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January 20, 2010

Jeff Wong, Ph.D.
Chief Scientist
Department of Toxic Substances Control (DTSC)
1001 I Street
P.O. Box 806
Sacramento, California, 95812-9806

Dear Dr. Wong,

On behalf of Bayer MaterialSciences LLC, we respectfully submit the enclosed response to DTSC's January 22, 2009 information call-in on carbon nanotubes.

We welcome any questions that you may have about this submission.

Sincerely,

Richard Canady, Ph.D.
Senior Advisor

Michael Boucher
Partner

Ann Grimaldi
Partner

Response to California Department of Toxic Substance Control's Information DTSC's Data Call-in on Baytubes

In a January 22, 2009 letter to Bayer MaterialScience LLC (BMS), California's Department of Toxic Substances Control (DTSC) asks the following six questions:

1) *What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what quantities? Who are your major customers?*

2) *What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement, and verification methodologies. Provide full QA/QC protocol.*

3) *What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?*

4) *What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?*

5) *What methods are you using to protect workers in the research, development, and manufacturing environment?*

6) *When released, does your material constitute a hazardous waste under California Health & Safety Code provisions? Are discarded off-spec materials a hazardous waste? Once discarded, are the carbon nanotubes you produce a hazardous waste? What are your waste handling practices for carbon nanotubes?*

Preliminary considerations

BMS offers the following preliminary responses before providing specific responses to DTSC's questions:

- First, many of DTSC's questions already have been addressed in materials that BMS has provided to our customers and that are available to the public. For example, the Baytubes Carbon Nanotubes Safe Handling Guidelines and the Material Safety Data Sheet address several of the questions regarding worker protections, monitoring, and knowledge about safety. These documents are attached.

- DTSC's data call-in authority, Assembly Bill (AB) 289, defines a "manufacturer" subject to reporting under the law as "a person who produces a chemical in this state or who imports a chemical into this state for sale in this state." Cal. Health & Safety Code § 57018(a)(4). BMS manufactures Baytubes in Germany and does not import them into California for sale there. Accordingly, BMS is not a "manufacturer" within the meaning

AB 289. In the interest of establishing a productive dialogue with DTSC and the public about Baytubes, however, BMS is providing a full and timely response to DTSC's January 22, 2009 letter request. The fact and contents of BMS's response are not an admission that BMS is legally subject to the requirements of AB 289 with respect to Baytubes, and BMS reserves the right to challenge the application of AB 289 to the company, if and as appropriate.

- At times, the level of detail required to respond to DTSC's questions is unclear. Therefore, further dialogue with DTSC may be necessary to complete BMS's response. Several of DTSC's questions are general in nature, e.g., ask for examples and expression of knowledge and, apparently, can be answered in general terms without the submission of data. Other DTSC questions seek specific information, such as sampling and analytical methods and measures to protect workers. However, even the responses to such specific questions appear to require a general consideration of broad topics, such as overall industrial hygiene practices and what the measured entity is at various points in time and under different conditions.

  Some questions also appear to require consideration of data sets across many individual companies, for example, for commercial uses and end-of-life disposal of materials. However, the mechanism for BMS's obtaining this information from other companies is not clear to us. In other words, the level of detail and degree of integration across companies that is required to respond fully to DTSC's questions is unclear, and further dialogue with DTSC is needed to clarify its interests.

- We have not included either confidential business information (CBI) or trade secret information in this response, because our interpretation of DTSC's questions does not require such information. However, we do refer to CBI in the response as supporting information. As our dialogue with DTSC progresses, we may provide DTSC access to CBI in a manner that protects it from publication and release to BMS's competitors.

- Response to DTSC's questions also requires decisions about what materials being developed or produced by BMS are subject to the data call-in. DTSC's questions solicit information on "your carbon nanotubes," "your chemical," and "your material," but these terms are not defined by DTSC. Formulating questions in this way is understandable in terms of DTSC's broad, initial information needs, but in some cases, DTSC's approach obscures what information DTSC needs and what its risk management objectives are. In consideration of this need to identify the "response entity," we note that BMS's present responses address only the commercial product "Baytubes." [1]

- Finally, DTSC should not group Baytubes in with other carbon nanotubes (or other nanomaterials) when overall risk management needs are considered. The physical form and quality of carbon nanotubes vary too greatly across manufacturers to permit any broadly based approach to risk perception or risk management.

[1] http://www.baytubes.com/jp/downloads/datasheet_baytubes_c_150_p.pdf ; see also http://www.baytubes.com/news_and_services/faq.html

Baytubes are a specific, pure substance made through a well-controlled, high-volume process at BMS's facility in Germany. The physical form and purity of Baytubes are not like the carbon nanotubes that have been associated with the potential for serious health effects in some animal studies. To the contrary, the form of multiwalled carbon nanotube (MWCNT) in Baytubes has repeatedly been found in studies by BMS and by others to not show harmful effects at levels anticipated to be found in the workplace or environment.

The focus on "carbon nanotubes" in DTSC's questions is a good step away from generalized consideration of, and confusion about, whether "nanomaterials" have risks as a class of materials. However, putting Baytubes into a category including other materials that have been associated with health effects in animal studies is not appropriate. We hope that DTSC's data call-in and the subsequent evaluations and discussions will help DTSC and the public to see that materials produced by nanotechnology must be considered on a case-by-case basis, just as we do with chemicals.

Initial, detailed responses to DTSC's questions

1) ***What is the value chain for your company?***

For example, in what products are your carbon nanotubes used by others?

