Nanomaterial Risk Assessment Worksheet
DuPont™ Light Stabilizer

Step 1 - Describe Material and Its Applications
Develop basic descriptions - general overviews – of the nanoscale material and its intended uses.

General Overview:[1]
Titanium is the ninth most common element in the earth's crust and is present naturally as the minerals rutile (TiO_2), ilmenite ($FeTiO_5$)and sphene ($CaSiTiO_5$) among others. DuPont extracts titanium from titanium minerals using chemistry and engineering and reforms the titanium into rutile titanium dioxide crystals (TiO_2, titania).

The overwhelming majority of titanium dioxide produced and marketed globally today is pigmentary titanium dioxide used to impart whiteness into paints, plastics, and paper. Pigmentary titanium dioxide has a median particle size in the range of 250 –350 nm. In commerce since 1912, over 11 billion pounds of titanium dioxide are produced and consumed each year Approximately 2.5 billion pounds of pigmentary titanium dioxide are consumed in plastics each year.

DuPont will produce a new product, DuPont™ Light Stabilizer, for use as a polymer additive. DuPont™ Light Stabilizer is an ultrafine rutile titanium dioxide surface treated with aluminum hydroxide, amorphous silica, and a silane, siloxane, or a polyol for compatibility with end use systems.

DuPont™ Light Stabilizer is a fine white powder with a distribution of particle sizes centered in the range of 130-140 nm on a weight basis. A portion of the distribution falls within the "nano" range, <100nm, and that portion is in the range of 10-20%. The morphology of the particles ranges from nearly spherical to polyhedral. The material can be made water dispersible by applying certain surface treatments. Other surface treatment will render the material hydrophobic. Surface area of the material is in the range of 30 – 60 m2/g.

The material in dry bulk form tends to agglomerate into clumps of particles due to interaction of the particle surfaces. Degree of agglomeration will depend on the nature of the specific surface treatment, the relative humidity, sample aging, and other factors. In use, DuPont™ Light Stabilizer will be dispersed in a polymer matrix where the particles are effectively embedded and encapsulated.

Titanium dioxide is a semiconductor. Electrons can be promoted from the valence band to the conduction band through the absorption of a photon in the ultraviolet region of the spectrum. Titanium dioxide is often surface treated to prevent the interaction of electrons and holes with the surrounding environment, such as a polymer matrix. Most often the rutile phase of titanium dioxide is used in applications where low interaction with the surrounding matrix is desired. In other cases titanium dioxide is left untreated and the photocatalytic nature of TiO_2 is used. Most often an untreated anatase phase of titanium

[1] Descriptions sufficient to guide development of more detailed profiles of the material's properties, hazard and exposure potential at various lifecycle stages such as manufacture, use, and end-of-life. Information in the possession of the user or available in the literature.

dioxide is used in photocatalyst applications. The product described herein is a surface treated high-rutile phase titanium dioxide.

Titanium dioxide has a high refractive index: about 2.7 for rutile and 2.5 for anatase. The high refractive index and the lack of absorbance in the visible light spectrum make it an ideal material for use as a white pigment. Manufacture of titanium dioxide with a median particle size range of 250 to 350 nm results in particles that are optimized to scatter visible light and functions as a very effective white pigment (pigmentary titanium dioxide). Reduction of the particle size distribution of the titanium dioxide particles results in more scattering of ultraviolet radiation. DuPont's product has been optimized to absorb and scatter ultraviolet light so that it is effective as a UV stabilizer and UV screener for polymers and to protect substrates.

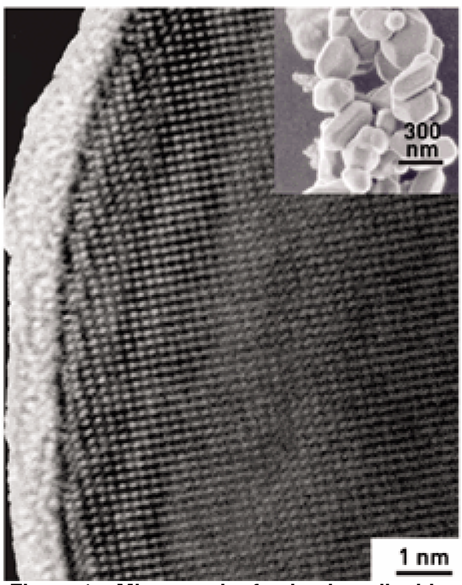

Figure 1. Micrograph of a titanium dioxide pigment particle with a nanolayer coating – in this case the coating is amorphous silica.

