SELF-REGULATION OF NANO-PRODUCTS IN THE MALAYSIAN MARKET – A PERSPECTIVE

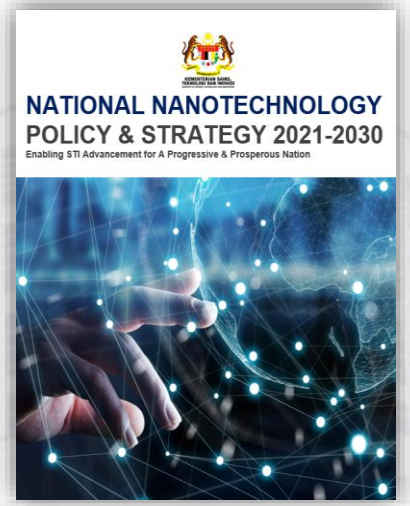
KEMENTERIAN SAINS, TEKNOLOGI DAN INOVASI
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

HELME HELAN
National Nanotechnology Center, MOSTI

KEMENTERIAN SAINS, TEKNOLOGI DAN INOVASI
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

NATIONAL NANOTECHNOLOGY CENTER

National focal point for the development of nanotechnology-related research, technology and product



STRATEGIC THRUST 4
Strengthening Standard, Safety and Regulation

STRATEGY
Promoting the Importance of Standard and Safety

INITIATIVE
Developing a comprehensive nano database as an inventory of local nano-based products as well as reference on nanosafety, standard & regulation

NANO-PRODUCTS

REGULATION

CHARACTERIZATION

GUIDELINE

TECHNICAL COMMITTEES
ISO/TC 229
Nanotechnologies

ISO/TS 18110:2015 Nanotechnologies – Vocabularies on science, technology and innovation indicators

3.5

nanotechnology product

one or more of:

a) manufactured nanomaterial or engineered nanomaterial

b) nano-enhanced/ nano-enabled intermediate product

c) nano-enhanced/ nano-enabled final product

Note 1 to entry: Within supply chains, an intermediate product may be considered as a final product, however, process intermediates are excluded.
Note 2 to entry: Final products which are assembled with one or a number of nanotechnology final products as components or parts should not be considered as nanotechnology products. This exclusion prevents multiple counting of nanotechnology final products in a product value chain.

TECHNICAL COMMITTEES
ISO/TC 229
Nanotechnologies

ISO 80004-1:2023 Nanotechnologies – Vocabulary – Part 1: Core vocabulary

3.1.4 **nanomaterial**
material with any external dimension in the *nanoscale* (approximately from 1 nm to 100 nm) or having internal structure or surface structure in the nanoscale

3.1.8 **engineered nanomaterial**
nanomaterial designed for specific purpose or function

3.1.9 **manufactured nanomaterial**
nanomaterial intentionally produced to have selected properties or composition

3.1.14 **nano-enabled**
exhibiting function or performance only possible with *nanotechnology*

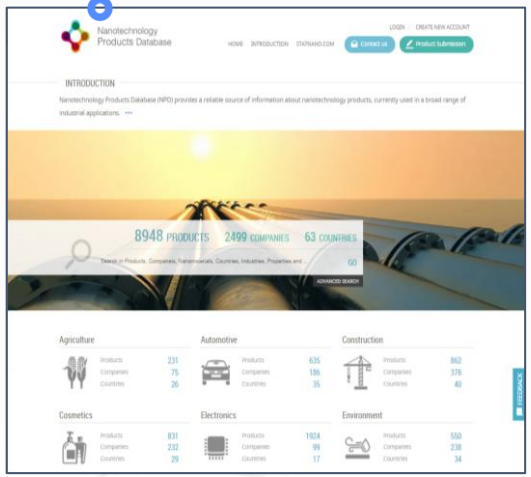
3.1.15 **nano-enhanced**
exhibiting function or performance intensified or improved with *nanotechnology*