The market for Baytubes the United States is small but growing. Because of this dynamic situation, a full response to this question requires consideration of the current and near-term applications for the material. Under the United States Environmental Protection Agency's (EPA's) TSCA § 5(e) Consent Order for Baytubes, the permissible uses of Baytubes are limited to the following:[2]

- Up to 10% by weight as filler in thermoplastic polymers for antistatic applications and/or mechanical reinforcement,
- Up to 5% by weight as a filler in metal for mechanical reinforcement, and
- Up to 2% by weight as a filler in thermosetting polymers for antistatic applications and/or mechanical reinforcement.

Baytubes are not be available to the public and are not used in an unbound state in finished products.

Based on initial uses and research and development in materials, BMS envisions the near-term uses of Baytubes to be as follows:

[2] TSCA § 5(e) Consent Order for Baytubes.

Lighter and stronger materials

In combination with special epoxy resins, Baytubes boost the strength and load-bearing capacity of composites used in shipbuilding, automotive applications, and rotor blades of wind power plants.

Less expensive automotive manufacturing

Plastics containing Baytubes used in car body parts, such as fenders, lower automobile production costs by eliminating the conductive primer usually needed for electrostatic coating processes.

Increased energy storage performance for batteries

When added to the graphite layer as a conductivity component, Baytubes stabilize the graphite matrix in lithium ion batteries during the charging/discharging process. Their structure prevents the negative effects of volume changes, resulting in high storage capacities and long battery life.

Safe packaging for sensitive devices

Baytubes are used in conductive and antistatic plastic films and trays to provide low-cost, secure packaging for computer chips and electronic components.

Safer and lighter containers

Until now, 1,000-liter intermediate bulk containers have been the only cost-effective alternative to steel drums for packaging used in explosion-protected zones. New multiwall containers with a conductive outer layer containing Baytubes can save time and money, even where only small volumes are involved.

In what quantities?

The total quantities of Baytubes used in the United States are in the range of one to five (1-5) tons a year, at present. Given the growing demand, any specific statistics on use volumes within a particular product type at this time may be misleading with regard to overall use patterns in the future. However, as a current snapshot, between eighty and ninety percent (80-95%) of the present use of Baytubes is as an additive to plastics in antistatic applications, for example, to protect sensitive electronic equipment or contain flammable liquids. The remaining use of Baytubes is as filler in metals for mechanical reinforcement in lightweight structural components, for example, in aircraft and automobiles.

Who are your major customers?

We can provide the identities of specific BMS customers to DTSC and claim such information as a trade secret. Business relationships have been initiated within the electronics, aerospace, sports equipment, automotive, and energy generation industries (solar and wind power) in the United States. BMS does not have specific information on the use rates for Baytubes by its U.S.

customers, because BMS is only a supplier of Baytubes as a raw material. Furthermore, the use rates are growing daily. So, a full understanding of the customers' products and value chains should consider the growing market for Baytubes.

2) ***What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment?***

Provide a full description of all required sampling, detection, measurement, and verification methodologies.

Provide full QA/QC protocol.

No Baytubes are produced in the United States. Therefore, the responses to this question refer to procedures and methods used at the Baytubes manufacturing facility in Germany.

Safety approach for Baytubes

Before describing detection and measurement methods for monitoring the presence of Baytubes, it is important to place such methods in context of the need for them and their role in managing health risks. Evaluation of the potential for release is an essential step in the overall planning of safety and risk management. The kind of sampling and monitoring that is selected for risk management is based on the potential for release and the potential routes of exposure. Therefore, a response to this question about sampling and detection methods should begin with a description of the physical characteristics of Baytubes that affect any release during their manufacture and distribution.

Furthermore, BMS is handling Baytubes with care to protect workers, even though the toxicity and exposure studies that BMS has conducted for Baytubes have not shown evidence of any human health risk at the very low theoretical exposure levels that might occur. BMS has well-developed worker protection and monitoring procedures, both as a general practice and specifically for Baytubes. The BMS procedures to ensure occupational and environmental safety during the manufacture of Baytubes begin with a commitment to Responsible Care and Sustainable Development.[3]

BMS was one of the first companies to complete and submit a TSCA § 5 pre-manufacturer notice (PMN) to EPA for a multiwalled carbon nanotube. BMS is a world leader in product safety and stewardship across all materials produced, and BMS complies fully with worker safety and environmental protection standards in Germany, where all Baytubes are produced.

BMS also is a founder and leader of research consortia that seek to improve monitoring and safety data for all types of carbon nanotubes, so that they can be developed safely and

[3] http://www.bayer.com/en/Responsible-Care.aspx; http://www.bayer.com/en/Sustainability-and-Commitment.aspx

consistently across all manufacturers and so that continuous improvements in safety and monitoring will occur.[4]

Physical characteristics of Baytubes

Baytubes are solid pellets of agglomerated material that look like grains of sand. The pellets range in size between a tenth of a millimeter and one millimeter (0.1-1.0 mm) in diameter.