<u>APPLICATION DESCRIPTION</u>

DuPont™ Light Stabilizer - Inorganic Light Stabilizers for Polymer Applications

DuPont's ultrafine powder described above can be incorporated into polymer systems and serves to protect the polymer matrix and the substrate below a polymer film from degradation due to the Sun's ultraviolet radiation.

Inorganic UV stabilizers are those based on inorganic oxide compounds such as titanium dioxide or zinc oxide. Other titanium dioxide manufacturers produce ultrafine titanium dioxide. Ultrafine titanium dioxide and zinc oxide have been sold commercially for cosmetic sunscreens and other applications for well over a decade, although this is not the intended use of DuPont™ Light Stabilizers and DuPont does not currently plan to sell the product into these markets. Organic UV stabilizers hold most of the market for light stabilizers today. Organic UV absorbers are those based on carbon, hydrogen, nitrogen and oxygen.

DuPont™ Light Stabilizer is manufactured at a DuPont facility and packaged for shipment. It is generally incorporated into plastic products in a two-step process. It is 1) combined with a polymer to form "masterbatch" or "concentrate" at higher concentrations (~30%) and then 2) this concentrate is blended with additional polymer resin to produce a final low concentration polymer pellet or object.

Powdered DuPont™ Light Stabilizer is delivered in plastic bags to a plastics masterbatch/concentrate producer where they are stored in a warehouse until needed. Plastics masterbatch producers combine various ingredients into polymers at high loadings. These polymers are termed "carriers" because they are used to carry the functional additives into the end polymer products. Masterbatch producers add the ultrafine powder to hoppers on extruders where the powders are conveyed into the machine and intimately mixed with a molten polymer. Rotation of the machine internals induces shear within the hot polymer causing mixing of the powder additive with the polymer. At the discharge of the machine the polymer melt is rapidly cooled and formed into pellets. The masterbatch pellets are discharged into containers for shipment to polymer processing facilities. Pigmentary titanium dioxide and ultrafine carbon black are other powders that have for over half a century been processed to make masterbatch in this fashion.

At polymer processing facilities the polymer pellets are placed into hoppers and conveyed to various types of processing equipment. A lesser amount of masterbatch pellets are mixed with larger portions of polymer resin pellets and melted in the machines. The molten polymer is processed in various ways depending on the end-use application. Thermoplastic processes include: 1) extrusion, 2) injection molding, 3) thermoforming and 4) rotational molding. The polymer can be processed into sheets, films, parts, fibers, or coatings. http://www.polymerprocessing.com/operations/index.html

Light stabilizers are added to many types of polymers including polypropylene, polyethylene, ABS (acrylonitrile-butadiene-styrene copolymer), polystyrene, polycarbonate, PVC, and others. The maximum addition level in the end polymer product is usually 3% or less. Nearly 100 million pounds per year of light stabilizers are used to protect plastics or substrates from damage due to the Sun's ultraviolet rays. This translates to tens of billions of pounds of UV protected polymer end products per year.

Examples of applications of light stabilized polymer products include:

- Automotive interior parts
- Sporting Goods
- Packaging such as shampoo bottles and drink bottles
- Agricultural films
- Fabrics and clothing
- Outdoor furniture

Extending the lifetime of these products has a significant positive impact on our environment and the conservation of resources. See "Potential benefits/positives of these materials" below for additional information.

Other Applications
DuPont does not currently intend to manufacture ultrafine titanium dioxide for use in cosmetic applications such as sunscreens. However, should the intended use of the product change resulting in a significant new use such as this, it would trigger a detailed review using this framework.

