BEFORE THE NATIONAL GREEN TRIBUNAL (SZ) CHENNAI

MEMORANDUM OF APPLICATION

(Under Section 18(1) read with Sections 14, 15 of National Green Tribunal Act, 2010)

Application No. 66 of 2017 (SZ)

BETWEEN:

Vallapureddy Gari Govardhan Reddy …Applicants

Vs.

Union of India & Ors. …Respondents

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Dated this the 10th day of February, 2022

Counsel for the Applicant

A. Yogeshwaran

Regulating Nanomaterials under the Canadian Environmental Protection Act

National Consultation on Nanomaterials and its Implications for Human Health and Environment

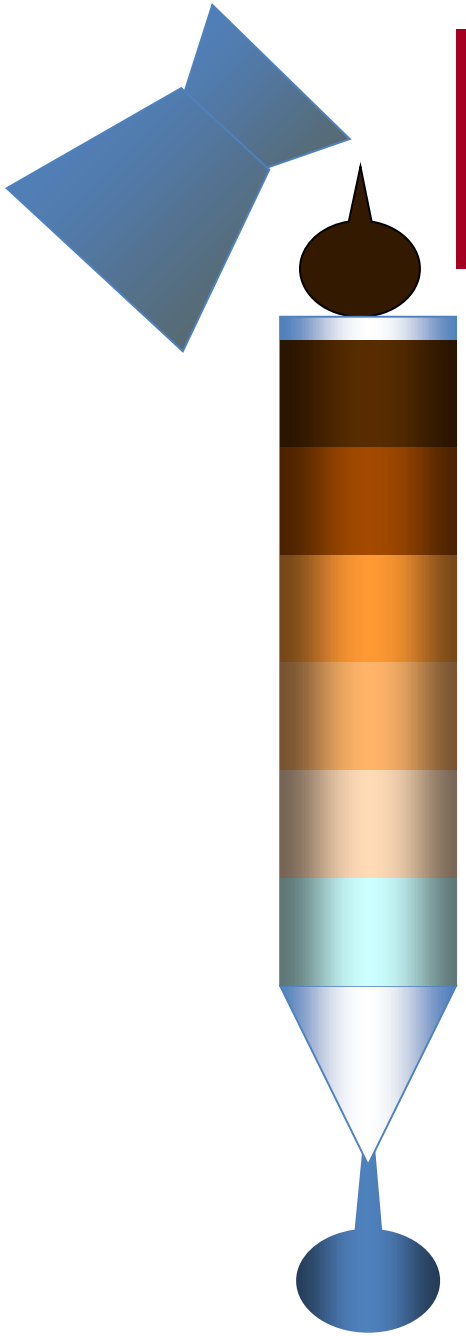
January 27-28, 2016
Montreal, Quebec

Regulation of Nanomaterials

- Most jurisdictions and OECD members have stated that existing regulatory frameworks and statutes provide a firm foundation for the regulation and oversight of nanomaterials (NMs)
- Nanomaterials are implicitly covered under the definitions of chemical substances in existing regulatory frameworks
- The US and Canada agreed in 2014 to adopt the "Policy Principles for decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials" as part of the Regulatory Cooperation Council (RCC) Action Plan

> *The Government of Canada will continue to foster innovation associated with nanomaterials and nanotechnology, while protecting Canadians and their environment. It is expected that federal programs will consider the principles described herein while implementing their areas of regulatory responsibility for the oversight of nanomaterials and nanotechnology and that* ***the assessment and management of nanomaterials will continue to be evidence-based and application-specific as appropriate under the applicable programs.***

Canadian Legislative Framework for Safety Assessment



Feeds →	*Feeds Act*
Fertilizers →	*Fertilizers Act*
Pesticides →	***Pest Control Products Act***
Consumer Products →	***Canada Consumer Products Safety Act***
Novel Foods, Drugs, Medical Devices, Vet. Drugs, Cosmetics →	***Food and Drugs Act***
Industrial Chemicals →	***Canadian Environmental Protection Act, 1999***

Health Canada's Working Definition of NM

- No internationally agreed upon regulatory definition exists

Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be a nanomaterial if:

- *It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;*
- *It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.*

For the purposes of this definition:

- *The term "nanoscale" means 1 to 100 nanometres, inclusive;*
- *The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,*
- *The term "manufactured" includes engineering processes and the control of matter.*

http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php

Current Regulatory Regime for Toxic Substances

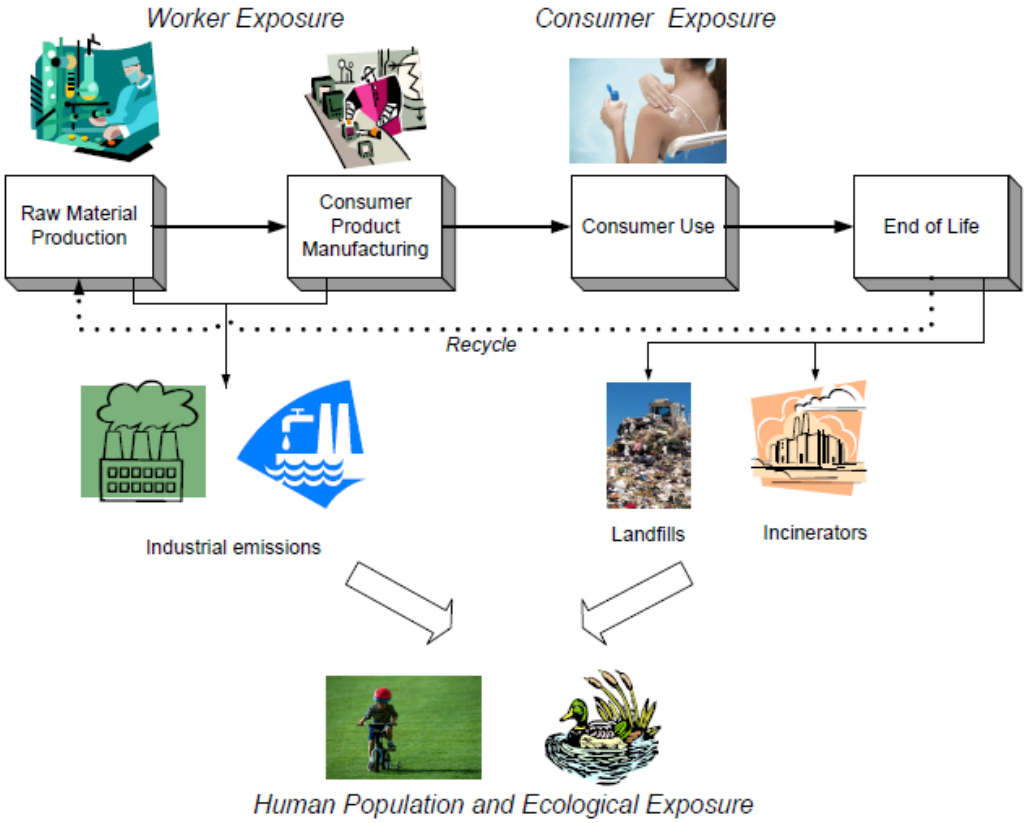
- **Although CEPA does not specifically define nanomaterials, the meaning of substance as described under subsection 3(1) of the Act is broad enough to include nanomaterials**
- Part 5 of CEPA 1999 (Controlling Toxic Substances):
  - Requires the notification and assessment of "new" substances (incl. nanomaterials) prior to import into or manufacture in Canada
    - Under CEPA, a new substance is a substance not listed on the Domestic Substances List (DSL)
  - Provides for the assessment of "existing" substances (incl. nanomaterials) already on the Canadian market
    - No specific data requirement or timeframe
- Assessments objective: to determine whether the substance poses or may pose a risk to the environment or human health

Canadian Regulatory Framework for New Substances

New Substances Notification Regulations (Chemicals and Polymers)

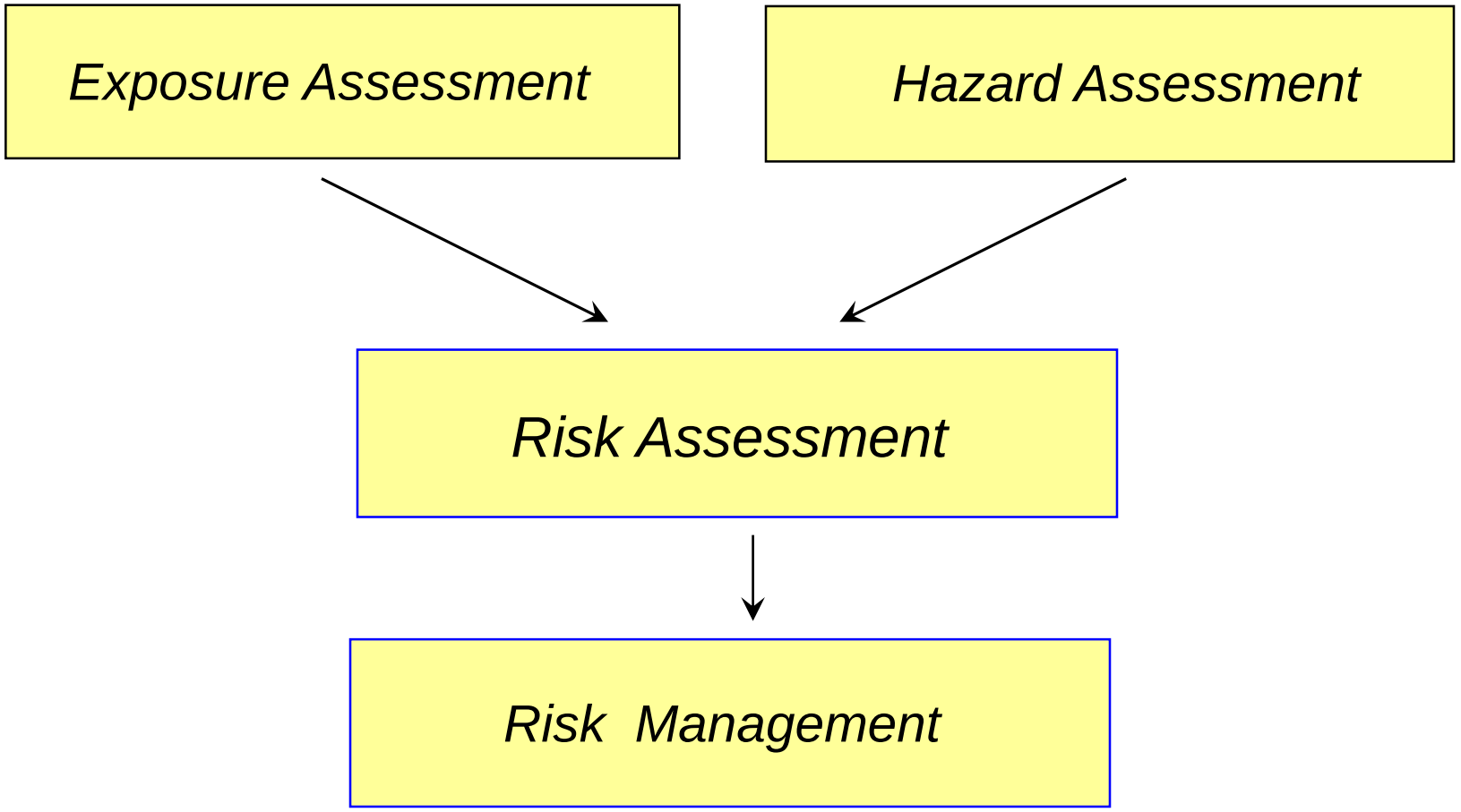
- Any substance, including a nanomaterial, that is not listed on the DSL is classified as a new substance
- Prior to manufacture or import of a new substance above trigger quantities, a notification must be submitted
- Trigger quantities
  - Import/manufacture volume thresholds (by calendar year)
  - Range from 100 kg/yr to 10,000 kg/yr
  - Increasing information requirements as volumes increase
- Assessment period
  - Assessment period ranges from 5 to 75 days
  - If there are concerns with the use of the notified substance risk management options may include prohibitions, ministerial requests, or ministerial conditions
  - If there are concerns with a potential use of the notified substance , a request for additional information may be imposed through a Significant New Activity Notice (SNAc)