Figure 1
Naked eye view of Baytubes

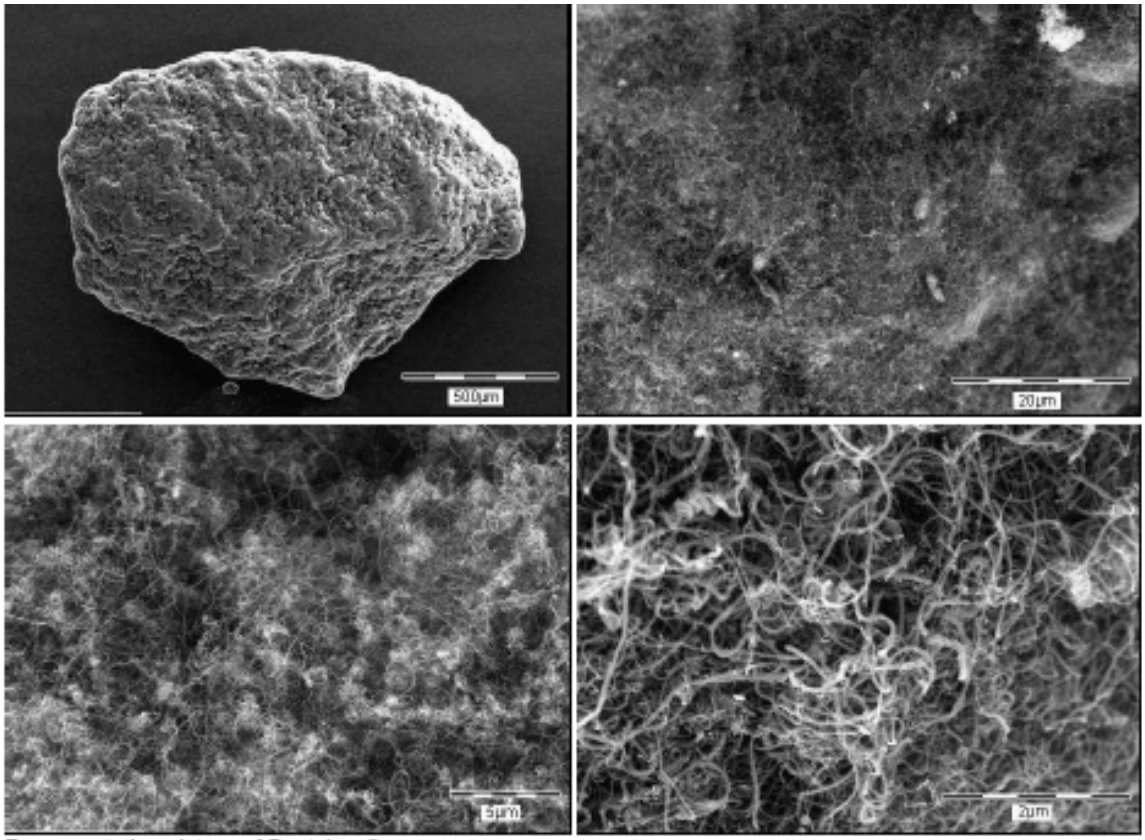
The process that BMS uses to produce Baytubes consistently produces a specific variety of MWCNT. Many important characteristics of "carbon nanotubes," such as thickness, length, and surface characteristics, vary substantially from one manufacturing process to the next. Furthermore, research has shown that such characteristics affect toxicity. Accordingly, risk management approaches should consider such characteristics in sampling and monitoring approaches, and in evaluating the potential for adverse health effects. Furthermore, secondary effects of the physical characteristics of the material, such as the relative tendency to agglomerate into tangled masses of fibers, also should be considered, as they affect transport in the environment and bioavailability. In short, it is essential that monitoring methods and results for a particular process and MWCNT not be used to judge a different process or MWCNT.

For example, the study of Poland et al. 2008 compared the toxic responses of thin and shorter MWCNTs to thicker and longer MWCNTs.[5] The thin and short fibers were described as forming "tightly packed spherical agglomerates" and "tangled agglomerates," and the thicker fibers were described as forming "dispersed bundles and singlets" or "regular bundles and ropes." The toxic effects noted by Poland et al. 2008 were caused by the thick and longer MWCNTs. This finding was expected by the authors, based on the extensive scientific understanding of the toxicity of

[4] http://www.cnt-initiative.de/en/

[5] Poland et al. (2008). Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study. *Nature Nanotechnology*, *3*, 423-428.

fibers and the effect on toxicity of their thickness and rigid length within a certain size range.[6] Toxicity also has been observed for these thicker and longer MWCNTs in other recent studies.[7] The MWCNTs that did not show toxic effect in the Poland et al. 2008 study were the ones described as "tangled agglomerates." The term "tangled agglomerates" accurately describes the form that Baytubes take.



Representative picture of Baytubes®

Figure 2
Four views of Baytubes "tangled agglomerate" under electron microscope
(magnification increases from top left to bottom right view)

[6] *See also* Donaldson et al. 2006 for a review of characteristics that may contribute to variation in toxicity across different MWCNT types. Donaldson et al. (2006). Carbon Nanotubes: A Review of Their Properties in Relation to Pulmonary Toxicology and Workplace Safety. *Toxicological Sciences, 92*(1), 5-22.

[7] Sakamoto et al. (2009). Induction of mesothelioma by a single intrascrotal administration of multi-wall carbon nanotube in intact male Fischer 344 rats. *The Journal of Toxicological Sciences, 34*(1), 65-76.

Takagi et al. (2008). Induction of mesothelioma in p53+/- mouse by intraperitoneal application of multi-wall carbon nanotube. *The Journal of Toxicological Sciences, 33*(1), 105-116.

Liu et al. (2008). Toxicological effects of multi-wall carbon nanotubes in rats. *Journal of Nanoparticle Research, 10*, 1303-1307.