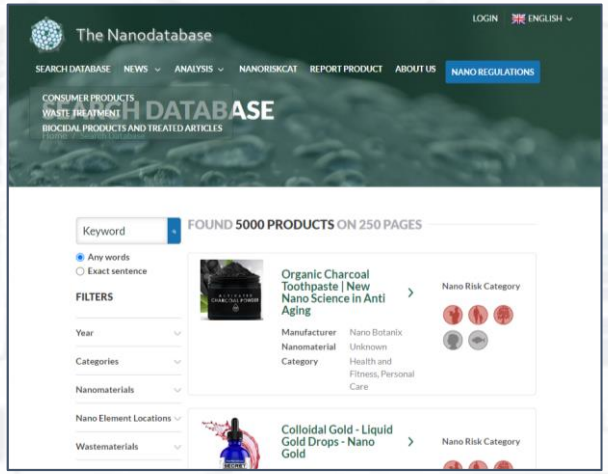
TWELFTH MALAYSIA PLAN 2021-2025

A Study to Benchmark the Risk of Nano-based Products (2020-2023)

SCOPE

- Market Studies
- Nanosafety Studies
- Environmental Fate Studies
- Life Cycle Assessment
- Stakeholders' Engagement





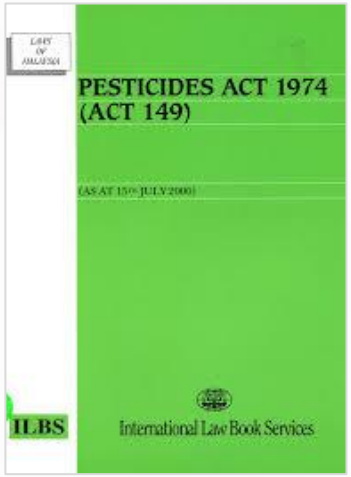
Visit NRS's Portal at https://nrs.mosti.gov.my

