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Secretary for
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Department of Toxic Substances Control



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«AddressBlock»

VIA CERTIFIED MAIL

FORMAL REQUEST FOR CHEMICAL INFORMATION AND ANALYTICAL TEST METHODS FOR SPECIFIED NANOMATERIALS

«GreetingLine»:

The Department of Toxic Substances Control (DTSC) formally requests information regarding the chemical and physical properties, including analytical test methods and other relevant information, about six specified chemicals. DTSC has identified your company or institution as a manufacturer who produces or imports one or more of the following nanomaterial chemicals:

- Nano Silver
- Nano Zero Valent Iron
- Nano Cerium Oxide
- Nano Titanium Dioxide
- Nano Zinc Oxide
- Quantum Dots

DTSC seeks information about these nanomaterial chemicals because their commercial uses and applications are growing; yet, information about analytical test methods, physicochemical properties, toxicity, and fate and transport of these nanomaterial chemicals are generally unknown or unavailable. DTSC is specifically interested in information related to analytical test methods for these chemicals in environmental matrices, including water, air, soil, sediment, sludge, and chemical waste. California law (Health and Safety Code sections 57018 – 57020) authorizes state agencies to request such information so industry and interested stakeholders—working in partnership with state government agencies—can develop and use appropriate analytical test methods to ascertain how these chemicals may affect public health and our environment. Under law, manufacturers (including importers) must provide the requested information in writing to DTSC no later than one year from the date of this letter; however, your timely attention and response is preferred. The pertinent statutory sections are enclosed.

DTSC has had extensive dialogue and conducted research about the six specified nanomaterial chemicals. We collaborated with the U.S. Environmental Protection Agency in these efforts. DTSC announced our initial interest and intent to call-in the six nanomaterial chemicals (above) on our website in April 2009. During the last year and a half, DTSC has conducted a search for information on manufacturers of the six nanomaterial chemicals, analytical test methods for those chemicals, and other relevant information. The bibliography of our research is posted on the DTSC's website at:

http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Round_Two_Biblio.pdf. We have also

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called, emailed, visited and met with manufacturers and importers to discuss the information call-in program and the information sought about relevant analytical test methods. DTSC convened a public workshop on the six specified nanomaterial chemicals on September 22, 2010, in San Francisco.

The list of manufacturers who are receiving this notice can be found at: http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Round_Two_List_of_Letters_Sent.pdf. If you are aware of other manufacturers who should also receive this request, we welcome your input and comments. If you feel your institution or organization has received this formal request in error, please notify the DTSC, in writing, and state your reasons for why the information call-in request does not apply to you.

The statute anticipates a collaborative process for compiling the requested information. The DTSC team is available to meet with you to discuss this information call-in. We request that you contact us within 60 days of this letter to discuss this call-in and your preliminary responses. This interaction will provide you the prospect of asking questions you may have regarding the call-in and obtaining potential resources available to assist you in the formulation of your comprehensive responses. California law assigns to manufacturers, either as a group or individually, the responsibility to provide information on the fate and transport of the specified chemicals as well as the analytical test methods to determine the identity and concentration of those chemicals in relevant environmental matrices. Accredited independent laboratories, universities, national laboratories, and reference laboratories may participate in the development and application of relevant analytical test methods. We welcome the opportunity to discuss this call-in with you and your colleagues.

Health and Safety Code section 57020 sets forth certain "trade secret" provisions. We encourage you to contact us to discuss this call-in, including any written information that you consider "trade secrets."

This letter is a formal information request and manufacturers subject to the statute are required to provide the information in writing to DTSC no later than Tuesday, December 20, 2011. We look forward to working with you in a collaborative and proactive manner. If you have questions or comments, please contact Hamid Saebfar at (818) 717-6530, hsaebfar@dtsc.ca.gov, or Donald Owen at (916) 445-2930, dowen@dtsc.ca.gov.