However, adverse effects also have been shown recently for very high-dose exposures to thin and flexible MWCNT fibers that form such agglomerates.[8] And a similarly conducted, very high-dose study of Baytubes demonstrated adverse effects associated with simple overloading of the lung's clearance capacity.[9] These studies found effects at levels of exposure many orders of magnitude above what is likely to occur under any conceivable workplace scenario. However, the studies also provide a basis for determining a concentration or particle number reference point on which detection and measurement methods, and their quality assurance ("QA")/quality control ("QC") procedures, should be evaluated.

Because Baytubes are an aggregation of long, thin fibers of high purity, Baytubes have a low inherent dustiness.[10] There is very little material that is in the form of free MWCNTs, other than when the material is dispersed just prior to incorporation in a matrix. The agglomerated/tangled state and low inherent dustiness of Baytubes inform the need for monitoring and the expectations of what one would find in such monitoring at manufacturing facilities. For example, the 100 micron- to millimeter-sized particles are not expected to present inhalation exposure risks, and measurements of air in the vicinity of manufacturing and use of the material are not likely to demonstrate the presence of Baytubes. This does not mean that workplace monitoring is unnecessary, only that one should not be surprised if and when monitoring of workplace air fails to detect carbon nanotubes.

Detection and measurement methods also should consider impurities, and Baytubes are greater than ninety-five percent (>95%) pure MWCNT.[11]

A conclusion that Baytubes present a low likelihood of release also is supported by the form in which Baytubes are shipped and the need for further processing steps in order to use them to make finished products. The entangled mass of high-purity carbon nanotube material created by BMS's manufacturing process requires further processing by customers in order to make "dispersions" of separated Baytubes in liquids to mix with other materials. These dispersions of Baytubes are then added to liquid polymers or metals in controlled and proprietary processes by BMS's customers, in order to impart the desired structural, heat-transfer, and electrical properties to the metals and plastics in which they are embedded.

[8] Ma-Hock et al. (2009). *Inhalation Toxicity of Multiwall Carbon Nanotubes in Rats Exposed for 3 Months*. *Toxicological Sciences*, *112*(2), 468-481.

[9] Pauluhn, J. (2010). Subchronic 13-week Inhalation Exposure of Rats to Multiwalled Carbon Nanotubes: Toxic Effects are determined by Density of Agglomerate Structures, not fibrillar Structures. *Toxicological Sciences*, *113*(*1*), 226–242.

[10] Standard method EN 15101 method B (http://webstore.ansi.org/RecordDetail.aspx?sku=DIN+EN+15051%3A2006) simulates conditions of continuous falling operations (conveying, discharging, filling, refilling, weighing, sacking, metering, loading, etc). Using this analysis method the dustiness of Baytubes is on the low end of the range for the "low" category of EN 15101.

[11] Bayer MaterialScience LLC. (2008). Baytubes® C 150P: Agglomerate of multi-wall carbon nanotubes. Product Information.

The expectation that free Baytubes are unlikely to be generated under normal, controlled conditions of use also is important to interpreting inhalation toxicity studies based on artificially generated, smaller particle sizes of Baytubes. Generation of unbound and respirable material for inhalation toxicity studies requires processing Baytubes in ways that are not normally done at BMS's facilities during the manufacture or shipping of Baytubes or, to BMS's knowledge, at its customers' facilities during the use of Baytubes. Such data should be considered in context of its application to real-world exposure scenarios.

Also un-embedded Baytubes are not available to consumers. Baytubes are used as additives incorporated in solid materials, such as plastics and metals. Baytubes typically are added to these materials in a closed process at controlled manufacturing facilities, followed by curing of the material to a solid matrix, which embeds the Baytubes. Therefore, direct human exposure to Baytubes as a raw material is not expected. Furthermore, the Baytubes fibers within finished plastics and metals are relatively large particles compared to standard chemicals and would not leak or leach as chemicals would.

Monitoring approach

Consideration of the physical properties of Baytubes leads to expected release rates well below levels that could potentially create a human health concern, and this expectation has been confirmed by release and environmental monitoring studies conducted under multiple conditions and using a variety of sampling techniques.[12] The confirmed release rates are well below levels presenting potential health concerns[13] and allow a confirmatory approach to monitoring rather than a continuous sampling approach. It is neither feasible nor necessary, for example, to perform continuous air filtration and exhaustive electron microscopic analysis of filtrate in order to demonstrate an insignificant presence of free Baytubes in the workplace. Sampling using trace analysis of materials known to be in Baytubes and normal workplace dust sampling, supplemented with periodic analysis using more specific methods like electron microscopy, can be used to provide a protective understanding of the likelihoods of occupational exposure.

Sampling methods and QA/QC

BMS has used a range of sampling methods to understand the potential for releases and workplace exposures, including methods that use the following:

[12] BMS can make these studies available to DTSC as "trade secret" information, if they are not otherwise available to the public, for example, reportable to EPA under the TSCA § 5(e) Consent Order for Baytubes or as substantial risk information under TSCA § 8(e) and, thereafter, available to the public under TSCA § 14 as a "health and safety" study. Alternatively, or in addition, BMS can make the studies available to DTSC in an on-line, read-only "reading room."