Material Description:

Material Source or Producer: DuPont
Manufacturing Process: Confidential DuPont Process
Appearance: Fine white powder
Chemical composition: Titanium Dioxide, rutile (see below) surface treated with aluminum hydroxide, amorphous silica, and a silane, siloxane, or a polyol for compatibility with end use systems.
Physical Form: powder
Concentration: see below
Size distribution: D50 ~130nm-140nm, Geometric Standard Deviation of Size Distribution ~1.3-1.4
Solubility in Water: Insoluble
State of Aggregation or Agglomeration: Agglomerated
Material CAS Number (if applicable):

Material	CAS Number	Composition
Titanium Dioxide	13463-67-7	75-95%
Aluminum Hydroxide	21645-51-2	0-20%
Amorphous Silica	7631-86-9	0-25%
Silane/Siloxane		0-5%
Polyol		0-5%

The exact composition of DuPont™ Light Stabilizer products are known and well characterized but are considered Competitive Business Information. The composition is carefully controlled during manufacturing.

Main applications (current or expected): Light stabilizer for polymers including coating applications.

Stage of development: Ready for commercial introduction.

General Physical and mechanical properties of this material: This material is a low bulk density material. Titanium dioxide is a semiconductor and, when not surface treated, is photoactive. DuPont™ Light Stabilizer is surface treated to avoid photoactivity. The product crystals are dense titanium dioxide that can not be broken down by ordinary mechanical action.

Past experience with this material or a similar material: DuPont is the world's largest manufacturer of pigmentary titanium dioxide, producing over 2 billion pounds annually, but up to this point has not commercially produced ultrafine titanium dioxide. Other titanium dioxide manufacturers produce ultrafine titanium dioxide via other processes. Ultrafine titanium dioxide has been sold commercially for sunscreen and other applications for well over a decade.

Why Light Stabilizers are Used:

When used in durable goods, light stabilizers, as a class of products, can substantially increase the lifetime of many products. Extending the lifetime of these products has a significant positive impact on our environment and the conservation of resources. Plastic products that are not protected from the Sun's UV rays have much shorter lifetimes than those that are protected with light stabilizers. The lifetime of the product will depend on the type of polymer used and the intensity and duration of exposure. However, it is not unreasonable to consider that unstabilized plastic product's lifetimes can be doubled by addition of light stabilizers. Products that normally would be discarded after a few years of service will last substantially longer. Light stabilizers protect the plastic from embrittlement, fading, off color and mechanical failure. Increasing the lifetime of durable goods reduces materials and energy consumption for replacement of these durable goods while reducing the volume of used materials going to landfill.[2][3]

Protecting the contents of packaged goods greatly reduces waste and spoilage. The Sun's ultraviolet rays can cause chemical conversions to take place in food and certain packaged goods. If these packaged goods spoil, they will be disposed of before they are consumed. Increasing the lifetime of packaged goods reduces materials and energy consumption for growing or replacement of these packaged goods while reducing the volume of spoiled products going to landfill.

Use of light stabilizers for UV screening and stabilization in agricultural films can boost crop yields and increase the lifetime of the film. Reduced consumption of agricultural films reduces materials and energy consumption for replacement of these films while reducing the volume of used materials going to landfill.

Lifecycle assessment is a means to quantify the environmental impact of products. Lifecycle assessment could be used to quantify the potential benefit of light stabilizers on the environmental impact of plastic products and we are pursuing calculations in this area.[4]

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[2] The Effect of UV Light and Weather on Plastics and Elastomers, L. Massey, 1996, ISBN 1-884207-25-1

[3] Handbook of Material Weathering, G. Wypych, ChemTec Publishing, 3rd Edition, 2003 (ISBN 1-884207-25-1.

[4] Life Cycle Assessment and Environmental Impact of Plastic Products, T,J. O'Neil, Rapra Review Reports, 2003 (ISBN 1-85957-364-9).

Potential risks/negatives of the material:

Health: Based on the toxicology studies enumerated below there doesn't appear to be significant differences in the health effects of DuPont™ Light Stabilizer and pigmentary titanium dioxide. Both have HMIS (Hazardous Materials Information System) health hazard rating of 1 (low). DuPont has set the AEL (acceptable exposure limit) for DuPont™ Light Stabilizer at 2 mg/m^3. The AEL was set by DuPont Haskell Laboratory after review of relevant literature data and subsequent internal toxicological testing results. The results of pulmonary toxicity studies show low toxicity and minor transient pulmonary inflammation at higher concentrations in rats.