Life Cycle Perspective for Risk Assessment

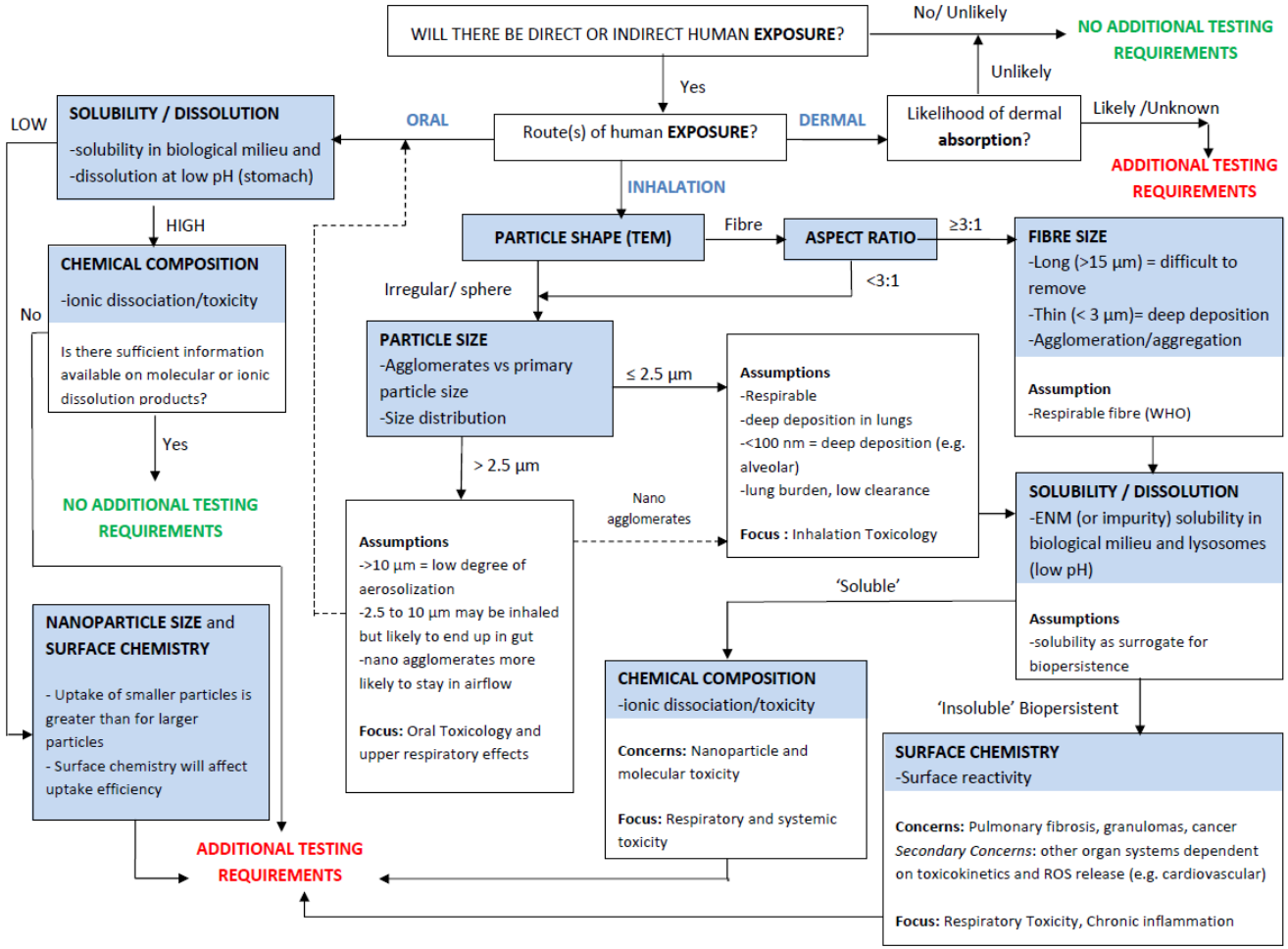


From: US EPA Nanotechnology White Paper, 2007
http://www.epa.gov/osainter/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf

Risk Assessment of Nanomaterials



Nanoparticle Screening Assessment Framework



Determination of Risk

In the absence of adequate hazard information, control measures are used to minimise exposure

$$Risk \ \alpha \ Exposure * Hazard$$

When a risk to human health is identified for the substance, risk management actions are recommended

Risk management actions could include:

- *Conditions of Use*
- *Prohibition*
- *Prohibition pending testing (Ministerial Request for additional information)*
- *Significant New Activity Notice (SNAc)*

To date, 58 nano-related risk assessments have been completed with 32 substances-specific control measures

Approach to Address Existing Nanomaterials

- Canada has developed a draft approach to address the legacy of nanomaterials that are already in commerce in Canada, much like the Chemicals Management Plan (*Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List , February 2015)*

- The approach would include the following elements:
  - Validation of current understanding of status of nanomaterials on our domestic inventory (Section 71, a mandatory information-gathering tool)
  - Development of a prioritization process for assessment of these nanomaterials
  - Examining priority nanomaterials for their potential impacts on the environment and human health

Useful Contacts

- Health Canada Website:

  http://www.hc-sc.gc.ca/index-eng.php

- New Substances Program Website:

  http://www.ec.gc.ca/subsnouvelles-newsubs/

- The Substance Management Information Line Experts:

  E-mail: substances@ec.gc.ca

  Telephone: 1-800-567-1999 (toll free in Canada)

  (819) 938-3232 (outside of Canada)

- My coordinates:

  myriam.hill@hc-sc.gc.ca or myriam.hill@canada.ca

Thank you!

Questions?

myriam.hill@hc-sc.gc.ca

Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

CONTACT US <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/forms/reviewing-new-chemicals-under>

Control of Nanoscale Materials under the Toxic Substances Control Act

News

EPA announced that changes need to be made to the size standards used to determine which small manufacturers and processors are exempt from TSCA Section 8(a) reporting. Read the Federal Register notice.

On this page:

Nanoscale Materials

Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). Specifically, chemical substances that have structures with dimensions at the nanoscale -- approximately 1-100 nanometers (nm) -- are commonly referred to as nanoscale materials or nanoscale substances. A human hair is approximately 80,000-100,000 nanometers wide.

These chemical substances may have properties different than the same chemical substances with structures at a larger scale, such as greater strength, lighter weight, and greater chemical reactivity. These enhanced or different properties give nanoscale materials a range of potentially beneficial public and commercial applications; however, the same special properties may cause some of these chemical substances to behave differently than conventional chemicals under specific conditions.

Regulatory Approach

To ensure that nanoscale materials are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, EPA is pursuing a comprehensive regulatory approach under TSCA including:

- An information gathering rule on new and existing nanomaterials
- Premanufacture notifications for new nanomaterials

Information Gathering Rule

As part of the Agency's effort to ensure a more comprehensive understanding of nanoscale materials in commerce, EPA issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on nanoscale chemical substances in commerce pursuant to its authority under TSCA section 8(a). This rule requires companies that manufacture (including import) or process certain chemical substances already in commerce as nanoscale materials notify EPA of certain information, including

- specific chemical identity;
- production volume;
- methods of manufacture;
- processing, use, exposure and release information; and
- available health and safety data.

EPA seeks to facilitate innovation while ensuring safety of the substances. The information collection is not intended to conclude that nanoscale materials will to cause harm to human health or the environment. Rather, EPA will use the information gathered to determine if any further action under TSCA, including additional information collection, is needed. EPA proposed and took comment on this rule. Persons who manufacture or process a reportable chemical substance during the three years prior to the final effective date of this rule must report to EPA within a year of the rule's effective date. On May 12, 2017, EPA extended the effective date of the rule to August 14, 2017.

- Read the Federal Register notice extending the effective date of the final rule to August 14, 2017 <https://www.federalregister.gov/documents/2017/05/12/2017-09683/chemical-substances-when-manufactured-or-processed-as-nanoscale-materials-tsca-reporting-and>
- Read the final rule
- Read the response to comments document
- Read the fact sheet <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/fact-sheet-nanoscale-materials>

EPA has developed guidance on this rule that provides answers to questions the Agency has received from manufacturers (includes importers) and processors of certain chemical substances when they are manufactured or processed at the nanoscale as described in the final rule.

Read EPA's guidance on the nanoscale materials information gathering rule. <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/working-guidance-epas-section-8a>

If you have questions not covered in this general guidance, please contact Jim Alwood (alwood.jim@epa.gov), and these questions will be answered on a case-by-case basis**.** EPA intends to add further questions/answers and update the guidance as warranted based on further questions we may receive.

Reporting under the Rule

- Sample Reporting Form <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/sample-tsca-ss8a-reporting-chemical>
- Login to the Central Data Exchange to access electronic reporting <https://cdx.epa.gov/>
- 40 CFR Part 704, (TSCA Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules)

Contact Us <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/forms/reviewing-new-chemicals-under> to ask a question, provide feedback, or report a problem.

Premanufacture Notifications

TSCA requires manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can take action to ensure that chemicals that may or will pose an unreasonable risk to human health or the environment are effectively controlled.

Manufacturers are encouraged to contact EPA if they need assistance determining whether their nanoscale materials are subject to new chemical notification requirements. <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/forms/program-contacts-and>

Read about EPA's regulation of new chemical substances. <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>

Since 2005, EPA has received and reviewed over 160 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes, and that number will increase over time. The Agency has taken a number of actions to control and limit exposures to these chemicals, including:

- Limiting the uses of the nanoscale materials,
- Requiring the use of personal protective equipment and engineering controls,
- Limiting environmental releases, and
- Requiring testing to generate health and environmental effects data.

EPA has permitted limited manufacture of new chemical nanoscale materials through the use of consent orders or Significant New Use Rules (SNUR) under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the exposure and environmental release limitations discussed above).

International Cooperation

Fully understanding the environmental applications and implications of nanotechnology requires the concerted efforts of scientists and policy makers across the globe. EPA is working collaboratively with stakeholders both domestically and internationally to address nanoscale materials and their research needs, and to develop international standards for nanotechnology.

International organizations such as the International Organization for Standardization (ISO) and the Organization for Economic Cooperation and Development (OECD), are engaged in nanotechnology issues.

Canada-U.S. Regulatory Cooperation Council (RCC) Nanotechnology Initiative

On February 4, 2011, Prime Minister Stephen Harper and U.S. President Barack Obama announced the creation of the Canada-U.S. Regulatory Cooperation Council to better align the two countries' regulatory approaches in various areas, including nanotechnology. As part of this initiative, a Nanotechnology Work Plan was developed to increase regulatory transparency and coordination between both countries with respect to nanomaterials.