[13] BMS has determined a safe occupational exposure limit (OEL) of 0.05 milligrams of Baytubes per cubic meter of inhaled air. http://www.baytubes.com/news_and_services/news_091126_oel.html. Derivation of the OEL can be found in: Pauluhn, J., Multi-walled Carbon Nanotubes (Baytubes®): Approach for Derivation of Occupational Exposure Limit, Regulatory Toxicology and Pharmacology (2010), doi: 10.1016/j.yrtph.2009.12.012 http://dx.doi.org/10.1016/j.yrtph.2009.12.012

- Simple portable dust monitors
- Scanning mobility particle sizers
- Nanometer aerosamplers
- Transmission electron microscopy
- X-ray electron spectroscopy
- Trace elemental analysis for cobalt catalyst that remains in the finished product (e.g., inductive coupled plasma-optical emission spectroscopy)
- "Dustiness" measures (EN 15051 method B)[14]

Sampling and analysis have been done for a variety of sampling locations and conditions to determine whether particles are released during manufacture, the nature of the released material, and whether free carbon nanotubes are detectable. BMS can describe each method that has been used in product stewardship practices to assist DTSC's review of this submission. However, considering the low likelihood of release, uncertainty regarding what the measured entity of interest is for DTSC, and the fact that Baytubes are not manufactured in the United States, BMS would like to discuss DTSC's objectives in requesting information about sampling and monitoring of Baytubes and obtain further guidance on answering this question.

For example, the combined results of a range of methods, from dust monitoring to electron microscopic analysis and trace cobalt analysis, are necessary to determine the overall exposure potential for MWCNTs that may be released from the manufacture and use of Baytubes. Furthermore, the results of these tests and the physical properties of Baytubes consistently demonstrate a low potential for exposure to free carbon nanotubes from Baytubes.

To address the present question from DTSC it would be helpful to know whether carbon nanotubes are detectable using electron microscopic analysis in periodic air samples during production. To answer this question, BMS has evaluated material collected in air samples using transmission electron microscopy. At this point in our understanding of DTSC's request, and considering the known properties of Baytubes, this method would seem to be the most direct way to answer this second question from DTSC.

However, on the basis of the combined analyses of dust levels and electron micrographic evaluation of filtration samples, BMS has determined that routine electron microscopy is not necessary to demonstrate continued lack of presence of the material at levels that would approach those of potential concern to health. Instead, a routine analysis of cobalt levels is instead used to monitor and ensure that levels are well below those that could potentially be of concern to human health. [15]

[14] http://webstore.ansi.org/RecordDetail.aspx?sku=DIN+EN+15051%3A2006

[15] See "Method for the measurement of Baytubes in the air" in the reference list provided.

3) *What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?*

BMS's present knowledge about current or projected presence of Baytubes in the environment is derived from a weight-of-evidence evaluation derived primarily from the following sources:

- Workplace controls that limit releases from the Baytubes manufacturing facility in Germany.
- Measurements of air during manufacture, which show very low potential for release of material that could be characterized as Baytubes.
- Consideration of the physical properties of Baytubes, which cause them to form large, immobile aggregates. These properties also would tend to cause Baytubes to precipitate out of air or water, if released. Therefore, Baytubes are likely to stay in the immediate vicinity of any release that does occur and "clump" into aggregates, which do not enter the air or lungs and do not easily pass through the skin or gut.
- The limited use of Baytubes as a filler embedded in plastics and metals. We understand that these metals and plastics would not release quantities of unbound Baytubes that would come close to levels of public health consequence.
- Current use restrictions that further limit the distribution of Baytubes, so that, generally speaking, the materials Baytubes are mixed into are limited in variety, are well understood, and are not likely to contribute to releases.

A. Workplace controls limit release

In an effort to control releases and manage potential risks for Baytubes, BMS has done the following:

- Adopted and implemented the Global Charter Responsible Care and Sustainable Development.[16]
- Developed Safe Handling Guidelines and Material Safety Data Sheets[17] specific to Baytubes.
- Worked with industry to develop a Code of Conduct for Nanotubes.[18]

[16] http://www.bayer.com/en/Responsible-Care.aspx; http://www.bayer.com/en/Sustainability-and-Commitment.aspx

[17] Material Safety Data Sheet for BAYTUBES C 150 P; and Baytubes Carbon Nanotubes Safe Handling Guidelines

[18] http://www.cefic.org/Files/Downloads/PACTE_Code%20of%20conduct.pdf

BMS's overall goal is to ensure the highest level of industrial hygiene and product stewardship for Baytubes. Workplace controls for the manufacture and handling of Baytubes in Germany include standard practices of ventilation and air filtration, wet wiping, and incineration of wastes containing Baytubes.

B. Measurements show low potential for release

Measurements made during manufacture and anticipated uses of Baytubes embedded in plastic matrices show that release rates of free Baytubes are very low under current and anticipated use scenarios. In fact, amounts of Baytubes are below the limits of detection for the advanced and sensitive methods that BMS has used. This inability to detect Baytubes under the conditions of manufacture and compounding of the material into polymer matrices is not unexpected, based on the physical characteristics of Baytubes.

For example, to examine the potential for release, BMS conducted transmission electron microscopic (TEM) analysis of filtered material taken from air collected in the BMS work environment. The sampling was done using two collection methods (a dust sampler and a nanometer aerosampler) over an extended period of time during manufacture of Baytubes in Germany. These are the most direct measures of the release of what could be termed "your material" related to Baytubes. BMS also performed simple measures of dust in the nanoscale range. Based on these measures, the nanoscale particle number (any kind of nanoscale particle, including normal dust in the work environment) was extremely low, and BMS detected no carbon nanotubes. This sampling and analysis demonstrated a low release potential.

