Regulatory Cooperation Council Nanotechnology Initiative

Work Element 4 Final Report

Assessment of Nanomaterial Uses in Canada and the US

1.0 Context

The goal of the RCC Nanotechnology Initiative is to help ensure that Canada and the United States apply similar regulatory approaches to nanomaterials, to the extent possible and consistent with their separate legal authorities, to reduce the risks to human health and the environment while fostering innovation. From the outset of the RCC Nanotechnology Initiative, the Canadian and US New Substances Programs (the Programs) felt that more complete and accurate information on the use of nanomaterials would improve their understanding of exposure information, make information requests more targeted, and ultimately help the two programs make regulatory decisions that are both more consistent and predictable.

The overarching action item identified for Work Element 4 in the Regulatory Cooperation Council (RCC) Nanotechnology Work Plan is to characterize existing commercial activities and identify gaps and priorities for future knowledge gathering for nanomaterials. The Work Plan action items are:

- 3 – 6 months: Share information and lessons learned from previous commercial data gathering activities.
- 6 – 12 months: Share non-Confidential Business Information (CBI) concerning industrial nanomaterials in the marketplace; identify areas where information is limited; invite stakeholder comment and input to help address these gaps.
- 12 – 18 months: Initiate an analysis of industrial nanomaterials uses in Canada and the United States.
- Beyond 18 months: Complete an assessment of industrial nanomaterial uses in Canada and the United States; Identify opportunities for and barriers to ongoing collaborations and regulatory alignment.

This report is the final deliverable for this work element. It addresses the action items up to 18 months, while the items beyond 18 months have already been initiated. This report presents the current state of knowledge on the uses of nanomaterials from data gathering efforts both prior to and during the RCC Nanotechnology Initiative. The results from this information gathering process have been brought together in the form of a Nanomaterials Use Matrix, which is the major output of this work element. The report also explores next steps for how Canada and the US can continue to build on and apply this knowledge in support of regulatory alignment for nanomaterials.

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2.0 Nanomaterial Notified in Canada and the US

The dataset used to begin the analysis of nanomaterial use information came from new nanomaterials notifications* in Canada and the US. In the US, Pre-Manufacture Notices (PMNs) regarding new substances are made under the *Toxic Substances Control Act* (TSCA); in Canada New Substances Notifications (NSNs) are submitted according the *New Substances Notification Regulations (Chemicals and Polymers)* of the *Canadian Environmental Protection Act 1999* (CEPA). As part of the Work Plan, the two countries shared non-Confidential Business Information (CBI) and analyzed trends in substances that had been notified to the Programs as being nanomaterials.

As of September 2013, the Canadian New Substances Program had assessed approximately 18 nanomaterials, whereas the US New Chemicals Program had assessed approximately 130. In terms of uses, there was considerable consistency between the two Programs, with coatings, mechanical strength additives (e.g., composites), chemical intermediates, conductive additives, and dyes/inks. Production volumes in notifications to the Programs ranged widely, from less than 100 kg to greater than 10,000 kg.

3.0 Comparison with Findings from other Commercial Data Gathering Activities

As per the RCC Nanotechnology Work Plan, the two countries also shared information and lessons learned from other commercial data gathering activities. This information is summarized below, and where possible, compared with the information on the nanomaterials notified under the New Substances Programs in Canada and the US.

United States

One such voluntary initiative was the United States Environmental Protection Agency's (EPA) Nanoscale Materials Stewardship Program (NMSP). The NMSP requested voluntary submissions of information from manufacturers, importers, processors and users of nanomaterials. From 2008 - 2009, twenty-nine companies and trade associations submitted information to the US EPA covering 123 nanoscale materials based on 58 different chemicals. Approximately 75 – 80% of these submissions included some type of use information (US EPA 2009); however, this information was very limited (no submission contained sufficient information for EPA to conduct an exposure assessment). When the US EPA compared the information obtained through the NMSP with available information, including the Woodrow Wilson Project on Emerging Nanotechnology Consumer Products Inventory (PEN 2013), they found there were likely over 200 existing chemicals being produced at the nanoscale for commercial and R&D purposes. Of these, 28 chemicals were included in the NMSP submissions (US EPA 2009). The chemicals were generically identified as metals, metal oxides, carbon nanotubes, amorphous silica, organic polymers, and nanoclays. Reported uses were similar to what has been notified as PMNs, including imaging agents, plastic additives, catalysts, coatings,

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sunscreen, cells for batteries, and composite parts for marine, aircraft, and automobile applications.