An important outcome of the initiative was the development of consistent policy principles on the regulatory oversight of nanomaterials, which have now been endorsed by Canada.

The initiative recommended ways Canada and the United States can align their work on nanomaterials that are classified as new substances, regulated in Canada and the United States under the Canadian Environmental Protection Act, 1999 (CEPA, 1999) and TSCA, respectively.

Learn more about the Canada-U.S. Regulatory Cooperation Council Nanotechnology Initiative. EXIT

Organisation for Economic Cooperation and Development (OECD)

OECD has established a Working Party on Manufactured Nanomaterials (WPMN);that is engaged in a variety of projects to further understanding of the properties and potential risks of nanomaterials:

- Testing and assessment
- Risk assessment and regulatory programmes
- Exposure assessment and mitigation
- Cooperation on the environmentally sustainable use of nanotechnology

Learn more about OECD's Working Party on Manufactured Nanomaterials. EXIT
<http://www.oecd.org/science/nanosafety/>

EPA is actively participating in the Working Party and contributes to all of the projects which help leverage international expertise and resources. EPA hosted the OECD Expert Meeting on Categorization of Manufactured Nanomaterials on September 17-19, 2014, in Washington, DC. The outcome of the workshop and these OECD projects will contribute to EPA's efforts to evaluate the potential impacts of nanoscale materials on human health and the environment.

Read the materials from the OECD Expert Meeting on Categorization of Manufactured Nanomaterials.
<https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/meeting-materials-oecd-expert>

International Organization for Standardization (ISO)

The ISO has established a technical committee to develop international standards for nanotechnology. This technical committee, ISO/TC 229, is working to develop standards for terminology and nomenclature, metrology and instrumentation, including:

- Specifications for reference materials,
- Test methodologies,
- Modeling and simulation, and
- Science-based health, safety and environmental practices.

Other Resources and Related Links

- TSCA Inventory policies on nanoscale materials <https://epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory#nanoscale>
- EPA Nanotechnology White Paper <https://epa.gov/osa/nanotechnology-white-paper>
- Nanotechnology for Site Remediation <https://epa.gov/remedytech/nanotechnology-site-remediation-fact-sheet>
- Research on Evaluating Nanomaterials for Chemical Safety <https://epa.gov/chemical-research/research-nanomaterials>

Reviewing New Chemicals under the Toxic Susbstances Control Act (TSCA) Home <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>

Basic Information <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new>

EPA's Review Process <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epas-review-process-new-chemicals>

Filing a Premanufacture Notice with EPA <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>

Regulatory Actions Under TSCA section 5 <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5>

Premanufacture Notice Status <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#tab-3&#status>

Contact Us <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/forms/reviewing-new-chemicals-under> to ask a question, provide feedback, or report a problem.

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Follow.

LAST UPDATED ON JULY 9, 2021

August 2017

Working Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce

Important Note:

- This general guidance will not provide answers to all of the potential questions that will arise as manufacturers and processors seek to comply with the rule. Commenters to the draft guidance asked several questions that would require more details or information before EPA could respond to their question.
- If this general guidance does not answer those questions or other questions you have about the rule, please contact Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8974; email address: alwood.jim@epa.gov. EPA will answer these questions on a case-by-case basis**.** EPA intends to add further questions/answers and revisions to this guidance based on questions identified by persons who may be subject to the rule.

Section 1: What Chemicals are Reportable?

Question 1: Can you describe what is considered a reportable chemical substance? Is there some way to differentiate between genuinely new nanoscale materials in commerce and traditional products?

Under this rule, a reportable chemical substance is defined as a solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that is intentionally manufactured or processed to exhibit unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates, and agglomerates, measured by weight are in the size range of 1–100 nm in at least one dimension. This definition focuses on nanoscale materials that are intentionally manufactured or processed to exhibit unique or novel properties because of size in the 1-100 nm range.

The definition of a reportable chemical substance is consistent with the ISO concept of a 'nano-enabled' property. However, EPA does not consider ISO 'nano-enhanced' properties to generally be considered as unique and novel properties.

Question 2: What properties are considered unique and novel?

The rule includes a definition of unique and novel properties. Unique and novel properties are any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance not in the size range of 1-100 nm, and such properties are a reason that the chemical substance is manufactured or processed in that form or size (the rule therefore includes an element of intent in manufacturing or processing). In order to be reportable it is not

sufficient that a chemical substance contains particles in the size range of 1-100 nanometers; it must also have a size-dependent property different from properties at sizes greater than 100 nanometers, and those properties are the reason that the chemical substance is manufactured or processed in that form or size. The fact that a chemical substance is in the size range of 1-100nm, in at least one dimension, does not in itself mean that the chemical substance is a reportable chemical substance. Size is not considered to be a unique and novel property.

Gold at the nanoscale has novel, size-dependent properties. Intentionally manufacturing or processing nanoscale gold so that it exhibits a red or purple color instead of a yellow color is an example of a unique and novel optical property (in this case, tuned to absorb different wavelengths of light) seen at the nanoscale that is not observed where the particles are larger than nanoscale. In addition, gold exhibits different colors at different sizes *within* the nanoscale. While producing gold at the nanoscale would likely result in concurrent changes of other material properties (i.e. surface area, reactivity, etc.) those other properties are not the reason gold is being manufactured or processed in a nanoscale form. In this example, gold is being produced at the nanoscale for its optical properties, and those are the unique and novel properties.

A chemical substance such as carbon black which doesn't change its color because of its size would not exhibit a unique and novel property on the basis of color, because its nanoscale form is not a different color. Nanoscale carbon black when oxidized by nitric acid is used as a heavy metal sorbent, a property it does not have outside the nanoscale. This unique metal absorbing property of the oxidized form of nanoscale carbon black would meet the definition of a unique and novel property.

Titanium dioxide is an opaque white pigment when particles are greater than 100 nm. It is also an opaque white pigment when particles are less than 100 nm in size. Other nanoscale forms of titanium dioxide are colorless and transparent when manufactured or processed at less than 100 nm in size; this version of titanium dioxide has different functionality than the form greater than 100 nm and has properties which would be considered unique and novel.

Question 3: Can enhanced properties or continuously scaling properties (such as thermal conductivity or surface area) be considered unique and novel properties?

Enhanced or continuously scaling properties are properties which do not intrinsically change on the nanoscale and instead scale proportionately with particle size; this can include increased reactivity, surface area, and thermal conductivity, among others. These are not considered unique and novel properties. See also the answer to Question 5.

An example of a continuously scaling property could be density, which decreases with decreasing particle size. A material may be engineered on the nanoscale such that it has a lower density and remains suspended in solution compared to a corresponding macroscopic sample of the material, but this is not unique and novel as density scales proportionately with particle size. Intentionally manufacturing or processing nanoscale gold to change the thermal conductivity of a dispersion would not be considered unique and novel, as the changes in thermal conductivity with nanoparticle size follow the same behavior as larger particles. A pigment which adds, at all sizes, blue tones to a resin, but the blue tones are more apparent when the

pigment is on the nanoscale (1-100 nm), is an enhanced property. If the pigment only added blue tones when used on nanoscale (1-100 nm) and not at other particle sizes, that would be a unique and novel property.

Question 4: My company manufactures a nanoscale material in the form of primary particles less than 100 nanometers in the reactor system but almost immediately due to van der Waals forces forms aggregates and agglomerates with particle sizes far greater than 100 nanometers(nm). Are these types of nanostructured materials with particle sizes greater than 100 nm considered reportable chemical substances under this rule?

No. The definition of a reportable chemical substance is a combination of particle size and unique and novel properties. For the example given in the question, the form consisting of primary particles at "creation" would not meet the definition of a reportable chemical substance, unless the manufacturer was making a material consisting solely of those primary particles that also exhibit size dependent properties. Because in the example the particle size of the aggregates and agglomerates is greater than 100 nm, that form of material as manufactured is not a reportable chemical substance.

Question 5: Some companies may domestically manufacture or import substances with differing surface areas. The aggregate sizes of some grades may be larger than 100 nanometers and others may have an aggregate size between 1-100 nm. Differing surface area is a reason that these grades are domestically manufactured or imported. In this circumstance, does surface area meet the definition of a "unique and novel property" such that grades having aggregate sizes of 1-100 nm may be reportable under the final rule?

Surface area is not considered a unique and novel property. It will vary proportionately with a smaller particle size. However, if another intrinsic property changes as a result of the smaller particle size/increased surface area, and if that other property is the reason that the substance is manufactured at that particle size range, than that other intrinsic property would be considered a unique and novel property and the material would be reportable.

Question 6: To what objects and collections of objects does the 1-100 nm measurement apply? In other words, does that mean any form with particles 1-100 nm or does that include aggregates and agglomerates greater than 100 nm but based on primary particles less than 100 nm?

The 1-100 nm measurement applies to chemical substances with particles 1-100 nm, but not aggregates or agglomerates greater than 1-100 nm. This applies even if the aggregate or agglomerate contains primary particles less than 100 nm.

Question 7: If a reportable chemical substance is reported as a new chemical for one use but later has a different use from the one reported, would this require reporting under this rule?

Because this rule is one-time reporting of nanoscale forms of chemical substances in commerce, new uses of reportable chemical substances that have been reported previously pursuant to this rule or were previously reported on or after January 1, 2005 as a new chemical do not need to be

reported under this Section 8(a) reporting requirement. However, if a person manufactures or processes a new discrete form of the reportable chemical substance for the new use, then that person would be required to report the new discrete form under this rule. Note that there may be notification requirements unrelated to this Section 8(a) reporting rule if a company manufactures or processes the chemical substance for a use that is subject to a significant new use rule (SNUR) for the chemical substance.

Question 8: Are mixtures ever reportable under this rule? What about aqueous dispersions? The IUPAC definition of emulsions limits them to liquid-in-liquid mixtures, are they therefore exempt?

Mixtures are not required to be reported under this rule. However, any components of the mixture that meet the definition of a reportable chemical substance would be reported. Manufacturing (including import) or processing chemical substances as part of a mixture requires evaluation of each chemical substance in the mixture to determine which, if any, are reportable. Nanomaterials incorporated into emulsions, aqueous dispersions, colloids, and other solid-in-liquid or solid-in-solid mixtures that meet the definition of a reportable chemical substance are reportable. This can also apply to nanomaterials formed in situ, even if not separable from the solvent. Mixtures (including liquid in liquid emulsions) themselves are not reportable – only solid nanomaterials which fit the description of reportable chemical substances which are incorporated into or formed within the mixture, dispersion, emulsion, colloid, etc. are reportable.

Question 9: Is "reporting for mixtures" notifier-specific or substance-specific? For example, if a manufacturer reports and sells to 10 processors, does each processor report?

Reporting for mixtures is not required, but you must report each individual reportable chemical substance in a mixture. Any reportable chemical substance that is incorporated into a mixture or substrate would require reporting for manufacturing or processing of that chemical substance. If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor is also required to report the nanomaterial (but not the mixture itself). As an example, a manufacturer who incorporates reportable gold nanoparticles into an emulsion is required to report the gold nanoparticles only, and all processors to which this emulsion is distributed must also report the gold nanoparticles, even if the nanoparticles are never separated from the emulsion.

Question 10: Please clarify the criterion to exclude chemical substances that dissociate completely in water to form ions that are smaller than 1 nm. How fast or what is the rate of dissociation?