This low release potential for Baytubes is corroborated by sampling of work areas for the cobalt catalyst used in production of Baytubes. A small amount of the cobalt remains in finished Baytubes. Therefore, if Baytubes are released, then the cobalt should be detected. This approach provides a very sensitive method to determine the possible presence of Baytubes, because modern analytic techniques allow extremely low detection levels for cobalt. Based on the level of cobalt in finished Baytubes and the air sampling rate, the maximum concentration of Baytubes would have been less than 1.2 micrograms per cubic meter under the specific conditions sampled in the workplace that was evaluated by BMS in Germany. These combined measurements, from dust measurement to TEM and cobalt trace analysis, corroborate the expectation from Baytubes' physical properties that release rates would be very low for free Baytubes during their manufacture and use.

C. Physical properties of Baytubes limit release and migration in the environment

Baytubes emerge from the manufacturing process as pellets of solid material that range in size from approximately one tenth of a millimeter to one millimeter (0.1-1.0 mm) in diameter. The Baytubes within these pellets are thin, long, and flexible compared to other carbon nanotubes, and the tubes themselves are very strong and difficult to break apart. These properties cause the Baytubes to naturally form strong, dust-free aggregates that tend to remain as aggregates. As a consequence, there is very little material that is in the form of free nanotubes and that might be conveyed by air or dust transport away from the places where, or the materials in which,

Baytubes are used.[19] Unlike chemicals that can evaporate or leach from the bulk forms (such as leaking drums of materials), Baytubes will tend to stay where they are. Therefore, there is a low likelihood of release to the environment from Baytubes, as imported into the United States and distributed by BMS.

D. The uses of Baytubes restrict their presence in the environment

The entangled mass of the high-purity material created by BMS's manufacturing process requires further processing by customers in order to put it into a form that can mix with the plastics or metals of final products. These "dispersions" of Baytubes created by BMS's customers are added to liquid polymers or metals in order to impart the desired structural, heat-transfer, and electrical properties to the metals and plastics in which they are embedded.

BMS provides Baytubes to manufacturers in sealed drums. Baytubes are then added from the drums to mixing and compounding equipment via a funnel typically situated under a ventilation duct. As a condition of the customer's purchase of Baytubes from BMS,[20] the technician adding Baytubes to the compounding equipment would wear suitable personal protection equipment, as recommended in the material safety data sheet (MSDS), safe-handling guidelines, and TSCA § 5(e) consent order for Baytubes..

For the thermoplastic application, the compounding process is mechanical and takes place in closed equipment. Baytubes are dispersed into the polymer matrix and encapsulated. Further processing steps for this application may involve molding into an article. Typical end uses for the thermoplastic applications of Baytubes include use as an antistatic agent in packaging, housings, and automotive components.

For the thermosetting application, Baytubes are typically dispersed into low- to medium-viscosity resins. Typical dispersion methods include stirring, jet dispersion, and ultrasound treatment. The Baytubes are dispersed into the polymer matrix and encapsulated. To the best of our knowledge, the thermosetting application does not include roll-coat or dipping methods, and further processing may involve the manufacture of pre-pregs and curing of the pre-pregs into articles. Typical end uses for the thermosetting application of Baytubes include use as an antistatic agent in adhesives, coatings, and other composites.

For the metal processing application, aluminum and magnesium are typically used. Due to the chemical reactivity of these metals, processing usually takes place in a gas-tight system. Typical end uses for the metal application of Baytubes include use as a filling agent for mechanical reinforcement in aeronautic and automotive components. Further details on customers' processing of metals are not available due to the proprietary nature of this information.

[19] Standard method EN 15101 method B simulates conditions of continuous falling operations (conveying, discharging, filling, refilling, weighing, sacking, metering, loading, etc). Using this analysis method the dustiness of Baytubes is on the low end of the range for the "low" category of EN 15101.

[20] The TSCA § 5(e) Consent Order for Baytubes specifies that BMS may only sell to "a person who has agreed in writing" to "[c]omply with the same requirements and restrictions required of" BMS for worker protection.

In all end-use applications, Baytubes are encapsulated in the matrix medium. The matrix containing Baytubes is ultimately incorporated into articles or finished products. Thus, the potential for exposure to Baytubes in end-use applications is extremely low.

E. Use provisions for Baytubes restrict their distribution

Baytubes are not be available to the public and are not used in an unbound state in finished products. Furthermore, the TSCA § 5(e) Consent Order for Baytubes provides that Baytubes can only be sold to users who agree that they will use it solely as filler in plastics or metals. Specifically, users must agree in writing to not use Baytubes "other than in industrial settings" and in the following concentrations:

- Up to 10% by weight as filler in thermoplastic polymers for antistatic applications and/or mechanical reinforcement,
- Up to 5% by weight as a filler in metal for mechanical reinforcement, and
- Up to 2% by weight as a filler in thermosetting polymers for antistatic applications and/or mechanical reinforcement.

These uses of Baytubes as embedded in a matrix of plastic or metal make it unlikely that free nanotubes will be released into, or found in, the environment.

4) *What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?*

In the context of predictive risk management for products that are beginning to be used in commercial products, "knowledge about the safety" of a material is determined by evaluating hazard and exposure information during manufacture and anticipated uses. BMS has addressed both the hazard and exposure components for Baytubes in studies prior to marketing.[21] The studies and exposure data that BMS has generated have been reviewed and evaluated with respect to occupational safety, public health, and the environment by EPA and German federal regulatory authorities. Based on such evaluations, BMS has received authorizations that allow the manufacture, processing, distribution, and use of Baytubes in Germany and the importation, processing, distribution, and use of Baytubes in the United States.