The NMSP is considered a limited success, primarily due to under-participation, and because a number of environmental health and safety data gaps still exist. No particular uses predominated. Many submissions were for research and development only, with a small proportion also later submitted as PMNs. Overall, however, the NMSP improved the US EPA's understanding of nanomaterials and the nanomaterials industry, contributed to EPA's engagement with other agencies and international bodies, and informed next steps on regulatory and research issues.

Canada

In Canada, the federal Department of Industry maintains a Company Directory for Nanotechnologies. There are approximately 120 companies listed in the directory. Available information by company may include: company information and description; product, service or licensing information; technology and market profiles; and sector information (Industry Canada 2011). Since this directory is populated with information supplied directly by companies, the level of detail by company may vary. Furthermore, the database is not comprehensive since some companies may not have self-identified, despite being involved in nanotechnology. A major limitation in being able to analyze the database is that the type of nanomaterial being used is not generally identified.

Provincial associations in Canada have also undertaken efforts to understand the companies, nanomaterials and uses in their jurisdictions. For example, in 2009 Alberta Innovates Technology Futures (AITF) produced what is known as an asset map, which aimed "to present a snapshot of nanotech activity in the province" (AITF 2009). The report identified 22 nanotechnology companies operating in Alberta and placed them into five categories based on industrial uses. The five categories listed were: nano-intermediates (38%); nano-enabled products (33%); nano-services (13%); nanomaterials (12%); and nano-tools (4%) (NanoAlberta 2009). Information was also gathered by engaging NanoQuebec to look at research and industrial activities (NanoQuebec 2013). It was found that there are at least 64 companies in Quebec using and/or testing nanomaterials for commercial purposes. The main nanomaterials used in Quebec are nanocrystalline cellulose (NCC), carbon nanotubes, and quantum dots. The nanomaterials are intended to be used in a range of products including: industrial and medical membranes, protective coatings, imaging devices and agents, drugs, lab-on-a-chip applications, paper, printed electronics applications, fuel cells, solar cells, textiles, security clothing, and food packaging. Environment Canada and Health Canada hope to continue working with NanoQuebec, NanoAlberta, and other provincial nanotechnology associations to gain a more complete understanding of the nanomaterials being manufactured, imported and used in Canada.

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Information was also gathered from an online database called Nanowerk (Nanowerk 2013). This database contained information that was not believed to be updated on a regular basis, nor validated for accuracy. Therefore, the Program did some verification of the information (e.g. web searches).

Based on information gathered to date, there are at least 100 companies manufacturing, importing or using nanomaterials in Canada. Some basic analysis revealed that a fairly even proportion of nanomaterial companies are producers versus integrators. Geographic clusters of companies can be found in Toronto, Vancouver, Montreal and Ottawa. The main nanomaterials in Canada are: nanoparticle metals (e.g. iron, copper), metal oxides, metalloids (e.g. silica), carbon nanotubes, and organic (e.g. nanocrystalline cellulose). The main use categories of these nanomaterials are: coatings, composites, and dyes/pigments/inks. These findings are consistent with information received through the Canadian New Substances Program.

Global Trends

A report on the global nanotechnology industry released in January 2013 by Future Markets (a London UK-based technology consulting firm with an expertise in nanotechnology) provided a review of the main nanomaterials suppliers, and user markets for 30 nanomaterials (Future Markets Inc. 2013). Nanomaterial production and demand for nanomaterials by end user market was forecasted from 2010 through to 2020. The report predicts that the global nanotechnology market will continue to grow over the coming decade. It also highlights the difficulty in obtaining accurate information, even on current nanomaterial use. Conservatively, it was estimated that 2010 global production of nanomaterials was around 400,000 tons per year, projected to rise to about 1 million tons by 2020. “Optimistically”, it was estimated that 2010 global production was already at around 1 million tons per year, and could rise as high as 6 million tons per year. In 2012, the largest markets for nanomaterials were paints and coatings (19%), medical applications (14%), and electronics/optics (14%). The report predicts that in the coming decade, the most innovation and growth will likely occur in the latter two areas. Cosmetics/personal care (10%) and composites (8%) were also identified as major areas of current marketplace application. The percentages cited above represent the estimated demand in 2012 for nanomaterials in those areas. These findings confirm that coatings are currently the major use of nanomaterials, as has been reported in notifications to the Canadian and US New Substances Programs.