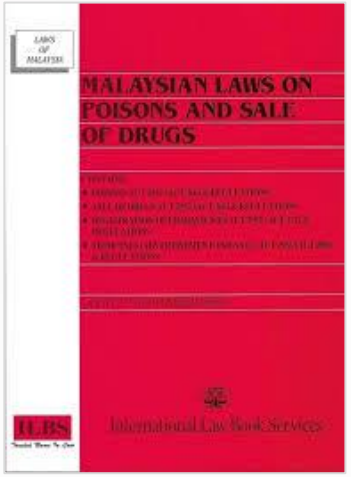
NANO-PRODUCTS

REGULATION

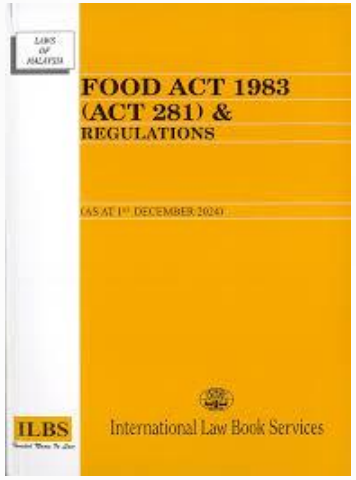
CHARACTERIZATION

GUIDELINE

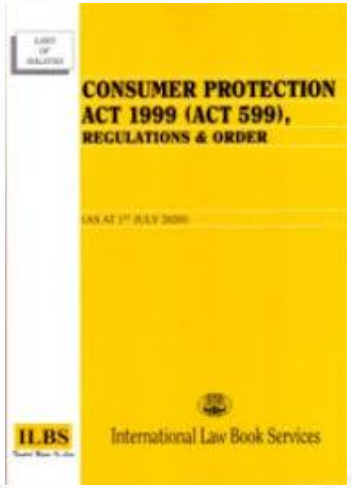

PESTICIDES ACT 1974
(ACT 149)
ILBS
International Law Book Services

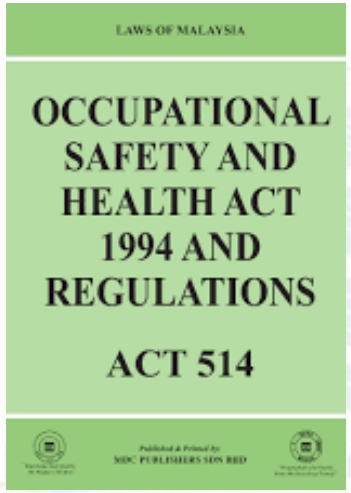

MALAYSIAN LAWS ON POISONS AND SALE OF DRUGS
ILBS
International Law Book Services

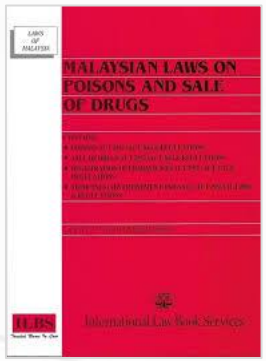

LAWS OF MALAYSIA
MEDICAL DEVICE ACT 2012
ACT 737


FOOD ACT 1983
(ACT 281) &
REGULATIONS
ILBS
International Law Book Services


LAWS OF MALAYSIA
FEED ACT 2009
ACT 698


CONSUMER PROTECTION ACT 1999 (ACT 599),
REGULATIONS & ORDER
ILBS
International Law Book Services


LAWS OF MALAYSIA
OCCUPATIONAL SAFETY AND HEALTH ACT 1994 AND REGULATIONS
ACT 514



ANNEX IV - Part 1

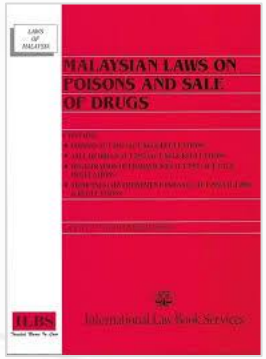
List of colouring agents allowed for use in cosmetic products

Colour index number: 77266 (nano)

Colour: Black

Limitation/ Requirements:

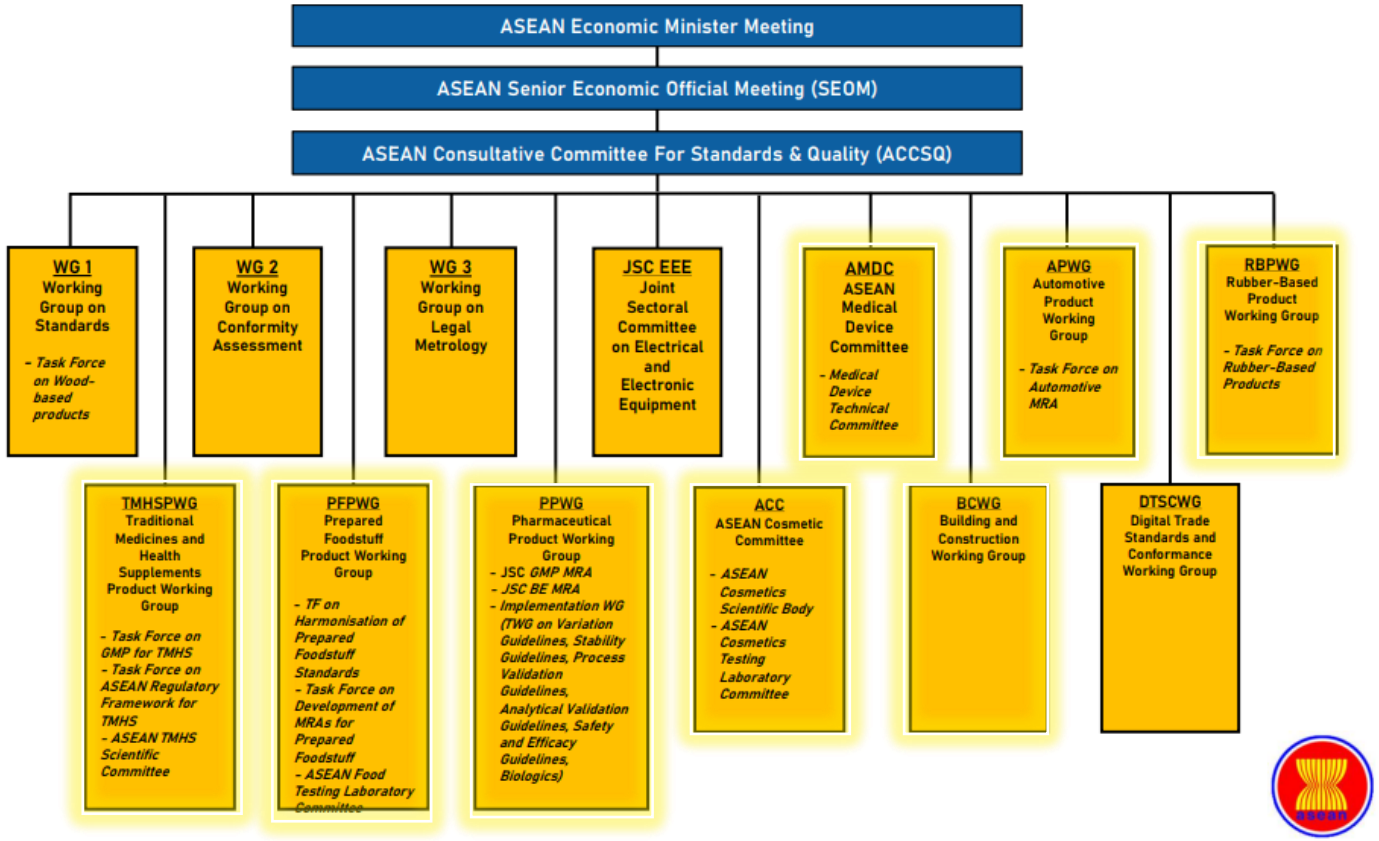
- 10% maximum concentration in the finished product
- Not to be used for inhalation application
- Purity >97%
- Primary particle size >20 nm