Environmental: Based on the environmental toxicology studies enumerated below there doesn't appear to be significant differences in the environmental effects of DuPont™ Light Stabilizer and pigmentary titanium dioxide.

Sources of additional information:

The material has characteristics of the bulk properties of pigmentary titanium dioxide of similar composition. A summary of the key physical properties of titania can be found at the following link: http://www.azom.com/details.asp?ArticleID=1179.

Additional background information on the manufacture and use of titanium dioxide can be found in the book Titanium Dioxide by Jochen Winkler, Hannover: Vincentz, 2003 or in the book Titanium, Its Occurrence, Chemistry and Technology, J. Barksdale, 2nd edition, The Roland Press Company, 1966.

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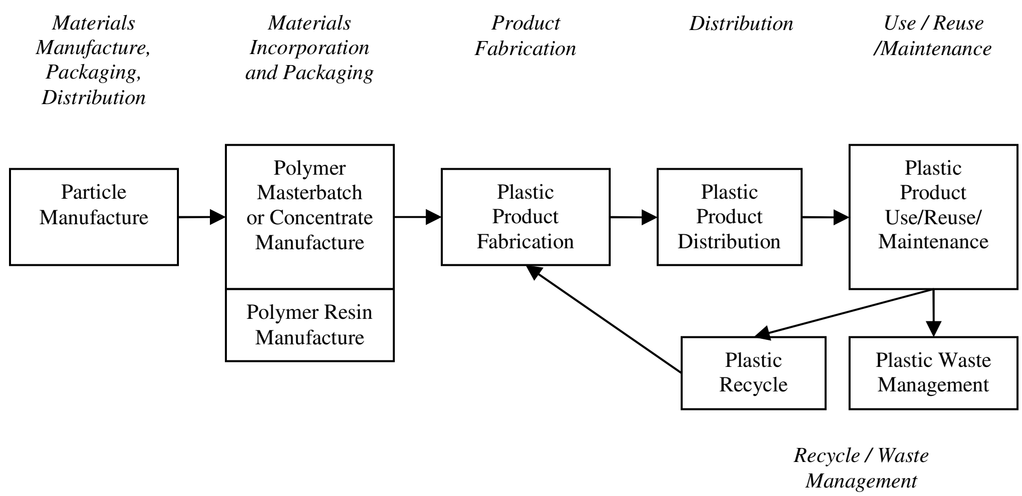
Step 2 –Profile Lifecycles

Table 2 below defines and catalogs the known and anticipated activities in the lifecycle of this product. Figure 2 provides a high level diagram of the steps involved.

Figure 2. Lifecycle Profile for DuPont™ Light Stabilizer



Note that the material can have different lifecycles depending on the process used in product fabrication, the use of the article, and the method of ultimate waste management.

The Risk Assessment performed on this material selected a consumer article in a residential use as the worst-case potential exposure pathway for conducting the assessment because this pathway provides a conservative risk characterization.

Materials Manufacture and Packaging
Particle manufacture occurs at one manufacturing facility and is not expected to extend to other facilities in the foreseeable future. During manufacturing, raw materials are converted to ultrafine dry powder with up to 20% (by weight) of its particle distribution in the “nano” range. Individual particles consist of a TiO2 core with a surface coating which will typically be aluminum hydroxide.

Product Fabrication and Distribution
DuPont™ Light Stabilizer is delivered in plastic bags to a polymer concentrate or resin manufacturer where it is stored in a warehouse until needed. Polymer concentrate or resin manufacturers add DuPont™ Light Stabilizer to hoppers where they it is processed to mix it with a molten polymer. The polymer melt is rapidly cooled and formed into pellets which typically contain 0.5 to 30% DuPont™ Light Stabilizer. DuPont™ Light Stabilizer is encapsulated with polymer in the process. If the polymer contains 5 to 30%

DuPont™ Light Stabilizer it is termed a "polymer concentrate" and will be reduced in concentration in later processing." The resin or resin concentrate pellets are discharged into containers for shipment to polymer processing facilities.