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4.0 Nanomaterials Use Matrix

Purpose

The information gathered throughout the RCC Nanotechnology Initiative, outlined in Sections 2.0 and 3.0, has been brought together in the form of a Nanomaterials Use Matrix. The

Nanomaterials Use Matrix represents the most up-to-date information the Programs have collected from a range of sources, including information from the two regulatory programs, publicly available and third party information, and input from expert stakeholders. The matrix lists nanomaterial uses that are commercially available, or at an advanced stage of commercial development in Canada and the US.

Overall, the purpose of developing this matrix was to assemble a common foundation of information on uses of nanomaterials in Canada and the US – beyond solely those that are covered by new substances requirements under CEPA and TSCA - that will enable the Programs to have a better understanding of potential for exposure associated with identified use scenarios. This should, in turn, focus Program information collection efforts on those uses with greatest potential for exposures and be used for the refinement of generic use scenarios. However, the use matrix in this document is not, by itself, a prioritization list or a categorization of nanomaterials of concern/no-concern.

The Programs recognize that the categories in the Use Matrix inevitably lead to areas of overlap due to some categories representing more specific application areas than others. As an example, silver is used in electronics and also in inks. An overlap occurs because nanosilver is used in inks that are used to create wires in electronics. The use matrix will continue to evolve as information becomes available.

Furthermore, the use matrix includes some information that may be outside the scope of uses managed under TSCA and CEPA (e.g. medical implants, pesticides, cosmetics). This is because the Programs incorporate information for all known uses to evaluate exposure in risk assessments of substances under these statutes. Regardless of whether a particular use falls under TSCA or CEPA jurisdiction, being aware of the various applications of a given nanomaterial will help the Programs understand how its properties are being applied in materials or products (e.g. antimicrobial properties of silver nanoparticles being used in textiles). It is important to note that the use categories in the matrix may not correspond to specific legal categories under other statutes and regulations.

Discussion of findings from the Nanomaterials Use Matrix

The Nanomaterials Use Matrix is attached in Annex 1. The Figure 1 shows the number of nanomaterials that were found per use category. The categories in which the greatest number of nanomaterials are currently used are coatings, electronics, catalysts, inks and pigments, batteries, plastics, ceramics and paints. This is consistent with the findings of the Programs from their NSNs and PMNs.

It should be noted that the figure does not take production/import volumes into consideration, since this information is not readily available to the Programs. Volume information could be used to enhance the resolution of the list of uses in the figure, which will better inform exposure scenarios. For example, electronics have a large number of nanomaterial uses listed in the

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matrix, but the total volume of nanomaterials used may be very low. Carbon nanotubes are the only nanomaterial used in the sporting goods category; however they may be used in high volumes.

Another way to examine the information in the Use Matrix is to see which nanomaterial classes are represented in the various uses. Figure 2 provides a breakdown of the number of uses within each class of nanomaterials. Metal oxides/metalloid oxides, are the most frequently used nanomaterial, followed organics, carbon nanotubes, metals/metalloids, inorganic carbon, and quantum dots. Enhancing Figure 2 with volume data (once available) would provide further insight into the relative importance of different classes of nanomaterials in Canada and the US.