EPA evaluation of safety data for Baytubes

EPA evaluated the toxicity testing and exposure data that BMS provided for Baytubes, also considered the available safety data from the available scientific literature for materials similar to Baytubes, and has authorized the import, distribution, processing, and use of Baytubes under conditions set forth in a TSCA § 5(e) Consent Order for Baytubes. EPA concluded that there is a low potential for exposure of the general public to Baytubes and, consequently, a low risk to the general public from Baytubes:

[21] *See supra* note 12. Many of the studies are briefly described in the Baytubes Carbon Nanotubes Safe Handling Guidelines.

> *Risk to General Public: A qualitative evaluation of estimated releases indicates that there is relatively low potential for exposure to the general population and the environment from water or landfill releases [Baytubes] due to its very low water solubility and vapor pressure, as well as use in pellet form as an entrained substance. Exposures to the general population and the environment from incineration might be problematic, but at this time such exposures cannot be quantified.*[22]

Based primarily on consideration of information from studies of other MWCNTs, and of uncertainty in the database for carbon nanotubes, EPA also concluded that there may be health risks, if high exposures to Baytubes were to occur in the workplace and, so, concluded that protective measures for workers were required. BMS has measured release rates of Baytubes under a variety of manufacturing and compounding settings, however, and found that release rates were below detection. Furthermore, the detection limits were well below any adverse effects noted in toxicity studies of Baytubes. Nonetheless, EPA concluded as follows:

> *Risk to Workers: Based on the expected occupational exposures to respirable particles of [Baytubes] and the hazards identified in the toxicological review, EPA concludes the [Baytubes] may present a risk. To mitigate this risk, use of respiratory protective equipment with an APF of 50 is required. Further, in order to more accurately quantify occupational inhalation risks, development of definitive particle-size distribution data across the range of processing and use operations is required.*[23]

EPA has specified that gloves, protective clothing, and respirators must be used by any BMS workers in the United States who import, process, or use Baytubes. In addition, every U.S. customer of Baytubes must agree to the same worker protection measures. This cautionary approach provides added safety to the overall handling and use of Baytubes. If customers do not comply with the required worker protection measures, BMS must stop supplying them Baytubes and also may be required to notify EPA.

Based on uncertainty regarding whether health effects may occur for some carbon nanotubes, and despite the low potential for exposure to Baytubes, EPA also required BMS to conduct a 90-day inhalation study of Baytubes in the rat . BMS understands that EPA has required the same kind of inhalation study for all manufacturers and importers that have submitted PMNs for carbon nanotubes. Therefore, EPA's assessment has not identified Baytubes as having a differential risk across the wide variety of types of MWCNTs that can be made. Rather, by requiring a 90-day inhalation study of all PMN submissions for carbon nanotubes, EPA is showing a general degree of caution. This caution is understandable, given the findings in the

[22] Quoted from the TSCA § 5(e) Consent Order for Baytubes. If needed, the Consent Order for Baytubes can be made available to DTSC in a manner that does not disclose any information previously claimed by BMS as "confidential business information" under TSCA.

[23] *Id.*

literature for health effects of some very specific forms of carbon nanotubes and the general consideration that some fibers can cause overloading of the lung's ability to clear itself, if sufficient quantities are inhaled.

For example, as noted previously in this response, thicker and longer MWCNTs were shown to cause cancer-like health effects in rats under artificial exposure conditions in the preliminary results of Poland *et al* 2008.[24] However, thinner and shorter MWCNT did not show adverse health effects in that same study. Thinner and shorter MWCNT also did not show cancer effects in a two-year bioassay.[25] Baytubes have characteristics like the fibers not found to cause cancer (thin fibers forming tangled aggregates), suggesting a low likelihood of risk given our current understanding of both hazard and exposure. BMS's own exposure and toxicity studies have confirmed a low likelihood of risk.[26]

However, studies of some thinner MWCNTs have shown potential for other effects. Therefore, more information is needed before broad generalizations about the biological interactions of MWCNTs are understood well enough to make risk management decisions without individual studies of toxicity.[27] At this time, a generalized model for risk management of MWCNTs cannot be generated. In lieu of such a generalized model, it is essential to generate information specific to each MWCNT.

For example, results from the 90-day inhalation study of Baytubes in rats indicate a very low likelihood of effects at the low levels that might be encountered in BMS's German manufacturing facility or in facilities within the United States that compound Baytubes into plastics and metals intended for specific commercial applications.[28] As expected, BMS's subchronic inhalation study showed that it is possible to overload the lungs with very large inhaled amounts of Baytubes. The large amount of Baytubes in air required to overload the rat lungs would not exist even in the most extreme workplace conditions; however, the ability to create and study the health effects of high artificial air concentrations allows BMS to more confidently rule out the possibility of health effects at low concentrations of Baytubes. With this

[24] Poland et al. (2008). Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study. *Nature Nanotechnology, 3*, 423-428.

[25] Muller et al. (2009). Absence of Carcinogenic Response to Multiwall Carbon Nanotubes in a 2-Year Bioassay in the Peritoneal Cavity of the Rat *Toxicological Sciences, 110(2), 442–448 (2009)*

[26] *See supra* note 12. Many of the studies are briefly described in the Baytubes Carbon Nanotubes Safe Handling Guidelines.