The rate of dissociation or how fast that dissociation occurs in water does not affect which chemicals are excluded. If the chemical substance completely dissociates to form ions smaller than 1 nm, it is not a reportable chemical substance.

Question 11: What are the criteria to discern one shape from another shape? At what point is different morphology in nanomaterials reportable? Is every different morphology

of a nanomaterial reportable? What about the natural shape variation within a distribution of nanoparticles?

A different morphology would be any change in the shape of particles. Different morphology does not include random shape changes or natural variation in shapes of particles that are not definitive and that occur in a continuum. Some nanoscale materials are engineered to give all the particles a certain morphology or shape. The change in shape needs to be a specifically engineered change in the shape of particles of a nanoscale material, to effect a change and form a unique and novel property for a chemical substance in the particle size range of 1-100 nm in at least one dimension. For example, colloidal gold nanoparticles have a plasmon resonance which evolves with particle size/diameter, while gold nanorods exhibit two plasmon resonances, which can be tuned precisely by aspect ratio; the change in shape dramatically alters optical properties and each shape is engineered purposefully for those specific optical properties. As the unique and novel property has changed, both forms are discrete and reportable.

Question 12: What does the rule mean by coating? How is coating different from surface treatments?

The term "coating" in the rule describes coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting, even if all of the other intrinsic characteristics of the reportable chemical substance remain the same. Surface treatments such as oxidation or neutralization of the surface are typically used as preparative or cleaning measures resulting in particles which are not isolated. Such surface treatments therefore do not create a separate reporting requirement.

Question 13: Why are coated nanomaterials defined separately from chemical mixtures? There are cases where discrete nanomaterials are surface treated (commonly coated with polymeric substances) in a similar fashion as defined for chemical mixtures.

Coating a nanoscale material results in a nanoscale material with different properties. The rule does not require that every chemical substance coated with another chemical substance be reported, but only that reportable chemical substances which are coated be reported as discrete substances. The nanomaterial itself remains the reportable chemical substance, not the coating (i.e. report the coating and nanoparticle, not just the coating). Coating does not refer exclusively to full encapsulation of a nanoparticle, but also to discontinuous and random coverage. The concept of "seven standard deviations" to distinguish discrete forms is not applicable here – the particle is either coated or it is not. There is no percentage limit on distinguishing different compositions of surface coating; when the coating imparts differential function from a different coating composition, it is a new discrete form and reportable (assuming the original nanomaterial was also reportable). This could encompass the above example in which a nanomaterial is coated with a polymeric substance – if the nanomaterial was a reportable chemical substance before coating, then coating generates a new discrete reportable form of that nanomaterial. If the coating changes the size of the particle such that there is a new unique and novel property, then that is a new discrete form and it is reportable.

Comment 14: Is it EPA's intention to require reporting on large molecules within the size range of 1 – 100 nm, which are not normally considered to be nanoscale materials (for example, monomers, polymers, colloids, organic and inorganic pigments and dyes, polymer dispersions, etc.)? Are polymers or metals attached to ligands which are larger than 1 nm in size also considered a nanoscale material for reporting?

In order to be a reportable chemical substance, the chemical must not only be a solid particle in the size range of 1-100 nanometers in at least one dimension, it must also have a unique and novel property, which is any size-dependent property that varies from those associated with other forms or sizes of the same chemical substance, and such property is a reason that the chemical substance is manufactured or processed in that form. While these categories of large molecules are not automatically exempt, monomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are solid particles manufactured or processed at the nanoscale to exhibit unique and novel properties that are not exhibited by other forms or sizes of the same chemical substance. Large molecules and chemicals attached to ligands greater than 1 nm that do not meet the definition do not need to be reported.

Section 2: Who is Required to Report?

Question 15: My company manufactures ink/toner products and is planning to import their products, which include a chemical substance with particle sizes of 1-100 nm, used as a pigment and/or additive in toner and ink cartridges. Is my company required to report even though the chemical substance is incorporated into a formulation that is not manufactured or processed in the United States?

Under TSCA, the definition of manufacture is not limited to domestic manufacture; the definition of manufacture includes import. This includes importing a chemical substance as part of a formulation. The chemicals in the formulation are subject to any manufacturing reporting requirements under TSCA including the reporting and recordkeeping rule for chemical substances that are nanoscale materials. If the chemical substance is imported in a form that meets the definition of a reportable chemical substance, the importer of the toner must report under 40 CFR 704.20.

Question 16: My company is currently processing carbon nanotubes for research and development (R&D). Within the next few years there is a probability that we will be selling products containing the carbon nanotubes. At that point, we would not be exempt from this reporting requirement. Would it be proactive for us to report to the EPA now, even though we are still in the R&D phase, or should we wait until we are processing for production?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule. The rule will become effective on August 14, 2017. By August 14, 2018, you would need to report any non-exempt processing of a reportable chemical substance that occurred before August 14, 2017. If you begin non-exempt processing of a reportable chemical substance after August 14, 2017, you would need to report at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except if you have not formed

an intent to manufacture or process at least 135 days before commencing such manufacture (including import) or processing, in which case the information must be filed within 30 days of the formation of such an intent. You are the best judge on when to report to meet the requirement of reporting 135 days before processing a reportable chemical substance or within 30 of forming an intent to manufacture or process.

You will also need to determine if the carbon nanotubes you are processing meet the definition of a reportable chemical substance. Not all carbon nanotubes contain particles less than 100 nm in at least one dimension, although most of them would be described as having unique and novel properties.

EPA considers most forms of carbon nanotubes as new chemical substances (See 73 FR 64946). Are you importing the carbon nanotubes or purchasing the carbon nanotubes from a domestic supplier? Can your supplier confirm they are on the TSCA Inventory? If you cannot confirm they are on the TSCA Inventory, then rather than reporting under this Section 8(a) rule, you may need to submit a pre-manufacture notice (PMN) under TSCA Section 5 for the carbon nanotubes if you are the importer of record, or your domestic supplier may need to submit a PMN. You can learn whether your nanotubes are on the TSCA Inventory by submitting a *bona fide* request to EPA pursuant to procedures in 40 CFR 720.25.

Question 17: What is required of processors who do not know about the nanomaterial-related characteristics of formulations they process or use? Where in the supply chain must a reportable chemical substance be reported: at every point in the supply chain, or only at the point of manufacture? Would this include incorporation into articles and substrates?

Reporting of information under the rule is required only to the extent that information is known or reasonably ascertainable. The term “known to or reasonably ascertainable by” is defined at 40 CFR 704.3. It means “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.” This standard includes, but is not limited to “information that may be possessed by the [submitter], including persons involved in the research, development, manufacturing, or marketing of a chemical substance and includes knowledge gained through discussions, symposia, and technical publications. Examples of types of information that are considered to be in a person's possession or control, or that a reasonable person similarly situated might be expected to possess, control, or know, include files maintained by the submitter, such as marketing studies, sales reports, or customer surveys; information contained in standard references, such as SDSs, that contain use information or concentrations of chemicals in mixtures; and information from the CASRN and from the D&B number.” (Chemical Data Reporting Final Rule 76 FR 50816, 50829).

Under the “known to” portion of the standard, a submitter must ascertain what they know about the manufacturing, processing and use of a chemical substance it manufactures (including imports) or processes, without confining its inquiry to what is known to managerial and supervisory employees. A submitter would also be expected to review other information which the manufacturer (including importer) or processor may have in its possession. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be

as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable the processor to determine whether the supplier is selling them a nanoscale material subject to reporting and, if so, provide them with what reportable information they have. Their supplier is not required to provide any additional information to the processor but might provide other supporting information, for example, whether their supplier has reported or intends to report the chemical substance under this rule. If the supplier provides information indicating that the substance is not reportable or if the processor lacks any other means of reasonably ascertaining whether the substance is reportable, the processor does not need to perform tests to determine whether the substance is reportable. No testing is required under this rule.

Information developed in the normal course of business or that the processor chooses to develop must also be used. The processor may want to document the steps they took to determine if reporting was required. Inquiry under the "reasonably ascertainable" portion of the standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Note however, that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable" to the submitter. Thus there is not a need to conduct new customer surveys for purposes of reporting under the rule. As described above, however, existing customer survey data may nevertheless be "known to" the organization.

Each manufacturer and processor in the supply chain must report reasonably ascertainable information on the reportable chemical substance. Once a chemical substance has been incorporated into an article, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting. Companies that purchase formulations from a source in the United States but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule. Importers that purchase formulations that contain reportable chemical substances from a source outside the United States are considered to be the same as manufacturers and are required to report under the rule even if they do not change or modify those formulations and only use the formulation.

Each circumstance requires companies to use the reasonably ascertainable standard. The obligations under that standard can be different depending on the situation.

Question 18: Is a processor of a reportable chemical submitted as a PMN required to report?

Only persons who submitted the Section 5 submission after January 1, 2005 are exempt from reporting. Other manufacturers and processors would still be required to report under the TSCA Section 8(a) rule.

Question 19: The physical properties that define discrete forms of a reportable chemical substance sometime cannot reliably be measured and the rule appears to require companies to conduct tests on these or other physical-chemical properties to determine whether they must report. Many of these tests are not commonly performed.

Testing cannot be required under a TSCA Section 8(a) rule. While manufacturers and processors are not required to test for the properties identified in the definition of discrete forms of a reportable chemical substance, they are still required to determine their compliance obligations under the rule based upon information that is in their possession or which is reasonably ascertainable. If information within a company's possession or that is reasonably ascertainable does not demonstrate that the company is manufacturing or processing a discrete form of a reportable chemical substance, there is no obligation to report.

Question 20: What if there is no corresponding bulk material for the manufacturer or processor to use in assessing whether the nanomaterial exhibits unique and novel properties?

In the event that there is no obvious bulk chemical substance for comparison with a nanomaterial, submitters are encouraged to contact EPA for further guidance. This particular situation may require reporting under Section 5 of TSCA as a new chemical substance.

Question 21: If a company manufactures or processes a reportable chemical substance solely for export, is the company subject to the reporting requirements?

Yes. Persons who manufacture or process reportable chemical substances solely for export are subject to the reporting requirements. TSCA Section 12(a) exemptions for export do not apply to Section 8(a) rules. Note, however, that reportable processing and use information is restricted to domestic activities, i.e., within the customs territory of the United States.

Question 22: Are importers of a reportable chemical substance required to report under the rule?

Yes. The definition of "manufacture" under Section 3(9) of TSCA includes import.

Question 23: If the properties change after processing and the chemical is no longer reportable, does the processor still have to report?

If the properties change after processing and the chemical substance is no longer reportable, then the processed substance is no longer reportable. However, the processor would still need to

report available information about how it processed a reportable chemical substance into a non-reportable substance.

Section 3: What information is to be reported?

Question 24: Can you clarify whether manufacturers and processors who are only required to report available or reasonably ascertainable information need to develop information to comply with the rule?

Manufacturers and processors are not required to conduct testing or develop information under this rule. However, they are required to report information that is known or reasonably ascertainable. Manufacturers are likely to know details on how the reportable chemical substance is manufactured, but processors and users are less likely to know the same details. See the answer to Question 17 for detailed discussion about the reasonably ascertainable standard.

Question 25: What are some examples of types of information that are considered to be in a person's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know?