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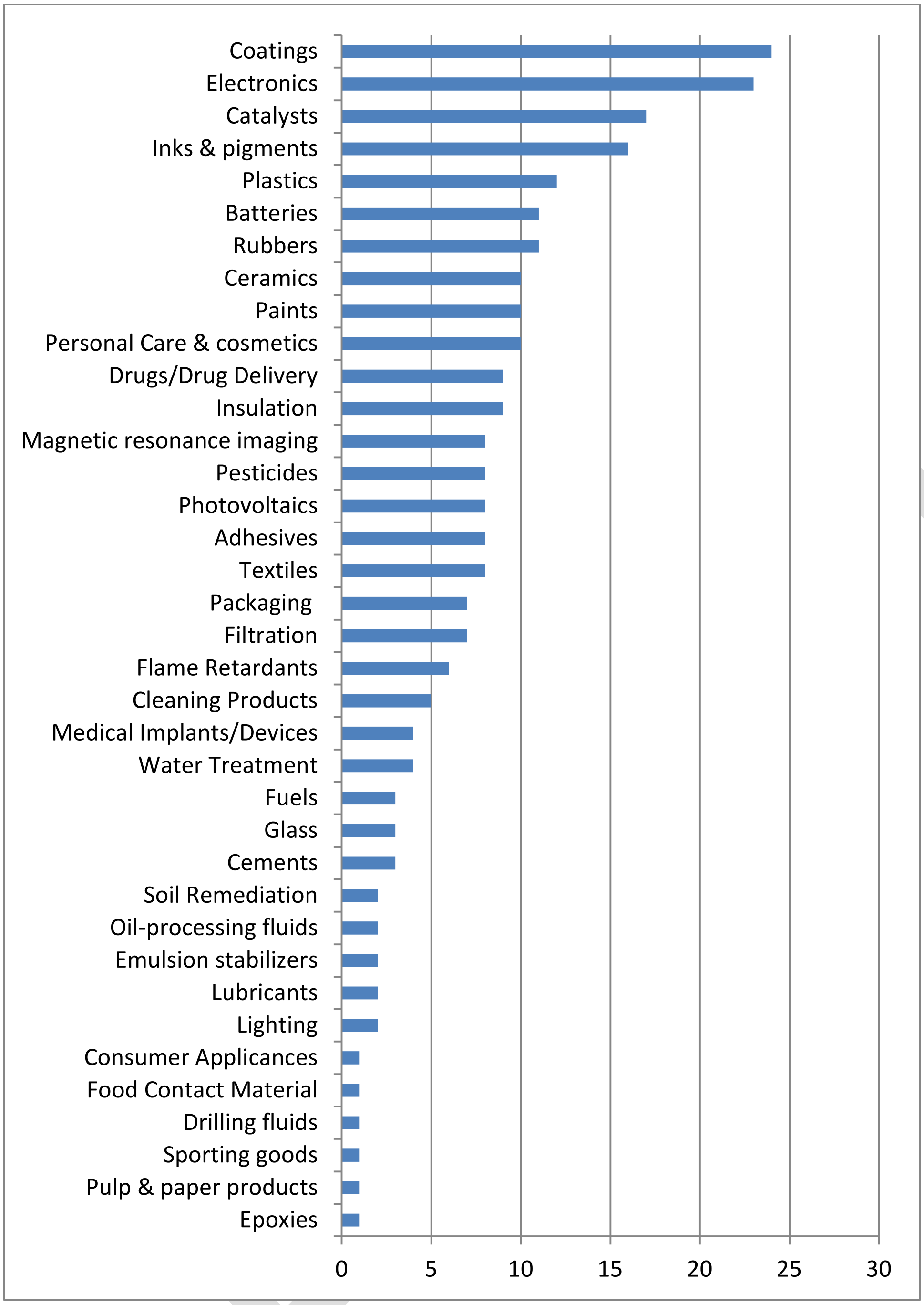