Sincerely,

Jeffrey Wong, Ph.D.
Chief Scientist

Enclosures (2)

STATE OF CALIFORNIA
Department of Toxic Substances Control

Health and Safety Code Section 57019 Chemical Information Call-in Information
for Nanometals, Nanometal Oxides, and Quantum Dots
December 2010

This enclosure is provided for your convenience. You may provide the requested information in writing, and attaching any supplementary materials or explanatory information, in letter or report form.

SECTION A: CHEMICAL(S) <i>(check each one which applies for your company)</i>		
<input type="checkbox"/> Nano Silver	<input type="checkbox"/> Nano Titanium Dioxide	<input type="checkbox"/> Nano Cerium Oxide
<input type="checkbox"/> Nano Zero Valent Iron	<input type="checkbox"/> Nano Zinc Oxide	<input type="checkbox"/> Quantum Dot(s)

SECTION B: BUSINESS IDENTIFICATION INFORMATION <i>(check one and complete items 1 - 10)</i>				
<input type="checkbox"/> Sole Owner	<input type="checkbox"/> Corporation	<input type="checkbox"/> Limited Liability Company (LLC)	<input type="checkbox"/> Limited Liability Partnership (LLP)	<input type="checkbox"/> Unincorporated Business Trust
<input type="checkbox"/> Spouses' Co-ownership	<input type="checkbox"/> Registered Domestic Partnership	<input type="checkbox"/> General Partnership	<input type="checkbox"/> Limited Partnership	<input type="checkbox"/> Other: <i>(describe)</i>

1. Name of Sole Owner, Corporation, Partnership, Institution, Other.

2. Business Trade Name ("Doing Business As," if any)

3. Business Address (physical location of your business: street number and name, city, state, country, zip or postal code)

4. Mailing Address (street name and number, P.O. box, city, state, country, zip or postal code, if different from 3)

5. Business Website Address(es):

6. Name of Owner, Responsible Corporate Officer, Partner, Other.

7. Contact Information for Person in 6 above.

Name: _____ Title: _____

Business Telephone: _____ Email: _____

8. Number of Employees (California employees).

9. NAICS Code(s) for this business: Primary: _____ Other: _____ Other: _____

10. Nano Chemical Business Type: (check applicable) Manufacturer Importer Researcher

SECTION C: CERTIFICATION (FOR THIS COMPLETE SUBMITTAL)

I am duly authorized to prepare and submit this information, as a formal response to the request pursuant to Health and Safety Code section 57019(d)(1), and certify the information and statements made herein, and in the attachments, are correct to the best of my knowledge and belief.

Name: <i>(type or print)</i>	Signature:	Date:

SECTION D: NANOMATERIAL CHEMICAL AND PHYSICAL PROPERTIES (Attach additional pages as needed)

PRODUCT / PRODUCTION INFORMATION

NANO CHEMICAL NAME: (Use a separate page for each unique chemical.)

COMMERCIAL NAME(S):

ANNUAL PRODUCTION VOLUME:

PRODUCTION METHOD(S):

IDENTIFICATION OF THE SUPPLIER(S):

PARAMETER	VALUE / RANGE ^{1/} (include units)	NAME OF ANALYTICAL METHOD(S) ^{2/}
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PHYSICAL PROPERTIES

SHAPE (MORPHOLOGY)		
DENSITY		
SURFACE AREA		
PARTICLE SIZE DISTRIBUTION	Air	
	Liquid	
	Solid / Powder	
OTHER (Specify)		

CHEMICAL PROPERTIES

CHEMICAL COMPOSITION		
SURFACE MODIFICATION (COATING, FUNCTIONALIZATION)		
PURITY		
SURFACE CHARGE		
DISPERSION ^{3/}	Air	
	Liquid	
	Solid	

IDENTIFYING AND DETERMINING CONCENTRATION OF NANO CHEMICAL, ITS METABOLITES, AND DEGRADATION PRODUCTS IN SPECIFIED MATRICES^{4/}

Water, Air, Soil, Sediment, Sludge, Chemical Waste, Fish, Blood, Adipose Tissue, Urine, Other (specify)

SOLUBILITY	Water Solubility		
	Solubility in Organic Solvent		

N-OCTANOL-WATER PARTITION COEFFICIENT

STABILITY AND REACTIVITY	Flammability		
	Explosiveness		
	Oxidizing Properties		
	Oxidation Reduction Potential		
	Storage Stability and Reactivity (Container Material)		
	Stability to Thermal, Sunlight, and Metal(s)		

Notes for Section D:

Indicate "*Unknown*" if you do not know one of the requested parameters or information items. Indicate "*To Be Developed*" if your company has not yet developed the information. Indicate "*Not Applicable*" only if the specific parameter does not apply for your nano chemical.