Examples of such types of information include:

- Files maintained by the submitter or employees in the submitter's company, such as marketing studies, sales reports, or customer surveys;
- Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
- Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

Question 26: A company manufactures or processes chemical substances but often does not know how these chemical substances are used by downstream customers. Does EPA intend for submitters to send questions to customers requesting information about downstream uses?

It depends on what is meant by sending "questions to customers." Submitters need not send out a comprehensive set of identical questions to multiple customers in order to fulfill the reporting standard. That is, they need not conduct a new survey of their customers. However, one way of fulfilling the reporting standard might involve limited inquiries outside the organization (e.g., contacting a major customer or examining that customer's public website) to fill in gaps in the submitter's knowledge, where the submitter's current knowledge is less than what a "reasonable person similarly situated might be expected to possess, control, or know." See 40 CFR 704.3.

Question 27: All of a company's products are used to make commercial products through various process steps by different manufacturers. Should the company provide information about consumer uses even if its chemical substance is not the end use product?

Yes. If the chemical substance is present in a consumer product, the company would still report the information if it is known to or reasonably ascertainable by the company, even if the

company does not manufacture the consumer product. The information provided on the reporting form about downstream use is associated with the processing and use of reportable chemical substances and typically relates to processing or use that is outside of the manufacturing, importing, or processing site, unless, of course, the manufacturer, importer, or processor also processes or uses the reportable chemical substance.

If the chemical substance is not present in the consumer product, then a manufacturer or processor would only need to report that it would be used to manufacture a consumer product to the extent it is known or reasonably ascertainable.

Information on subsequent industrial users and processors and on commercial and consumer uses of the reportable chemical substance would be reported on the reporting form to the extent the information is known to or reasonably ascertainable by the manufacturer (includes import) or processor of the subject chemical substance. A company which is a manufacturer or processor must report information about the distribution and use of the chemical substance that is known to or reasonably ascertainable by the company. To the extent the information is not known or reasonably ascertainable, the company may report NKRA (i.e., "not known or reasonably ascertainable").

Section 4: When is Reporting Required?

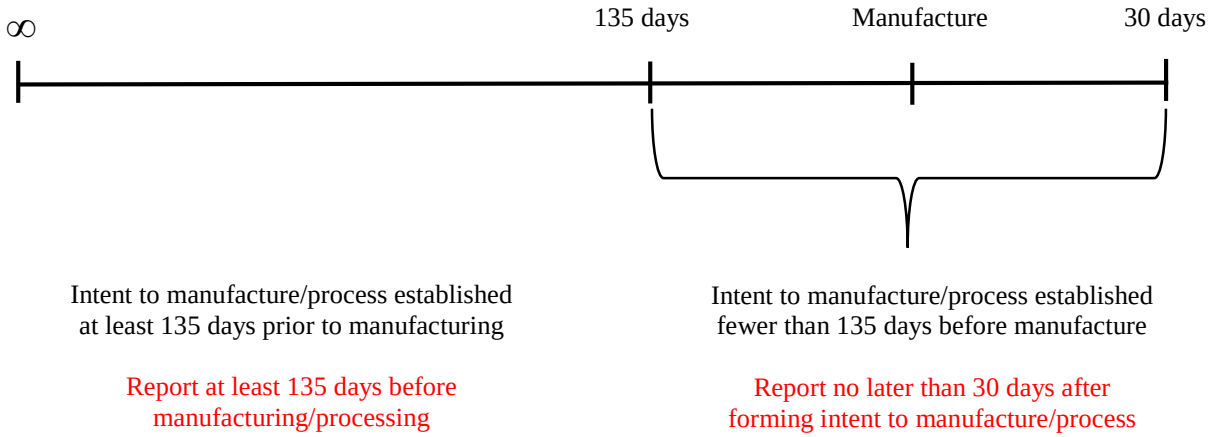
Question 28: Please clarify how the 135-day reporting requirement for new discrete forms would work. For example, can commercialization begin after notification to EPA or after 135 days after notification to EPA?

The 135-day period is not a formal review-period that prohibits manufacture or processing before the end of the 135-day period. Rather, based on EPA's experience with the PMN reviews in the new chemicals program, EPA believes that in most cases companies have the requisite intent to manufacture or process a reportable chemical substance at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent. However, if a company does not form the requisite intent 135 days ahead of time, the company must report within 30 days of the formation of such an intent. Moreover, if a company desires to begin manufacture or processing earlier than expected after the submission for this rule is made, the company is free to do so. There is no obligation upon the company to wait 135 days after reporting to manufacture or process.

The reporting requirement for discrete forms can be described in two different circumstances:

1) If the company forms the intent to manufacture or process 135 days or more (it is not unusual for companies to form intent 6 months or more in advance) before it manufactures or processes a discrete form: Reporting under the rule would occur at least 135 days before manufacturing or processing.

2) If the company forms the intent to manufacture or process fewer than 135 days before it manufactures or processes a discrete form: Reporting under the rule should occur as soon as possible but no later than 30 days after forming the intent.



A company can begin to manufacture or process the new discrete form any time after it has reported under the rule, because reporting under Section 8(a) does not establish a formal review period or require EPA to make any determination. Any follow-up action under TSCA including more information reporting would require a separate action under TSCA.

Question 29: Is there a mechanism or requirement to update any new information if there is a change in manufacture, processing or use after the initial reporting of a reportable chemical substance?

Because this rule only requires one-time reporting, updating with new information is not required unless the change in manufacture or processing creates a new discrete form of a reportable chemical substance. This would require separate reporting for the new discrete form of a reportable chemical substance.

Question 30: Can EPA clarify if the exemptions for new chemicals reported since January 1, 2005 and the Nanoscale Materials Stewardship Program (NMSP) would exempt information that has changed since the original reporting?

For a reportable chemical substance that was submitted as a new chemical substance under Section 5 of TSCA or as part of the NMSP, no updated information would need to be reported unless a manufacturing or processing change resulted in a new discrete form of the reportable chemical substance.

Question 31: What is the criterion for distinguishing new processing methods for a nanoscale material from existing methods? What would constitute a process change that would require filing a new report?

The type of process change is not the criterion; it is the intent and effect of the process change. Any manufacturing or processing change that is intended to change particle size and properties would be a process change that could result in a reportable chemical substance.

Section 5: General Questions

Question 32: The reporting rule was published in the Federal Register on January 12, 2017. When does this rule become law?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule 90 days; the rule became effective on August 14, 2017.

Question 33: Is there a minimum production volume below which no reporting is required, such as 10 or 100 kg?

There is no exemption based on production volume or reporting threshold based on production volume.

Question 34: (a) Is research and development exempt from reporting under the rule? (b) Can you define small quantities? (c) Can companies sell research and development quantities for profit? (d) Is reporting required if the core commercial activity of a company is research and development?

(a) Yes. As described in 40 CFR part 704.5(e), a person who manufactures (including imports), processes, or proposes to manufacture or process a substance subject to reporting under this rule only in small quantities solely for research and development is exempt from the reporting requirements of the rule.

(b) Small quantities solely for research and development (or ‘‘small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product’’) is defined in 40 CFR part 704.3 to mean quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(c) Yes. The exemption may apply even if a company sells research and development quantities for a profit.

(d) The research and development exemption applies to use for which the specific chemical substance is manufactured. It is irrelevant whether the main commercial activity of the company is research and development or industrial sales or use.

Question 35: Are articles exempt from reporting under this rule?

As described in 40 CFR 704.5(a), a person who imports, processes, or proposes to import or process a reportable chemical substance subject to this rule solely as part of an article is exempt from the reporting requirements of this part with regard to that substance. Manufacturers (including importers) or processors of a reportable chemical substance that is incorporated into an article would be required to report any required information for activities before the chemical

substance is incorporated into the article. An article is defined in 40 CFR 704.3 as a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Question 36: Please clarify on-site use of a reportable chemical (i.e. polishing) vs. those activities that constitute processing?

Processing for commercial purposes is defined in 40 CFR 704.3 as the "preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes." On-site use of a formulation containing a reportable chemical substance (i.e. for polishing or purifying other chemicals or articles) when the formulation is unchanged is not reportable. To better clarify when reporting is required, reporting would not be required by persons who *only* use a formulated product or polymer matrix. If someone both processes and uses a formulation with a reportable chemical substance, they would be required to report.

Question 37: Can imported metal powders ever be considered "articles" regardless of their end use?

No. Powders cannot be considered articles. The definition of article includes the statement that "fluids and particles are not considered articles regardless of shape or design".

Question 38: Is the purpose of the rule to compile an inventory of nanoscale material chemical substances in commerce?

No. The purpose of the rule is to collect information on the manufacture (including importation); processing; and industrial, commercial, and consumer uses of certain chemical substances that are nanoscale materials. This rule will allow EPA to obtain basic data from those that manufacture or process existing nanomaterials made from substances that are on the TSCA Inventory. EPA will use information gathered through this rule to inform the Agency's understanding about the manufacture, processing and use of nanoscale substances and to determine if any further action under TSCA, including additional information collection, is needed in specific instances.

Question 39: How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR 704.20 to determine your reporting requirements. You should consider the following three steps to determine whether you are

required to report for each chemical substance that you domestically manufactured (including imported) or processed in the United States:

- Step I: Is your chemical substance subject to the reporting rule?
- Step II: Are you a manufacturer (including importer) or processor who is required to report?
- Step III: What information must you report?

Question 40: Must a submitter conduct new chemical analyses to report information?

No. The regulation does not require submitters to perform new chemical analyses. The information required by the rule is limited to information that is "known to or reasonably ascertainable." This standard is applicable to all information reported in accordance with 40 CFR 704.20. Testing is not required under this regulation.

Question 41: What should a company do if it determines that it manufactures or processes a chemical substance that is not included on the TSCA Inventory?

In order to manufacture (including import) or process a chemical substance for a non-exempt commercial purpose, it must be: on the TSCA Inventory, a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.4(b)), or excluded by TSCA Section 3(2)(B). You can visit Substance Registry Services to determine whether your chemical substance is on the TSCA Inventory. If your chemical substance is not on the TSCA Inventory, you may need to submit a PMN to the new chemicals program. Please see EPA's PMN Requirement flowchart to determine if a notice must be submitted to the Agency prior to manufacture (including import). See: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new#who notifies. You can also phone the TSCA Hotline at (202)-554-1404 for assistance.

For a chemical substance that is not on the TSCA Inventory, a person must submit a notice as per 40 CFR 720.22(a)(1) prior to manufacture (including import), with certain exceptions, such as a naturally occurring chemical substance as defined by TSCA, or a chemical exempted excluded from the definition of "chemical substance" in TSCA Section 3(2)(B). See Question 42, below, for a discussion of chemicals excluded from TSCA.

If a person is manufacturing (including importing) a substance which is not on the TSCA Inventory and has not provided the required notice to EPA, each day of such manufacture or importation is a violation of Section 5 of TSCA and could subject the person to enforcement action. If a person finds that it has or may have manufactured a chemical substance in violation of TSCA, contact the Agency by following the instructions at: https://www.epa.gov/compliance/epas-edisclosure.

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a person has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the requirements at 40 CFR 704.20.

Question 42: If a company manufactures an otherwise reportable chemical substance for a non-TSCA use, is the company required to report under 40 CFR 704.20?

Substances exempted in TSCA Section 3(2)(B) need not be reported. Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide (but see Question 43 below regarding intermediates in the manufacture of an active ingredient in a pesticide); any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.

