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February 16, 2010

RE: Chemical Information Call-In: Carbon Nanotube use at Nanomix

Dear Dr. Wong,

The information below is being provided in response to the Chemical Information Call-In dated January 22, 2009.

- *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?*

Nanomix is currently developing a sensing platform for the detection of medically relevant biomarkers. The sensors use carbon nanotubes to enhance the performance of the sensors. The program is in the early phases of research and proof of concept demonstrations. We work with partner companies to develop sensors that will ultimately go into medical devices. The products will be distributed in conjunction with the development partners. The CNT functionalized sensors will be embedded within self-contained cartridge. A biological sample will be applied to the cartridge for a single use test. Once the test is complete the CNT sensor, along with the biological sample, remains contained within the cartridge. The cartridge will be disposed of by the end user, thus entering a traditional biomedical waste stream.

**The identity of the partners, development status, and the details of particular diagnostic tests being developed for our partners are confidential and proprietary.**

In terms of the raw materials that go into our devices we have obtained CNTs from a variety of vendors over the life of the company.

- MER Corporation
- Carbon Nanotechnology Inc-acquired by Unidym
- NanoLab
- Nanostructured and Amorphous Materials
- Carbon Solutions Inc
- SES Research
- Helix Material Solutions
- Nanothinx
- Nano TechLabs
- Cheap Tubes
- Nanocyl
- Bucky USA

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- *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.*

The answer to this question is in the context of how carbon nanotubes (CNTs) are used at Nanomix. At Nanomix we use CNTs in suspension form for functionalizing our devices. We use very small quantities of CNTs (microgram to milligram range). The powder form of CNTs is kept in the original container received from the manufacturer and sealed. All the suspensions of CNTs are made and stored in a fume hood. Devices with CNTs are stored and transported in a zip lock bag. After use devices functionalized with CNTs are discarded as solid waste via a licensed hazardous waste pick up, transportation and disposal company. Electrical and electrochemical data have shown the CNTs are stable on the devices. In the light of the above information there is less likelihood of the presence of CNTs in the work place.

Appropriate engineering controls, workplace safety practices and proper personnel protective equipment (PPE) are used to further minimize exposure to any CNTs. CNTs are prevented from being air borne by stable attachment to solid surfaces. The exact process is a trade secret. This minimizes the chance of exposure through inhalation. The risk of skin contact, ingestion, eye contact is minimized by engineering controls, proper training and use of PPE including gloves, lab coats, and safety glasses.

To the best of our knowledge, there is a lack of consensus in scientific literature and among government agencies about the most reliable method of monitoring the quantity of CNTs in air. In the absence of this information we take the steps mentioned above to protect the workplace and the environment.

- *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?*

The application of CNTs on our devices uses very small quantities of CNTs. We have used less than 10g of CNTs over the life of the company (10 years). As mentioned previously, CNTs are very stable on our devices and do not come off. The CNTs we use are applied to sensors within prototype medical devices. Currently, all the CNTs manufactured and bought are used inside the company and do not leave the facility. Ultimately the devices will be used at partner facilities. In either case the devices are treated as biomedical/hazardous materials waste. After any external evaluation the devices would be returned to Nanomix for disposal. All the CNT waste is segregated. For end of life disposal we use a hazardous waste handling company with treatment, storage, disposal facility (TSDF). The deposition of CNTs on our devices takes place in a clean room environment. Use of sticky mats, disposable lab coats, gloves, and shoe covers ensure the containment of CNTs within the facility.

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

Based on the fact that we use very small amounts of CNTs, we implement personnel training, safety practices, engineering and administrative controls, safe handling and disposal by a licensed hazardous waste handling company, we believe our employees are protected from exposure to CNTs and that the CNTs are not released in an unsafe manner to the environment.

Our knowledge about the effects of CNTs to the environment and different life forms is based on published scientific literature.

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

All new employees undergo initial safety training, a supervisor recommended lab training and an annual training. Minimizing the amount of CNTs used, minimizing CNT waste, following specific SOPs for handling CNTs in solid and liquid forms is practiced. In theory workers can get exposed to CNTs in solid or suspension form via inhalation, eye or skin contact and ingestion. We employ the following methods to protect workers for CNT exposure. Some relevant information from the answer to the first question is pasted here:

The powder form of CNTs is kept in the original container received from the manufacturer and sealed with parafilm. All the suspensions of CNTs are made and stored in a fume hood. Devices with CNTs are stored and transported in a zip lock bag. After use devices functionalized with CNTs are discarded as solid waste via a licensed hazardous waste pick up, transportation and disposal company. Electrical and electrochemical data has shown the CNTs are stable on the devices. In the light of the above information there is less likelihood of the presence of CNTs in the work place.

Appropriate engineering controls, workplace safety practices and proper personnel protective equipment (PPE) are used to further minimize exposure to any CNTs. CNTs are prevented from being air borne by stable attachment to solid surfaces. The exact process is a trade secret. This minimizes the chance of exposure through inhalation. The risk of skin contact, ingestion, eye contact is minimized by engineering controls, proper training and use of PPE including gloves, lab coats, and safety glasses. In the case of accidental release, facilities and equipment for containment and clean up are available similar to any other hazardous material.

- *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?*

To the best of our knowledge the hazardous properties of CNTs are not fully understood. In the absence of any reliable information, we treat CNTs as a hazardous material. All in spec and off spec materials are treated as hazardous lab waste. CNTs in solid form, liquid suspensions, and waste generated during processing and device functionalization, devices functionalized with CNTs are collected separately and disposed in a timely manner by a licensed hazardous waste pick up, transportation and disposal company hired by us. The waste is stored in a sealed container until disposal.

Sincerely,

A handwritten signature in black ink, appearing to read "Ray Radtkey".

Ray Radtkey, Ph.D.  
Vice President, Product Development

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