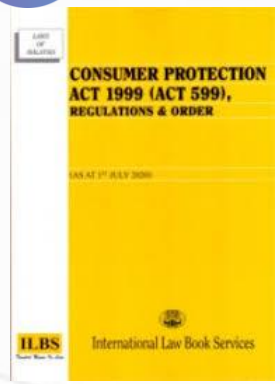


ANNEX VII - Part 1 List of permitted UV filters which cosmetic products may contain		
Reference number	:	A29a
Substance	:	Zinc oxide (nano)
Max authorized	:	25% (D50 >30 m)
Reference number	:	23a
Substance	:	MBBT (nano)
Max authorized	:	10% (D50 >120 nm)
Reference number	:	27a
Substance	:	Titanium dioxide (nano)
Max authorized	:	25% (D50 > 30nm)
Reference number	:	29
Substance	:	Tris biphenyl triazine (nano)
Max authorized	:	10% (D50 >80 nm)
Reference number	:	33
Substance	:	Bis- Diethylaminohydorxybenzoly Benzolyl
Max authorized	:	10% (D50 >50 nm)

ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS & QUALITY (ACCSQ)

ACCSQ STRUCTURE





Section 19. Safety standards

(1) The Minister may by regulations prescribe the safety standards in respect of -

(a) any goods or class of goods; and

(b) any services or class of services,

and may prescribe different safety standards for different goods or services, or classes of goods or services.

(2) The safety standard in relation to goods may relate to any or all of the following matters:

(a) the performance, composition, contents, manufacture, processing, design, construction, finish or packaging of the goods;

(b) the testing of the goods during or after manufacture or processing;

(c) the form and content of markings, warnings or instructions to accompany the goods.

(3) For the purposes of subsection (1), the Minister may, on the recommendation of the Controller and with consultation with the competent agency -

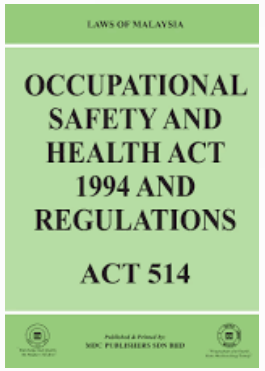
(a) adopt in whole or in part the safety standard used by the competent agency; or

(b) obtain advice from experts in the relevant field.