Question 43. A company manufactures Chemical C. Its customers use Chemical C for a variety of uses, including as an intermediate in the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Does the company need to report industrial processing and use data for this chemical substance?

Yes. The manufacture of a chemical substance that is a pesticide intermediate is manufacture under TSCA.

Question 44: If a company manufactures or processes a reportable chemical substance which may be used for purposes regulated by TSCA and also for uses which are excluded from regulation under TSCA Section 3(2)(B), should the entire quantity that the company manufactures or processes be reported in the submission?

No. Report the manufactured or processed quantity intended for the TSCA use and do not report the quantity that is exempt from TSCA in Section 3(2)(B).

Question 45: Are small manufacturers and processors exempt from reporting requirements of the rule?

Yes. A small manufacturer or processor is defined in the rule as any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million. When total annual sales exceed this value, the manufacturer or processor is no longer considered a small manufacturer or processor and would now be subject to the requirements of the rule.

Question 46: What role does the technical contact play?

The technical contact is the person whom EPA may contact for clarification of the information in a submission. The technical contact should be a person who can answer questions about the reported chemical substance(s). Typically, a person located at the manufacturing or processing

site is best able to answer such questions. However, companies may use their discretion in selecting a technical contact or multiple technical contacts. Submitters should consider, in selecting the technical contact, that EPA may have follow-up questions about a submission one or more years after the submission date. The technical contact need not be the person who signs the certification statement.

Question 47: When is the electronic reporting tool going to be available? Will EPA develop user guidance for the new CDR reporting module?

The reporting tool will be available when the rule becomes effective. There will be user guidance for the reporting module.

Question 48: Are joint submissions between manufacturers and processors going to be possible? Will consolidated submissions be permitted?

The electronic reporting tool does not currently allow manufacturers and processors to report jointly on one submission. It will allow additional companies to add support information to a submission not known to a manufacturer or processor if companies want to work together on a submission. EPA will work on adding functionality for joint submissions if companies are interested in that option. The electronic reporting tool does allow for consolidated submissions.

Please contact the EPA for additional details or specific questions regarding adding support information by companies other than the notification submitter. For consolidated submissions please contact EPA before submitting so that EPA can approve the number of reportable chemical substances in one submission and the reason for grouping certain reportable chemical substances.

Question 49: How do I identify a reportable chemical substance if I don't know the chemical identity or if I don't know the CAS number?

The reporting tool will allow companies that are reporting to use generic names or trade names if they do not know the chemical identity. A CAS number will not be required on the reporting form in such cases. If this information is known to or reasonably ascertainable by a company, then they are required to report it on the form.

Question 50: Can EPA clarify or give examples of the meaning of intent to manufacture or process?

A manufacturer or processor of a reportable chemical substance intends to manufacture or process a reportable chemical substance when it has begun one or more of the actions necessary to engage in that commercial activity. Below are some examples that would indicate an intent to manufacture or process a reportable chemical substance. These are not the only indications of an intent to manufacture or process a reportable chemical substance. These examples were identified by one of the commenters to this guidance.

- A company completes R&D efforts and begins efforts to scale up from a pilot process to a full-scale operation to enable the production or processing of a reportable chemical substance.

- A company executes a contract, purchase order, or similar document with a supplier which provides for delivery of a reportable chemical substances for use by the company.

- A company enters an agreement for delivery of a product that will incorporate a reportable chemical substance.

- A company makes significant modifications to its operations, processes and/or its production equipment to accommodate use of, or to generate, a reportable chemical substance.

- A company is taking steps to fulfill a request from a supplier or a customer which provide specifications to be followed to produce or process a reportable chemical substance.

Section 6: Confidentiality

Question 51: What are the requirements for submitting confidential information under the rule?

Information submitted under the rule may be claimed as confidential at the time it is submitted. Submitters must provide upfront substantiation of confidentiality claims for processing and use information as well as for confidentiality claims for site or chemical identity. See §704.20(h) of the rule, and EPA guidance on asserting confidentiality claims at https://www.epa.gov/tsca-cbi.

Question 52: What must generally be considered in making a claim of confidentiality under TSCA?

EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B and 40 CFR 704.20(h). TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires that for all claims for protection for any confidential information made with this submission, the submitter certify they have:
(i) taken reasonable measures to protect the confidentiality of the information;
(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to my competitive position; and
(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).

For further information about EPA's interpretation of confidentiality claims see Statutory Requirements for Substantiation of Confidential Business Information Claims Under the Toxic Substances Control Act (82 FR. 6524) (Jan. 19, 2017).

Question 53: Can companies reporting under the rule make and substantiate confidential business information claims for responsive information known to the submitter but belonging to suppliers or customers and provided under a non-disclosure agreement or a similar arrangement?

EPA considers third party confidentiality claims to be potentially within the ambit of the 704.20(h)(iii) statement regarding disclosure causing substantial harm to the competitive position of the person reporting.

Nanomaterials

Nanomaterials are chemical substances or materials with particle sizes between 1 to 100 nanometres in at least one dimension.

Due to an increased specific surface area by volume, nanomaterials may have different characteristics compared to the same material without nanoscale features. As a result, the physicochemical properties of nanomaterials may differ from those of bulk substances or particles of a larger size.

Many everyday products containing nanomaterials are already on the European market such as batteries, coatings, anti-bacterial clothing and cosmetics. While nanomaterials may offer technical and commercial opportunities, they may also pose risks to our health and the environment. Just like any other substance on the EU market, it is important to ensure that their uses are properly assessed and that any risks are adequately controlled.

ECHA works in close collaboration with Member State competent authorities, the European Commission, NGOs and industry associations as well as international organisations such as the Organisation for Economic Cooperation and Development (OECD), to help implement EU chemicals legislation for nanomaterials.

REACH and CLP | **Biocidal Products Regulation (BPR)**

Nanomaterials fall under the existing REACH and CLP definition of a substance, and provisions set by both regulations apply. In 2011, the European Commission released a recommendation for a definition of a nanomaterial. It is used in different European regulations, including REACH and CLP, to harmonise how nanomaterials are defined across legal frameworks.

As of 1 January 2020, explicit legal requirements under REACH apply for companies that manufacture or import nanoforms. These reporting obligations address specific information requirements, outlined in revised annexes to the REACH regulation:

- characterisation of nanoforms or sets of nanoforms covered by the registration (Annex VI);
- chemical safety assessment (Annex I);
- registration information requirements (Annexes III and VII-XI); and
- downstream user obligations (Annex XII).

The amendments apply to all new and existing registrations covering nanoforms.

ECHA's activities on nanomaterials under REACH and CLP

Since REACH and CLP cover nanomaterials, ECHA needs to be able to carry out its tasks for nanoforms within the various REACH (e.g. registration, evaluation, authorisation and restrictions) and CLP processes (e.g. classification and labelling) as it would for any other form of a substance, and needs to have sufficient scientific and technical capacity to do so.

NEWS

New OECD guidance documents for the risk assessment of nanomaterials, News release 27 July 2020

Companies need to provide more data on nanoforms, News release 24 February 2020

Updated guidance for registering substances in nanoform, News release 3 December 2019

Get ready for new REACH requirements for nanomaterials, News release 8 October 2019

Companies to provide more information on nanomaterials, Press release 3 December 2018

QUESTIONS AND ANSWERS

Nanomaterials under REACH

RELATED DOCUMENTS

Nanotechnology research - European Commission

Safety of manufactured nanomaterials - OECD

European Commission recommendation on nanomaterials definition [PDF]

With this aim, ECHA has increased its activities in this area since 2011 focusing on:

- Preparing new and updated **guidance documents**
- Internal and external **capacity building**
- **Sharing experience** with, and generating consensus among, Member State Competent Authorities and members of the risk assessment and Member State committees concerning safety information for nanomaterials in REACH registration dossiers
- Providing **feedback and advice** to companies that register nanomaterials
- **Participating** and contributing to ongoing **international regulatory activities** (such as the OECD Working Party on Manufactured Nanomaterials or the Malta Initiative for developing test guidelines)
- **Webinars** to inform and discuss the latest developments regarding REACH and CLP processes related to nanomaterials, and to help registrants prepare and submit dossiers that involve nanomaterials
- The **Nanomaterials Expert Group** (NMEG) was established in October 2012 with the support of the competent authorities for REACH and CLP (CARACAL) and for Biocides. This informal advisory group supports the implementation of ECHA's workplans for nanomaterials and provides information and advice on scientific and technical issues regarding the implementation of REACH, CLP and BPR legislation in relation to nanomaterials
- Hosting the **European Union Observatory for Nanomaterials** to increase transparency of information on nanomaterials

Guidance and manuals

ECHA

- How to prepare registration dossiers covering nanoforms [PDF] [EN]
- Guidance for identification and naming of substances under REACH and CLP [PDF] [EN]
  - Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification [PDF] [EN]
- ECHA Guidance on Information Requirements and Chemical Safety Assessment for nanomaterials:
  - Appendix to Chapter R.6: Guidance on QSARs and Grouping of Chemicals [PDF] [EN]
  - Appendix to Chapter R.7a: Endpoint specific guidance [PDF] [EN]
  - Appendix to Chapter R.7b: Endpoint specific guidance [PDF] [EN]
  - Appendix to Chapter R.7c: Endpoint specific guidance [PDF] [EN]
  - Appendix to Chapter R.8: Characterisation of dose [concentration] - response for human health [PDF] [EN]
  - Appendix to Chapter R.10: Characterisation of dose [concentration] - response for environment [PDF] [EN]
  - Appendix to Chapter R.14: Occupational exposure assessment [PDF] [EN]
  - Template to document practical constraints for fulfilling REACH Annex VII and VIII information requirements [PDF] [EN]

OECD

- OECD Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision [PDF] [EN]
- OECD Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials [PDF] [EN]

Webinars

Registering nanoforms: practical advice – 2020 | Webinar Q&A

Getting ready for revised REACH information requirements for nanoforms – 2019 | Webinar Q&A

Updated REACH Guidance for nanomaterials - what you need to know – 2017

How to ensure the safe use of nanomaterials under REACH - Part III: current best practices for human health and environmental exposure assessment and risk characterisation for nanomaterials – 2014

How to ensure the safe use of nanomaterials under REACH - Part II: Current best practices for human health and environmental hazard assessment for nanomaterials – 2013

How to ensure the safe use of nanomaterials under REACH Part I – 2012

RELATED

Search for nanomaterials on the EU market

ECHA Nanomaterials expert group

EU nanomaterials observatory (EUON): Overview of REACH Annex modifications and available methods

Group assessing already registered nanomaterials (GAARN) - meeting reports

Best Practices on physicochemical and substance identity information [PDF] [EN]

Assessing human health and environmental hazards [PDF] [EN]

Human health and environmental exposure assessment and risk characterisation [PDF] [EN]

Tagged as: Nanomaterials

(click the tag to search for relevant content)

LEGISLATION

REACH

CLP

BPR

PIC

POPs

CAD/CMD (OELs)