Figure 1: Number of Nanomaterials by Use Category

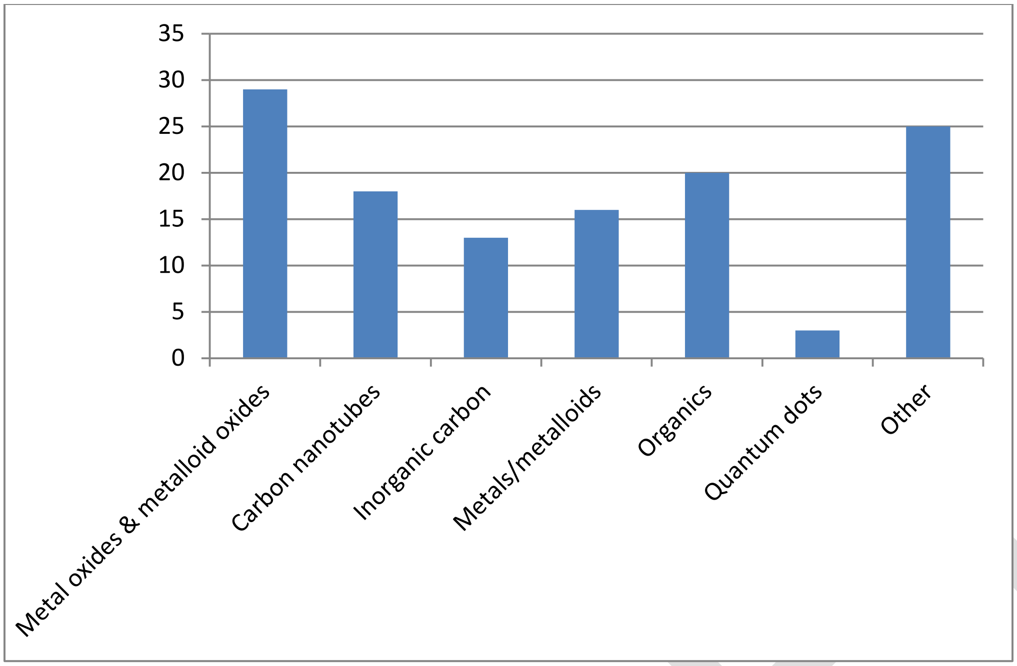

Figure 2: Number of Uses by Nanomaterial Class

5.0 Moving Forward

Considerations for gathering and sharing additional nanomaterial use information

As discussed in the analysis of the use matrix in the previous section, the lack of volume information limits the usefulness of the information in risk assessments of nanomaterials. For example, the information collected shows that nanomaterials have a variety of uses; however relative volume-share information for each nanomaterial is lacking, and the importance of the use in risk assessments could either be under or over-estimated. Volume information would provide an additional level of confidence on the relative use of a nanomaterial in the two countries. The Programs would therefore like to encourage notifiers to allow the US and Canada to share use information between the Programs. This can be done through forms obtained directly from the Programs.

Over the next 6 months, Canada is also looking to engage other provinces and provincial nanotechnology associations in order to gain a broader understanding of the Canadian nanotechnology marketplace.

Lastly, it became evident from this exercise that another way to analyze the use information would be to further organize it by the technical function that a nanomaterial has in a product (e.g., uses organized by function such as magnetism or tensile strength). Such information would help the Programs better identify potential uses for risk assessment and risk management and help in the derivation of environmental concentrations. This type of analysis will be conducted once the Programs have a better understanding of nanomaterial functions.

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Opportunities for and barriers to ongoing collaborations and regulatory alignment

A barrier to ongoing collaboration and regulatory alignment identified though this exercise was the ability to share Confidential Business Information (CBI) obtained through new substance notifications between Canadian and US New Substances Programs. A mechanism could be developed to allow for industry to voluntarily agree to the sharing of CBI from notified nanomaterials between the Programs. This could involve a simple "check-box" on notification forms authorizing the sharing of information between the two Programs. This approach will be pursued post-RCC and stakeholders will be kept appraised of progress.

There are many opportunities for ongoing collaboration and regulatory alignment for nanomaterials between Canada and the US. The information gathered through this exercise has brought a better understanding of the commercial uses of nanomaterials in Canada and the US, which will be used to inform both the risk assessment and risk management of nanomaterials. For example, uses such as paints, coatings and composites are significant uses in both Canada and the US, and could therefore be an area for refinement of exposure scenarios to better predict environmental concentrations in risk assessments. In terms of risk management, the use information will allow for more focused control measures (e.g. Significant New Activity Notices in Canada and Significant New Use Rules in the US).

Appendix 1 – Reference List

Alberta Innovates – Technology Futures/NanoAlberta. 2009. Creating Opportunity: Alberta's Nanotechnology Asset Map 2009.

Future Markets Inc. 2013. The Global Nanotechnologies and Nanomaterials Industry.