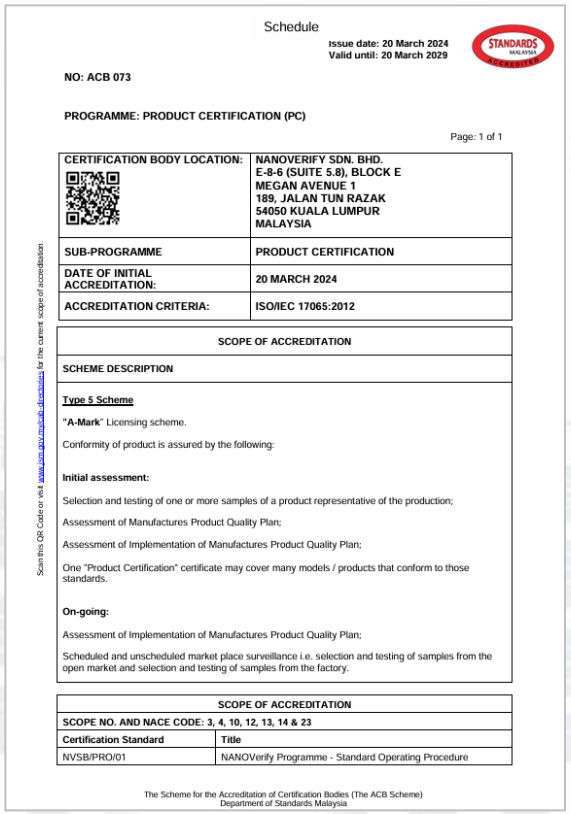
(4) Where no safety standard has been prescribed under subsection (1), the person supplying or offering to supply the goods or services shall adopt and observe a reasonable standard of safety to be expected by a reasonable consumer, due regard being had to the nature of the goods or services concerned.

Section 20. Compliance with safety standards

No person shall supply, or offer to or advertise for supply, any goods or services which do not comply with the safety standards determined under section 19.


LAWS OF MALAYSIA
OCCUPATIONAL SAFETY AND HEALTH ACT 1994 AND REGULATIONS
ACT 514


Department of Occupational Safety and Health
Ministry of Human Resources
Malaysia
GUIDELINE ON CONTROL AND SAFE HANDLING OF NANOMATERIALS
2018



Schedule

Issue date: 20 March 2024
Valid until: 20 March 2029

NO: ACB 073

PROGRAMME: PRODUCT CERTIFICATION (PC)

Page: 1 of 1

CERTIFICATION BODY LOCATION:	NANOVERIFY SDN. BHD. E-8-6 (SUITE 5.8), BLOCK E MEGAN AVENUE 1 189, JALAN TUN RAZAK 54050 KUALA LUMPUR MALAYSIA
SUB-PROGRAMME	PRODUCT CERTIFICATION
DATE OF INITIAL ACCREDITATION:	20 MARCH 2024
ACCREDITATION CRITERIA:	ISO/IEC 17065:2012

Scan this QR Code or visit www.sirim.my/mcb-directories for the current scope of accreditation.

SCOPE OF ACCREDITATION
SCHEME DESCRIPTION
Type 5 Scheme "A-Mark" Licensing scheme. Conformity of product is assured by the following: Initial assessment: Selection and testing of one or more samples of a product representative of the production; Assessment of Manufactures Product Quality Plan; Assessment of Implementation of Manufactures Product Quality Plan; One "Product Certification" certificate may cover many models / products that conform to those standards. On-going: Assessment of Implementation of Manufactures Product Quality Plan; Scheduled and unscheduled market place surveillance i.e. selection and testing of samples from the open market and selection and testing of samples from the factory.

SCOPE OF ACCREDITATION	
SCOPE NO. AND NACE CODE: 3, 4, 10, 12, 13, 14 & 23	
Certification Standard	Title
NVSB/PRO/01	NANOVerify Programme - Standard Operating Procedure

The Scheme for the Accreditation of Certification Bodies (The ACB Scheme)
Department of Standards Malaysia

