopilación y descripción de métodos in vitro e in vivo que pueden ser útiles para el examen toxicológico, incluida la detección ecotoxicológica de los nanomateriales manufacturados. Las pruebas de detección toxicológica incluidas en este Proyecto de Norma Mexicana se pueden utilizar para fines tales como la toma de decisiones iniciales en la investigación y el desarrollo de productos, retroalimentación rápida sobre posibles problemas toxicológicos o de seguridad, o para la evaluación preliminar de nanomateriales manufacturados. Este Proyecto de Norma Mexicana se divide entre ensayos de detección relacionados con humanos y ensayos de detección relacionados con el medio ambiente. Una prueba de detección es una prueba relativamente simple y económica que puede administrarse fácilmente y proporciona una indicación de los posibles efectos adversos y efectos sobre la salud humana o el medio ambiente.</p> <p>Esta Norma Mexicana pretende complementar otros esfuerzos internacionales que abordan la toxicología de los nanomateriales centrándose en los métodos de detección adecuados para la evaluación preliminar y no pretende duplicar esfuerzos similares en otras organizaciones internacionales como la Organización para la Cooperación y el Desarrollo Económico (OCDE). Si la prueba de detección proporciona una indicación temprana de peligro, la guía se referirá a los enfoques de otras organizaciones para la evaluación toxicológica a gran escala o estudios escalonados adicionales.</p> | |
| <p style="text-align: center;">Concordancia con Normas Internacionales</p> <p>Esta Norma Mexicana es idéntica (IDT) al Reporte Técnico ISO/TR 16197:2014 <i>Nanotechnologies-Compilation and description of toxicological screening methods for manufactured nanomaterials</i>.</p> | |
| <p style="text-align: center;">Bibliografía</p> <ul style="list-style-type: none"> ·[Aggarwal, 2009] Aggarwal P., Hall J.B., McLeland C.B., Dobrovolskaia M.A., McNeil S.E. Nanoparticle interaction with plasma proteins as it relates to particle biodistribution, biocompatibility and therapeutic efficacy. <i>Adv. Drug Deliv. Rev.</i> 2009, 61 pp. 428-437. ·[AFSA, 2018] Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed, disponible en https://www.efsa.europa.eu/en/efsajournal/pub/5327 La versión 2011 está disponible en http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm. ·[Aisaka, 2008] Aisaka Y., Kawaguchi R., Watanabe S. Hemolysis caused by titanium dioxide particles. <i>Inhal. Toxicol.</i> 2008, 20 pp. 891-893 ·[Alfaro-Moreno, 2008] Alfaro-Moreno E., Nawrot T.S., Vanaudenaerde B.M., Hoylaerts M.F., Vanoirbeek J.A., Nemery B. et al. Co-cultures of multiple cell types mimic pulmonary cell communication in response to urban PM10. <i>Eur. Respir. J.</i> 2008, 32 pp. 1184-1194 | |

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- [OECD 201] OECD 201, Freshwater Alga and Cyanobacteria, Growth Inhibition Test, 3 days
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Atentamente,

Ciudad de México, a 19 de febrero de 2020.- El Secretario Técnico de la Comisión Nacional de Normalización, **Alfonso Guati Rojo Sánchez**.- Rúbrica.