WFD

DWD

CONSULTATIONS

Consultations in the authorisation process

Substances of very high concern identification

Consultation on draft recommendation for inclusion in the Authorisation List

Applications for authorisation consultations

Submitted restrictions under consideration

Consultations on new scientific evidence

Current calls for comments and evidence

Testing proposals consultation

INFORMATION ON CHEMICALS

Registry of CLH intentions until outcome

Registry of restriction intentions until outcome

Registry of SVHC intentions until outcome

Registered substances

Annex III inventory

Pre-registered substances

EC Inventory

Dossier Evaluation status

PACT - Public Activities Coordination Tool

Assessment of regulatory needs list

PBT assessment list

SUPPORT

Getting started

Guidance

Q&As Support

Testing methods and alternatives

Webinars

Dossier Submission Tools

National Helpdesks

Practical examples of exposure scenarios

Practical examples of chemical safety reports

Small and Medium-sized Enterprises (SMEs)

Recommendations to registrants

Harmonised classification and labelling consultations

Harmonised classification and labelling targeted consultations

ECHA Executive Director’s requests related to the CLH process

Consultation on potential candidates for substitution

Consultation on derogation to the exclusion criteria

Previous consultations on ECHA’s Executive Director Requests to the Committees

ECHA's Executive Director Requests to the Committees

Consultation on a draft recommendation for amendment of Authorisation List entries

Occupational exposure limits - Call for comments and evidence

Occupational exposure limits – Consultations on OEL recommendation

Derogations for the protection of cultural heritage

Proposals for new POPs

Other calls for comments and evidence

Endocrine disruptor assessment list

Substance evaluation - CoRAP

Information on Candidate List substances in articles table

C&L Inventory

Substances restricted under REACH

Biocidal Active Substances

Biocidal Products

List of active substances and suppliers

Chemicals subject to PIC

Transitional Measures

Information from the Existing Substances Regulation (ESR)

PBT/vPvB assessments under the previous EU chemicals legislation

REACH registration statistics

Candidate List

Submitted recommendations

Adopted opinions and previous consultations on applications for authorisation

Authorisation List

Adopted opinions on restriction proposals

ECHA's current activities on restrictions

ECHA's completed activities on restriction

Mapping exercise – Plastic additives initiative

Occupational exposure limits substance evaluations

List of substances subject to POPs Regulation

List of substances proposed as POPs

EUCLEF

Registration phases

Substance identification

Restriction

Authorisation

Socio-economic analysis in REACH

Submission of CLH dossiers

How to improve your dossier

QSAR Toolbox

Mixture classification

UK withdrawal from the EU

ECHA accounts and EU Login

Technical completeness check

European Chemicals Agency

Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland

Oxford Reference

OVERVIEW

beneficiation

QUICK REFERENCE

The separation of an ore into the valuable components and the waste material (gangue). This may be achieved by a number of processes, including crushing, grinding, magnetic separation, froth flotation, etc. The dressed ore, consisting of a high proportion of valuable components, is then ready for smelting or some other refining process.

From: beneficiation in A Dictionary of Chemistry »

Subjects: Science and technology — Chemistry

Related content in Oxford Reference

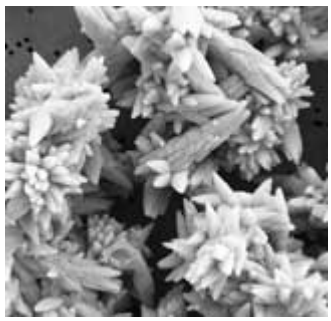
Reference entries

beneficiation
in A Dictionary of Chemistry (6)
Length: 55 words

View all related items in Oxford Reference »
Search for: 'beneficiation' in Oxford Reference »

Precipitated Calcium Carbonate

PCC stands for Precipitated Calcium Carbonate—also known as purified, refined or synthetic calcium carbonate. It has the same chemical formula as other types of calcium carbonate, such as limestone, marble and chalk: CaCO3. The calcium, carbon and oxygen atoms can arrange themselves in three different ways, to form three different calcium carbonate minerals. The most common arrangement for both precipitated and ground calcium carbonates is the hexagonal form known as calcite. A number of different calcite crystal forms are possible: scalenohedral, rhombohedral and prismatic. Less common is aragonite, which has a discrete or clustered needle orthorhombic crystal structure. Rare and generally unstable is the vaterite calcium carbonate mineral.

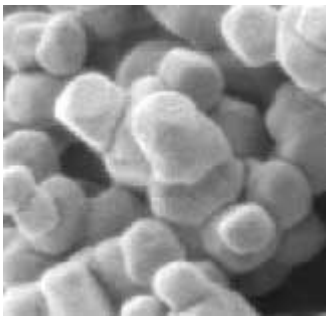
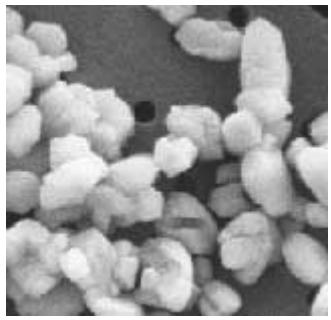
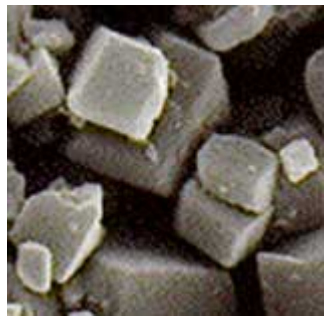


Calcium carbonates, including PCC, are considered to be non-toxic. In the U.S., the Food and Drug Administration has Affirmed calcium carbonate to be GRAS (Generally Recognized As Safe). As long as the PCC meets certain purity requirements, it can be used as a direct food additive, as a pharmaceutical or as an indirect additive in paper products that come in contact with food. Similar acceptances and approvals exist around the world where PCCs are widely used in these applications. Click on the Contact Us link below to inquire about specific regulations covering the use of PCCs in these health-related uses, or on the MSDS link to download a Material Safety Data Sheet covering a Specialty Minerals Inc.’s (SMI’s) PCC product.

When Did Precipitated Calcium Carbonate (PCC) Manufacture Begin?

PCCs have been made commercially for a long time—since 1841. The first producer was the English company, John E. Sturge Ltd., which treated the residual calcium chloride from their potassium chlorate manufacture with soda ash and carbon dioxide to form what they called precipitated chalk. In 1898, a new factory was built in Birmingham using the milk of lime process, which is described in more detail below. This PCC operation is now part of the Performance Minerals group of SMI.

PCC production in the U.S. dates from 1938, when the C.K. Williams Company in Adams, Massachusetts, began to make PCC using the limestone from their adjacent mine. This plant was acquired by Pfizer in 1962, and became part of the Performance Minerals group of SMI on the formation of our parent, Minerals Technologies Inc., in 1992.

How Is Precipitated Calcium Carbonate (PCC) Made?

Almost all PCC is made by direct carbonation of hydrated lime, known as the milk of lime process. The milk of lime process is simple in concept:

- Mine high purity calcium carbonate rock.
- Crush the rocks to the particle size needed for processing – small stones or powder.
- Separate some of the impurities from the crushed rock.
- Calcine (heat) in a kiln to 1850° F, which takes the calcium carbonate apart, forming lime (CaO) and carbon dioxide gas (CO_2). The carbon dioxide can be captured for reuse. **$CaCO_3$ + Heat → CaO + CO_2 ↑**
- Add the lime to water to form calcium hydroxide (hydrated lime or slake). **CaO + H_2O → $Ca(OH)_2$**

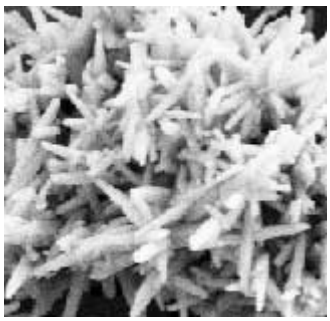
- Separate out additional impurities from the slaked lime.

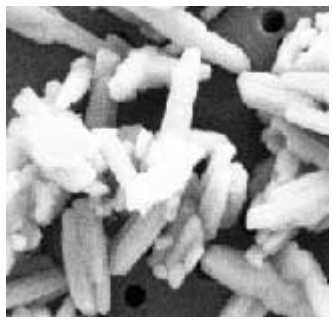
- Combine the captured carbon dioxide with the slaked lime. Calcium carbonate reforms, and since it is insoluble in water, precipitates out.
  $Ca(OH)2 + CO2 \rightarrow CaCO3 \downarrow + H2O$

- Separate additional impurities and grit from the PCC slurry.

- If the PCC is to be used in a paper mill or shipped to a latex paint plant, the lower solids slurry may be used as is, or processed to bring up the solids level, then tested before transfer or shipment.

- If the PCC is to be used as a dry product, the slurry is dewatered, dried, milled, packaged and tested.





While the process is simple on a laboratory scale, making precipitated calcium carbonates commercially on a large scale requires a great deal of process control and process technology to assure the right size, uniformity, shape, surface area and surface chemistry. This body of PCC technology developed by Specialty Minerals Research, is what makes SMI PCCs outstanding in quality and consistency.

What Is Precipitated Calcium Carbonate (PCC) Made From?

PCC is generally made from a high purity calcium carbonate rock called limestone. Specialty Minerals Inc. (SMI) uses high quality limestone sources for its PCC products, including some from the SMI limestone mine in Adams, Massachusetts, which has been in operation for more than 150 years.

This limestone deposit is the result of a very thick layer of prehistoric sea animal shells and skeletons being laid down on the ocean floor. These shells and skeletons were largely composed of calcium carbonate. Over a period of five hundred million

years this deposit was under high temperature and high pressure, and the deposit changed to a coarsely crystallized limestone. All of the organic matter that was in the deposit was removed by oxidation, a process called diagenesis.

If this kind of geological process continues a very long time, the crystals become very small, forming marble, an extremely hard form of calcium carbonate. If the time, temperature and/or pressures are not great, the seabed only partially metamorphoses, and the result is very soft chalk, such as that forming the White Cliffs of Dover in England. In chalks, remnants of animal shells and skeletons are often still seen.

Why Is All That Processing Done?

Two reasons. First, there are several points in the PCC process where the calcium carbonate can be purified, removing much of the rock from the deposit that is not calcium carbonate—there are always some impurities in any limestone deposit. These include feldspar and other silicaceous minerals, as well as heavy metals.

Second, the PCC process allows SMI to grow crystals of different shapes. The particle formed is dictated by the control of reaction time, temperature, agitation, pressure, rate of carbon dioxide addition, and post-crystallization processing. These shapes—clustered needles, cubes, prisms, rhombohedrons—have different physical properties such as powder density, surface area and oil absorption, which give them outstanding performance in many applications where ground calcium carbonate does not perform as well. Scanning electron micrographs (SEMs) of some of the these shapes are shown on this page.

The precipitation process also allows the growing of very fine particles, down to nanometers or hundredths of a micron—much finer than can be obtained by just grinding the limestone rock. These ultrafine nano PCCs have special applications where high performance is required. Click here to learn more about nano PCCs, which SMI has been manufacturing for more than 25 years.

What Is Unique About A Precipitated Calcium Carbonate?

The different shapes allow PCC to act as a functional additive in sealants, adhesives, plastics, rubber, inks, paper, pharmaceuticals, nutritional supplements and many other demanding applications. A formulator can choose a shape, and the physical

properties that result from that shape, that gives the best performance in the end use.

In the PCC process, products can be made with very small sizes, with high surface areas, high oil absorptions, and/or with different powder bulk densities— from ultra-low to super-high powder densities.

Why Are Some PCCs Coated?

PCCs are often coated with a low percentage (1-3 percent) of a fatty acid, such as stearic acid, or other organic material, for use in non-aqueous systems. These coatings increase the dispersibility of the PCC in the polymer or solvent as well as its compatibility with the polymer or solvent, which in turn maximizes the performance and efficiency of the PCC.