1. Specify the *units* (dimensions) for each parameter for which you are reporting values (test results), ranges, and analytical test methods.
2. Specify the *analytical test method(s)* which you currently use for each parameter and report the *value* or *range* for your nano chemical(s). For each method, provide the complete reference (or provide a copy of the complete method): For example, see USEPA 289.2 (1978), ARB Method 310, ASTM E01, OECD 201, as examples of established analytical test methods for chemicals. If you have developed an internal method, or engaged a consultant or external laboratory for a unique or custom test method, provide complete information regarding sample preparation, test protocol(s), limitations, accuracy, precision, bias, required special conditions, resolution limit, applicable matrices, etc. List the consultants, external laboratory personnel, and others with direct knowledge of specialized methods which you have applied for your nano chemical.
3. Describe the extent to which particles agglomerated (i.e., are held together in groups or clusters by attractive inter-particle forces or distribution of particles in the specific system) under "Dispersion."
Specify this parameter for three matrices: air, liquid, and solid.

SECTION E:

Provide a copy of your Globally Harmonized System (GHS) Safety Data Sheet (SDS), if you have prepared one.

SECTION F:

For each nanomaterial you produce or import, describe the analytical test method(s) that you use, or plan to use, to sample, prepare, and analyze a specific matrix to determine the identify and concentration of each specified nanomaterial. Use a separate page to describe the procedure for each, individual matrix, which must include water, air, soil, sediment, sludge, chemical waste, fish, blood, adipose tissue, and urine. Include the information requested in Section D above.

CALIFORNIA CODES
HEALTH AND SAFETY CODE
SECTION 57018-57020

57018. (a) For purposes of Sections 57019 and 57020, the following definitions shall apply:

(1) "Analytical test method" means a procedure used to sample, prepare, and analyze a specific matrix to determine the identity and concentration of a specified chemical and its metabolites and degradation product. An analytical test method shall conform to the standards adopted by the National Environmental Laboratory Accreditation Conference.

(2) "Bioconcentration factor" means the concentration of a chemical in an organism divided by its concentration in a test solution or environment.

(3) "Chemical" has the same meaning as a chemical substance, as defined in Section 2602 of Title 15 of the United States Code.

(4) "Manufacturer" means a person who produces a chemical in this state or who imports a chemical into this state for sale in this state.

(5) "Matrix" includes, but is not limited to, water, air, soil, sediment, sludge, chemical waste, fish, blood, adipose tissue, and urine.

(6) "Octanol-water partition coefficient" means the ratio of the concentration of a chemical in octanol and in water at equilibrium and at a specified temperature.

(7) "State agency" means the State Air Resources Board, the Department of Toxic Substances Control, the Integrated Waste Management Board, the Office of Environmental Health Hazard Assessment, the State Water Resources Control Board, and the California Environmental Protection Agency. "State agency" does not include the Department of Pesticide Regulation.

57019. (a) The California Environmental Protection Agency shall coordinate all requests for information from manufacturers made pursuant to this section on behalf of the state agencies.

(b) In coordinating the requests made pursuant to this section, the California Environmental Protection Agency shall seek to accomplish the following objectives:

(1) Minimize or eliminate duplicate requests for the same or similar information.

(2) Coordinate with manufacturers of the same chemical to develop and submit the requested information in an equitable and resource-efficient manner.

(3) To the extent practicable minimize the cost burden on individual manufacturers.

(4) Maintain a record of requests made pursuant to this section.