NANOVerify Programme

NANO TRUSTED — GENUINE NANOTECHNOLOGY PRODUCT — www.nanoverify.com.my

NANO VERIFIED — GENUINE NANOTECHNOLOGY PRODUCT — www.nanoverify.com.my

GRAPHENE VERIFIED — GENUINE GRAPHENE-BASED PRODUCT — www.nanoverify.com.my

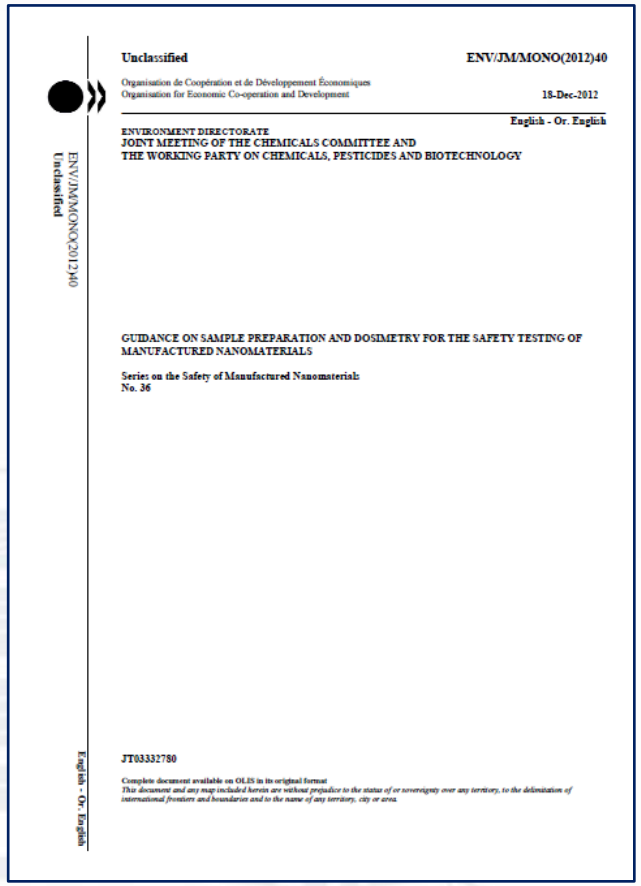
https://nanoverify.com.my/

NANO-PRODUCTS

REGULATION

CHARACTERIZATION

GUIDELINE



Unclassified ENV/JM/MONO(2012)40

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development 18-Dec-2012

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/MONO(2012)40
Unclassified

GUIDANCE ON SAMPLE PREPARATION AND DOSIMETRY FOR THE SAFETY TESTING OF MANUFACTURED NANOMATERIALS

Series on the Safety of Manufactured Nanomaterials
No. 36

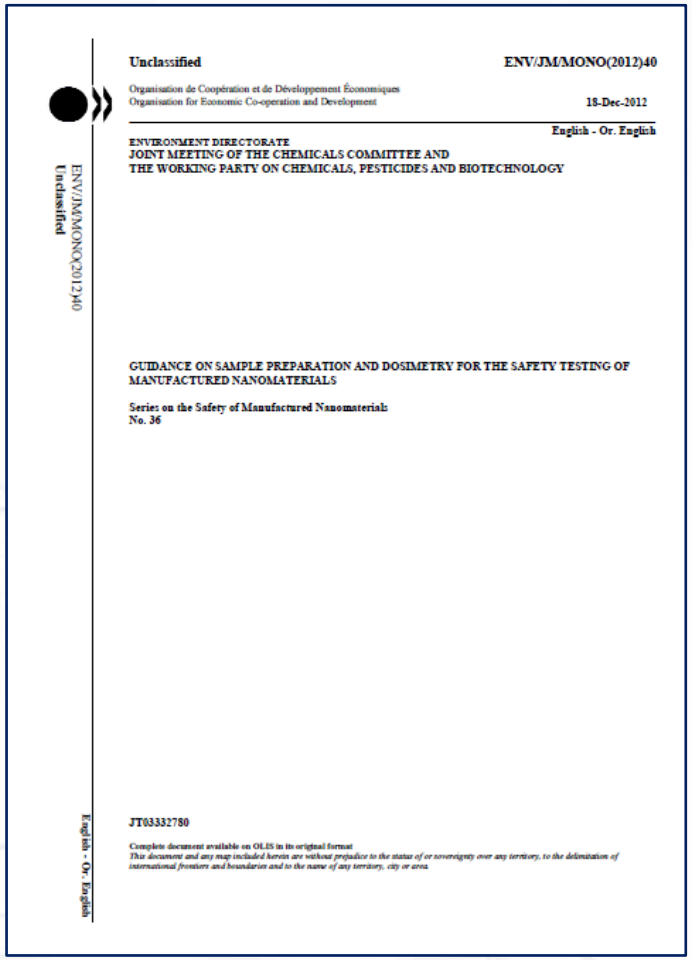
JT03332780

Complete document available on OLIS in its original format
This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