The choice of coating depends on the type of polymer the PCC will be used in and the performance desired. As polymers vary widely in polarity and solubility constants, different organics are chosen to give the best compatibility and/or the best balance of properties.

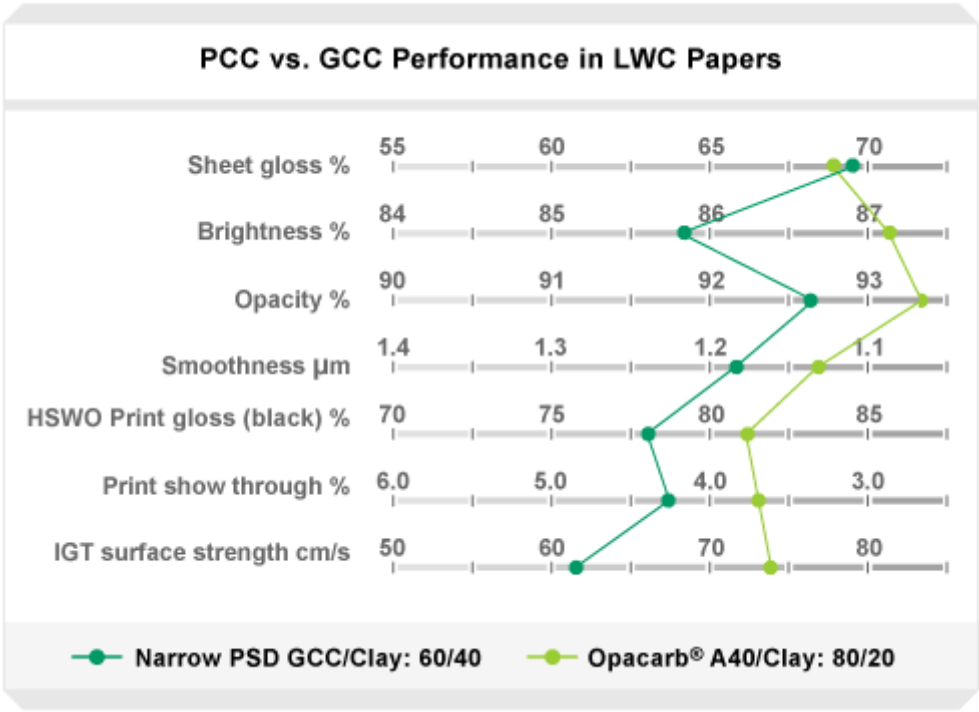
How Does Precipitated Calcium Carbonate Differ From Ground Calcium Carbonate (GCC)?

In chemical composition, they are the same. PCC is purer than the limestone from which it is made, and is lower in silica and lead.

PCC’s shape and size are different from that of ground calcium carbonate (GCC). Under high magnification, GCC is seen to be irregularly rhombohedral in shape. The PCC crystal shape depends on the product, and the particles are more uniform and regular.

The distribution of particle sizes in a GCC is much broader than for a PCC of the same size—that is, there are many more large particles and many more small particles than in a PCC, and the size of the largest of the particles (the "top size") is much greater for a GCC than for a PCC. The lower top size of a PCC gives better impact resistance in plastics than with a GCC. The narrower particle size distribution allows the generation of high oil absorptions, useful in certain applications.

These differences can be quickly seen in these photos of a PCC and a GCC of the same median particle size, 0.7 microns.



Specialty Minerals Precipitated Calcium Carbonates

SMI is the world's largest manufacturer of PCCs, with an output of over 4 million tons of PCC each year.

Some of our PCC products for paper and paperboard filling and coating include Opacarb®, Megafil®, and Velacarb® precipitated calcium carbonates.

For food, nutritional supplements, pharmaceutical and personal care products, the series of eight ViCALity® USP/FCC precipitated calcium carbonates and five CalEssence® ultra low lead PCCs are manufactured in Adams, Massachusetts, in the U.S. Five SturcalTM and Calopake® EP PCC healthcare grades are manufactured in Birmingham, U.K.

A wide variety of polymeric and water-based industrial products use Albacar®, Albaglos®, and Super-Pflex® PCCs, as well as the nano PCCs, Ultra-Pflex®, Multifex-MM® and a series of Thixo-Carb® PCCs, which come from Adams, Massachusetts, in the U.S. The Calopake® PCC and Calofort® nano PCCs come from SMI's Birmingham plant.

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HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH

The Nutrition Source

Calcium

Calcium is a mineral most often associated with healthy bones and teeth, although it also plays an important role in blood clotting, helping muscles to contract, and regulating normal heart rhythms and nerve functions. About 99% of the body's calcium is stored in bones, and the remaining 1% is found in blood, muscle, and other tissues.

In order to perform these vital daily functions, the body works to keep a steady amount of calcium in the blood and tissues. If calcium levels drop too low in the blood, parathyroid hormone (PTH) will signal the bones to release calcium into the bloodstream. This hormone may also activate vitamin D to improve the absorption of calcium in the intestines. At the same time, PTH signals the kidneys to release less calcium in the urine. When the body has enough calcium, a different hormone called calcitonin works to do the opposite: it lowers calcium levels in the blood by stopping the release of calcium from bones and signaling the kidneys to rid more of it in the urine.

The body gets the calcium it needs in two ways. One is by eating foods or supplements that contain calcium, and the other is by drawing from calcium in the body. If one does not eat enough calcium-containing foods, the body will remove calcium from bones. Ideally, the calcium that is "borrowed" from the bones will be replaced at a later point. But this doesn't always happen, and can't always be accomplished just by eating more calcium.

Recommended Amounts

The Recommended Dietary Allowance (RDA) for calcium for women 19-50 years of age is 1,000 mg daily; for women 51+, 1,200 mg. For pregnant and lactating women, the RDA is 1,000 mg. For men 19-70 years of age, the RDA is 1,000 mg; for men 71+ years, 1,200 mg. [1]

Calcium and Health

The reviews below specifically looked at the effect of calcium on various health conditions. Scroll down for links to more information on the health effect of specific foods rich in calcium.

- ▶ Blood pressure
- ▶ Cardiovascular disease
- ▶ Bone health
- ▶ Colorectal cancer
- ▶ Kidney stones

Food Sources

Calcium is widely available* in many foods, not just milk and other dairy foods. Fruits, leafy greens, beans, nuts, and some starchy vegetables are good sources.

- Dairy (cow, goat, sheep) and fortified plant-based milks (almond, soy, rice)
- Cheese

- Yogurt
- Calcium-fortified orange juice
- Winter squash
- Edamame (young green soybeans); Tofu, made with calcium sulfate
- Canned sardines, salmon (with bones)
- Almonds
- Leafy greens (collard, mustard, turnip, kale, bok choy, spinach)

*Bioavailability of calcium

Calcium is a large mineral and not so easy to break down in the gut. The amount of calcium listed on the Nutrition Facts label of a food product is the measure of calcium in the food, but not necessarily the amount the body will absorb. The amount that is actually absorbed and used by the body is called “calcium bioavailablity.” Some foods have higher calcium bioavailability than others.

For example, dairy foods have a bioavailablity of about 30% absorption so if a food label on milk lists 300 mg of calcium per cup, about 100 mg will be absorbed and used by the body. Plant foods like leafy greens contain less calcium overall but have a higher bioavailability than dairy. For example, bok choy contains about 160 mg of calcium per 1 cup cooked but has a higher bioavailability of 50%, so about 80 mg is absorbed. Therefore, eating 1 cup of cooked bok choy has almost as much bioavailable calcium as 1 cup of milk. Calcium-fortified orange juice and calcium-set tofu have a similar total amount of calcium and bioavailability as milk, while almonds have slightly lower total calcium and bioavailability of about 20%. This may be useful information for those who cannot eat dairy foods or who follow a vegan diet.

A downside to some plant foods is that they contain naturally occurring plant substances, sometimes referred to as “anti-nutrients.” Examples of anti-nutrients are oxalates and phytates that bind to calcium and decrease its bioavailablity. Spinach contains the most calcium of all the leafy greens at 260 mg of calcium per 1 cup cooked, but it is also high in oxalates, lowering the bioavailability so that only 5% or about 13 mg of calcium can be used by the body. The takeaway message is not to avoid spinach, which contains other valuable nutrients, but not to rely on spinach as a

significant source of calcium since most of it will not be absorbed by the body. You can also schedule your meals so that you do not eat “calcium-binding” foods like spinach at the same meal as calcium-rich foods or with calcium supplements.

If you are scanning food labels to reach a specific amount of daily calcium, continue to aim for the RDAs set for your age group and gender. The RDAs are established with an understanding of calcium bioavailability in food. Also keep in mind that the exact amount of calcium absorbed in the body will vary among individuals based on their metabolism and what other foods are eaten at the same meal. In general, eating a variety of calcium-rich foods can help to offset any small losses.

Signs of Deficiency and Toxicity

Deficiency

Blood levels of calcium are tightly regulated. Bones will release calcium into the blood if the diet does not provide enough, and no symptoms usually occur. A more serious deficiency of calcium, called hypocalcemia, results from diseases such as kidney failure, surgeries of the digestive tract like gastric bypass, or medications like diuretics that interfere with absorption.

Symptoms of hypocalcemia:

- Muscle cramps or weakness
- Numbness or tingling in fingers
- Abnormal heart rate
- Poor appetite

A gradual, progressive calcium deficiency can occur in people who do not get enough dietary calcium in the long-term or who lose the ability to absorb calcium. The first early stage of bone loss is called osteopenia and, if untreated, osteoporosis follows. Examples of people at risk include:

- *Postmenopausal women*—Menopause lowers the amount of estrogen in the body, a hormone that helps to increase calcium absorption and retain the mineral in bones. Sometimes physicians may prescribe hormone replacement therapy (HRT) with estrogen and progesterone to prevent osteoporosis.
- *Amenorrhea*—A condition where menstrual periods stop early or are disrupted, and is often seen in younger women with anorexia nervosa or athletes who physically train at a very high level.
- *Milk allergy or lactose intolerance*—Occurs when the body cannot digest the sugar in milk, lactose, or the proteins in milk, casein or whey. Lactose intolerance can be genetic or acquired (not consuming lactose in the long-term may decrease the efficiency of lactase enzyme)

> ▶ Guidelines if you are taking calcium supplements for osteoporosis

Toxicity

Too much calcium in the blood is called hypercalcemia. The Upper Limit (UL) for calcium is 2,500 mg daily from food and supplements. People over the age of 50 should not take more than 2,000 mg daily, especially from supplements, as this can increase risk of some conditions like kidney stones, prostate cancer, and constipation. Some research has shown that in certain people, calcium can accumulate in blood vessels with long-term high doses and cause heart problems. Calcium is also a large mineral that can block the absorption of other minerals like iron and zinc.

Symptoms of hypercalcemia:

- Weakness, fatigue
- Nausea, vomiting
- Shortness of breath
- Chest pain
- Heart palpitations, irregular heart rate

Did You Know?

Certain nutrients and medications may increase your need for calcium because they either lower the absorption of calcium in the gut or cause more calcium to be excreted in the urine. These include: corticosteroids (example: prednisone), excess sodium in the diet, phosphoric acid such as found in dark cola sodas, excess alcohol, and oxalates (see Are anti-nutrients harmful?).

▶ References

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