(c) A state agency, before requesting any information from a manufacturer pursuant to subdivision (d), shall do all of the following:

(1) Post on its Internet Web site and the Internet Web site of the California Environmental Protection Agency an announcement that it seeks information pursuant to subdivision (d), including the chemical for which it seeks information, the type of information it is seeking, and the reason for seeking the information.

(2) Conduct a search for the information it seeks of all known public sources of information on the chemicals for which an announcement has been posted pursuant to paragraph (1). All known public sources include public and electronically searchable databases maintained by the federal government, state governments, and intergovernmental organizations.

(3) Make reasonable attempts to contact all manufacturers of chemicals listed for which an announcement has been posted pursuant to paragraph (1) to obtain any relevant information that may be held by those manufacturers but is not publicly available.

(4) Make reasonable attempts to consult with all manufacturers of chemicals listed for which an announcement has been posted pursuant to paragraph (1) to determine what additional information, if any, those manufacturers need to develop to assist the state agency in evaluating the fate and transport of those chemicals in the relevant matrices.

(5) Make reasonable attempts to consult with all manufacturers to evaluate the technical feasibility of developing the information requested by the agency.

(d) (1) A state agency may request a manufacturer to provide additional information on a chemical for which an announcement has been posted pursuant to paragraph (1) of subdivision (c).

(2) Upon request of a state agency, the manufacturer, within one year, shall provide the state agency with the additional information requested for the specified chemical.

(3) The information that the state agency requests may include, but is not limited to, any of the following:

(A) An analytical test method for that chemical, or for metabolites and degradation products for that chemical that are biologically relevant in the matrix specified by the state agency.

(B) The octanol-water partition coefficient and bioconcentration factor for humans for that chemical.

(C) Other relevant information on the fate and transport of that chemical in the environment.

(4) The manufacturer responding to a request pursuant to this subdivision shall collaborate and cooperate with the state agency making the request to the extent practicable for the following

purposes:

(A) To ensure that the information being provided meets the needs of the state agency.

(B) To reduce disagreements over the information being provided.

(C) To decrease to the maximum extent possible the effort and resources the state agency must expend to verify and validate the information provided.

(e) The definitions in Section 57018 apply to this section.

(f) This section shall not be construed to limit the authority of a state agency to obtain information pursuant to any other provision of law.

57020. (a) Notwithstanding Section 6254.7 of the Government Code, if a manufacturer believes that information provided to a state agency pursuant to Section 57019 involves the release of a trade secret, the manufacturer shall make the disclosure to the state agency and notify the state agency in writing of that belief. In its written notice, the manufacturer shall identify the portion of the information submitted to the state agency that it believes is a trade secret and provide documentation supporting its conclusion.

(b) Subject to this section, the state agency shall protect from disclosure a trade secret designated as such by the manufacturer, if that trade secret is not a public record.

(c) Upon receipt of a request for the release of information to the public that includes information that the manufacturer has notified the state agency is a trade secret and that is not a public record, the following procedure applies:

(1) The state agency shall notify the manufacturer that disclosed the information to the state agency of the request, in writing by certified mail, return receipt requested.

(2) The state agency shall release the information to the public, but not earlier than 30 days after the date of mailing the notice of the request for information, unless, prior to the expiration of the 30-day period, the manufacturer obtains an action in an appropriate court for a declaratory judgment that the information is subject to protection under this section or for a preliminary injunction prohibiting disclosure of the information to the public and promptly notifies the state agency of that action. In order to prevent the state agency from releasing the information to the public, the manufacturer shall obtain a declaratory judgment or preliminary injunction within 30 days of filing an action for a declaratory judgment or preliminary injunction.

(d) This section does not authorize a manufacturer to refuse to disclose to the state agency information required by Section 57019.

(e) Any information that a court, pursuant to this section, determines is a trade secret and not a public record, or pending final judgment pursuant to subdivision (c), shall not be disclosed by the state agency to anyone, except to an officer or employee of a city or county, the state, or the United States, or to a contractor with a city or county, or the state, and its employees, if, in the opinion of the state agency, disclosure is necessary and required for the satisfactory performance of a contract, for the performance of work, or to protect the health and safety of the employees of the contractor.

(f) The definitions in Section 57018 apply to this section.