Industry Canada. 2011. Company Directories for Nanotechnologies. Available online at: http://www.ic.gc.ca/eic/site/aimb-dgami.nsf/eng/03503.html.

NanoQuebec. 2013. Mapping of Quebec Companies Using Nanomaterials in their Product Development and Highlight of Main Market/Application Trends.

Nanowerk. 2013. Nanotechnology companies in Canada. Available online at: http://www.nanowerk.com/nanotechnology/Nanotechnology_Companies_Research_and_Degree_Programs_in_Canada.php.

United States Environmental Protection Agency (US EPA). January 2009. Nanoscale Materials Stewardship Program Interim Report.

Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies (PEN). 2013. Nanotechnology Consumer Products Inventory. Available online at: http://www.nanotechproject.org/inventories/consumer/.

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Annex 1 – Nanomaterials Use Matrix

Uses of Nanomaterials that are Commercialized or in Commercial Development

1 - Carbon nanotubes
2 - Inorganic carbon
3 - Metal oxides & metalloid oxides
4 - Metals/metalloids
5 - Quantum dots
6 - Organics
7 - Other

		Coatings	Catalysts	Textiles	Paints	Rubbers	Epoxies	Electronics	Lighting	Adhesives	Lubricants	Plastics	Filtration	Pulp & paper products	Packaging	Sporting goods	Insulation	Emulsion stabilizers	Ceramics	Cements	Glass	Water Treatment	Batteries	Photovoltaics	Inks & pigments	Oil-processing fluids	Drilling fluids	Personal Care & cosmetics	Cleaning Products	Flame Retardants	Soil Remediation	Fuels	Pesticides	Medical Implants/Devices	Drugs/Drug Delivery	Magnetic resonance imaging	Food Contact Material	Consumer Applicances
1	**Carbon Nanotubes**	•	•	•	•	•		•		•		•	•		•	•			•	•	•		•	•	•					•								
2	**Graphene**	•	•		•			•									•						•	•						•			•					
2	**Fullerenes**	•	•			•		•				•					•		•				•	•				•		•								
3	**POSS** (Polyhedral oligomeric silsesquioxane)	•			•							•			•															•								
3	**Modified silica**	•			•	•		•		•																		•							•			
3	**Aluminum oxide**	•	•	•	•			•			•		•						•				•		•			•										
3	**Antimony tin oxide**	•	•					•													•		•															
3	**Bismuth oxide**	•										•																										
3	**Cerium oxide**	•	•																				•					•	•									
3	**Cobalt (II) oxide**		•					•											•	•			•	•	•								•		•	•		
3	**Copper (II) oxide**	•	•					•																	•				•				•			•		
3	**Indium Tin oxide**	•						•																														
3	**Iron (III)/(II/III) oxide**		•					•											•				•		•			•			•	•			•	•		
3	**Magnesium oxide**	•	•					•									•													•		•						
3	**Manganese (II&III) oxide**	•	•					•				•											•						•							•		
3	**Modified Iron oxide**																								•													
3	**Nickel (II) oxide**	•	•					•			•	•											•	•	•											•		
3	**Silicon oxide**	•	•			•		•		•							•		•																			
3	**Titanium dioxide**	•		•	•	•		•				•	•		•		•				•	•		•	•			•					•	•	•	•		
3	**Yttrium oxide**	•						•	•								•																					
3	**Zinc oxide**	•		•	•	•		•				•			•										•			•					•		•	•		
3	**Zirconium oxide**	•	•					•											•														•	•				
4	**Gold**		•					•																				•						•	•	•		
4	**Silver**	•	•	•				•		•		•										•			•			•	•				•	•			•	•
5	**Quantum dots**							•	•															•														
6	**Other Organics**	•		•	•	•				•			•						•					•	•										•			
6	**Nanocellulose**	•		•	•	•		•		•		•	•	•	•		•	•		•		•			•	•	•								•			
7	**Modified Barium phosphate**																								•													
7	**Calcium carbonate**					•				•		•													•													
7	**Nanofibers (Incl. Classes 1-4)**	•		•		•		•				•	•		•		•		•			•	•		•						•	•						
7	**Nanoclays**	•	•		•	•	•			•			•		•		•	•	•						•	•		•	•	•			•		•			

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