[27] Liu et al. (2008). Toxicological effects of multi-wall carbon nanotubes in rats. *Journal of Nanoparticle Research, 10*, 1303-1307.; Ma Hock et al. (2009). *Inhalation Toxicity of Multiwall Carbon Nanotubes in Rats Exposed for 3 Months*. *Toxicological Sciences, 112*(2), 468-481.; Mitchell et al. 2007. Pulmonary and Systemic Immune Response to Inhaled Multiwalled Carbon Nanotubes *Toxicological Sciences 100(1),* 203–214 (2007)

[28] Pauluhn, J. (2010). Subchronic 13-week Inhalation Exposure of Rats to Multiwalled Carbon Nanotubes: Toxic Effects are determined by Density of Agglomerate Structures, not fibrillar Structures. *Toxicological Sciences, 113*(*1*), 226–242.

specific knowledge, it is possible to make risk management decisions that confidently protect human health.

Exposure consideration

As stated elsewhere in this response, evaluation of safety requires consideration of both the potential for toxic effects and the potential for exposure. A low likelihood of release or presence in the environment derives from workplace controls, the physical characteristics of Baytubes, the uses of Baytubes in solid matrices, and the use-restrictions for Baytubes.

BMS is continuing to study Baytubes, to further describe biological and environmental interactions and to describe environmental presence. For example, BMS is conducting research through the Inno.CNT public-private partnership in Germany.[29]

5) ***What methods are you using to protect workers in the research, development, and manufacturing environment?***

The methods used to protect workers at BMS begin with general stewardship and industrial hygiene practices and extend through the specific research that BMS has conducted on the safety of Baytubes. For example, BMS is committed to the Global Charter Responsible Care and Sustainable Development,[30] which lays the framework for overall attention to safety in the development and manufacture of all materials produced by BMS. BMS also provides health monitoring and worker protection measures as a general practice, regardless of the materials to which workers are exposed. Also, as a matter of standard practice, BMS has developed Safe Handling Guidelines and MSDSs specific to Baytubes.[31] In addition, BMS has developed an occupational exposure limit for Baytubes based on health effects research conducted for BMS. Furthermore, BMS has worked with other members of industry to develop a Code of Conduct for Nanotubes, which addresses worker safety.[32]

BMS has also evaluated the exposure and hazard properties of Baytubes through specific studies and, based on the understanding of such studies, has evaluated the need for worker protection and implemented appropriate worker protection measures. BMS's evaluation of the safety of Baytubes is consistent with the evaluations by the German authorities and EPA in reviewing the same data set.

The protections provided to BMS's workers include the following:

- Standard practices of ventilation and dust control and overall industrial hygiene in consideration of the potential for exposure to any material that BMS produces.

[29] http://www.inno-cnt.de/de/backgrounder_carbosafe.php

[30] http://www.bayer.com/en/Responsible-Care.aspx; http://www.bayer.com/en/Sustainability-and-Commitment.aspx

[31] Material Safety Data Sheet for BAYTUBES C 150 P; and Safe Handling Guidelines for Baytubes.

[32] http://www.cefic.org/Files/Downloads/PACTE_Code%20of%20conduct.pdf

- Specific worker protections of gloves and protective clothing that are demonstrated to be impermeable to Baytubes using criteria specified in the TSCA § 5(e) Consent Order for Baytubes, and respirators with an Assigned Protection Factor[33] of 50. In addition, companies in United States that purchase Baytubes must agree to these same worker protections as a condition of sale.

6) ***When released, does your material constitute a hazardous waste under California Health & Safety Code provisions?***

Based on review of the available information, we believe that Baytubes do not constitute a "hazardous waste" under and within the meaning of California's Health and Safety Code. However, we would like to discuss the aquatic toxicity data requirement with DTSC to better understand the implications of the insolubility of Baytubes on the interpretation of the concentration limit (500 mg/L) in the California Code provisions defining "hazardous waste." No toxic effects have been observed in tests of Baytubes on fish up to concentrations of 100 mg/L, a concentration that can be reached only by using ultra-sonication of Baytubes in water.

Are discarded off-spec materials a hazardous waste?

Baytubes are not produced in the United States and, so, no off-spec material would be generated or disposed of in the United States.

BMS would like to discuss with DTSC what "off-spec" means in this question, and the methods that might be used to test "off-spec" materials. If something is "off-spec," then it could be any material that is not "in-spec," and something with such broad defining characteristics would be difficult, if not impossible, to test accurately for regulatory purposes.

Notwithstanding the foregoing discussion, BMS's manufacturing process for Baytubes is highly controlled and predictable. Therefore, any "off-spec" material is typically very close in composition and physical characteristics to the "in-spec" material. Therefore, the "in-spec" material is the most reliable surrogate to understand the "off-spec" material, and, as stated previously, "in-spec" Baytubes would not constitute a "hazardous waste" under California's Health and Safety Code.

Once discarded, are the carbon nanotubes you produce a hazardous waste?

We do not anticipate any transformation of Baytubes that would constitute a "hazardous waste" within the meaning of California's Health and Safety Code.

What are your waste handling practices for carbon nanotubes?

Waste containing Baytubes is disposed of by a licensed hazardous waste disposal company, which incinerates the waste. Baytube waste is collected and segregated for disposal according to the specified approved waste profile on file with the approved disposal company.

[33] http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=18846