English - Or. English

Guidance

- No 36. Sample preparation and dosimetry for the safety testing of manufactured nanomaterials
- No 40. Ecotoxicology and environmental fate of manufactured nanomaterials
- No 43. Genotoxicity of manufactured nanomaterials
- No 57. Towards the integration of risk assessment into life cycle assessment of nano-enabled applications
- No. 63. Physical-chemical parameters: measurements and methods relevant for the regulation of nanomaterials
- No 65. Physical-chemical properties of nanomaterials: evaluation of methods applied in the OECD-WPMN testing programme



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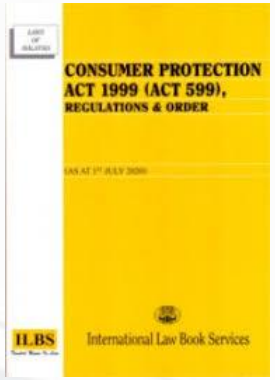
English - Or. English

No 65. Physical-chemical properties of nanomaterials: evaluation of methods applied in the OECD-WPMN testing programme

- Chemical composition
- Aggregation / agglomeration
- Particle size distribution
- Crystalline phase
- Dustiness
- Specific surface area
- Water solubility / dispersability
- Zeta potential
- Photocatalytic activity
- Porosity
- Redox potential
- Radical formation potential
- Crystalline size
- Surface chemistry

TECHNICAL COMMITTEES
ISO/TC 229
Nanotechnologies

Particle Size & Particle Size Distribution	ISO 21363; ISO 19749; ISO 13322; ISO 9276
Chemical Identity & Composition	ISO/TR 17200
Surface chemistry	ISO/TR 14187; ISO/TR 23173; ISO/TS 10797; ISO 10798
Aggregation and Agglomeration	ISO 21363; ISO 10798
Specific surface area	ISO 9277; ISO 18757; ISO/TS 10798
Surface charge/ Zeta potential	ISO 13100; ISO13099; ISO/TR 19997
Properties and Dispersion in water	ISO/TS 21357; ISO/TS 19590
Crystal structure / size	ISO/TS 17200; ISO 21363; ISO 10798
Dustiness	ISO/TS 12025
Porosity	ISO 9277; ISO 18757; ISO 13100



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TECHNICAL COMMITTEES
ISO/TC 229
Nanotechnologies

NATIONAL NANOTECHNOLOGY LABORATORY NETWORK (RMNK)

RANGKAIAN MAKMAL NANOTEKNOLOGI KEBANGSAAN

Makmal

Kekuatan Malaysia Dari Segi pengujian Nanoteknologi

Bilangan makmal

309

97 sintesis – 80 fabrikasi
48 modifikasi – 34 integrasi
42 lain-lain

Peralatan

Kekuatan Malaysia Dari Segi pengujian Nanoteknologi

Jumlah Peralatan

668

129 kimia – 164 fizikal
82 elektrik & elektronik
74 electron – 71 laser – 52 x-ray based
40 loji pandu

Penyelidikan

Kepakaran Penyelidikan Nanoteknologi

Jumlah Penyelidikan

298

42 bahan – 14 elektronik – 6 alam sekitar
12 bioteknologi – 152 nanoteknologi – 7 perubatan
3 tenaga – 9 kejuruteraan – 47 lain-lain

Harta Intelek

Jumlah Harta Intelek Bidang Nano

Jumlah Harta Intelek

279

153 paten
26 cap dagangan
87 hak cipta
13 lain-lain

Pengkomersialan

Produk Nano yang Dikomersialkan

Jumlah Pengkomersialan

102

Visit RMNK's Portal and System Directory at https://www.mosti.gov.my/rmnk/

NANO-PRODUCTS

REGULATION

CHARACTERIZATION

GUIDELINE

GUIDANCE DOCUMENT FOR INTERESTED PARTIES IN DETERMINING QUALITY OF NANO-PRODUCT INTENDED FOR TRADE BASED ON THE INTERNATIONALLY RECOGNISED NANOMETROLOGY TESTINGS

A comprehensive, detailed information on nano-product, serving as a reference guide for Malaysian stakeholders.

THANK YOU