At polymer processing facilities the resin concentrate polymer pellets are placed into hoppers and conveyed to various types of processing equipment. The resin concentrate is mixed with larger portions of polymer resin pellets and melted in the machines. The molten polymer is processed in various ways depending on the end-use application. Thermoplastic processes include: 1) extrusion, 2) injection molding, 3) thermoforming and 4) rotational molding. The polymer can be processed into sheets, films, parts, fibers, or coatings. Final products range from consumer articles to construction materials and are expected to contain less than 3% DuPont™ Light Stabilizer.

Use/Reuse/Maintenace

While DuPont™ Light Stabilizer can be used in a variety of end products, the Assessment performed in Steps 2c and 3 will focus on a consumer article that represents a potential exposure scenario – weathering of outdoor plastic furniture containing DuPont™ Light Stabilizer. Products containing DuPont™ Light Stabilizer can be recycled and recycling should be encouraged.

End of Life - Recycle/Waste Management

It is anticipated that plastics containing DuPont™ Light Stabilizers can be recycled in the same way as the plastics are today.

Post-consumer disposal of articles containing DuPont™ Light Stabilizer includes disposal in a municipal landfill and municipal incineration. Both scenarios will be assessed in Step 3.

Table 2. Lifecycle Profile		
Material Lifecycle Stage	**Material Form(s)**	**Operations and Activities**
Particle Manufacture (DuPont)	• Raw materials converted to dry powders.	• Synthesis of dry powders • Separations • Packaging/Storage/Shipping • Recycle/Waste disposal
Polymer Masterbatch/Concentrate Polymer Resin Manufacture	• Dry powders incorporated into plastics resin pellets	• Receiving • Handling and Mixing operations • Dispersion into polymer • Packaging/Storage/Shipping • Clean-up • Recycle/Waste disposal
Resin Intermediaries (Distributors)	• Resin pellets	• Storage • Handling and shipping
• Resin molders • Film producers • Extrusion producers • Fiber producers	• Resin pellets • Molded parts • Formed parts • Fibers • Films	• Further compounding • Pellet melting/reforming by molding, blowing, extrusion • Cutting, shaping, machining, surface finishing • Packaging/Storage/Shipping • Recycling/Waste disposal
• Original Equipment Manufacturers • Packagers • Customers for shapes, parts, films, fibers	• Molded parts • Formed parts • Fibers • Films	• Assembly • Cutting, shaping, machining, surface finishing • Packaging/Storage/Shipping • Recycling/Waste disposal
Distribution (e.g., retailer)	• Assembled systems • Packaged goods • Construction materials	• Receiving • Storage • Handling and shipping
Use / Reuse / Maintenance (e.g., consumer)	• Assembled systems • Packaged goods • Construction materials	• Use • Mechanical wear and tear • Weathering
End of Life (e.g., recycling, disposal, etc.)	• Assembled systems • Packaged goods • Construction materials	• Waste transportation • Recycle - Separation, cleaning, grinding, chopping, milling, mixing, remelting, repelletizing, compounding • Disposal/Landfill • Incineration with Offgas Scrubbing

Step 2A – Develop Lifecycle Properties Profile
Identify and characterize the nanoscale material's physical and chemical properties, including property changes, throughout the full product lifecycle.

Summary:
A summary of relevant physical and chemical properties is included in Table 2.
The powder is manufactured in a proprietary process. Rutile is the major crystal form with surface treatments of aluminum hydroxide, amorphous silica and silane, siloxane, or polyol. These materials have been well-characterized with respect to their physical and chemical properties and detailed data regarding their character are stored in an internal proprietary database that can be readily accessed and are also stored in laboratory notebooks should additional details on properties be required.

After manufacture, DuPont™ Light Stabilizer is incorporated into a polymer matrix through melt processing. Molten polymer encapsulates the particles. DuPont™ Light Stabilizer is inherently stable. It is not expected to undergo chemical changes throughout its lifecycle. When DuPont™ Light Stabilizer absorbs ultraviolet light, the chemical structure of the crystal and its surface treatment act in a way that turns it into tiny amounts of heat while not changing its chemical structure. This process can be repeated infinitum.

Data needs and actions: No additional data needs are anticipated.

Table 2A. Lifecycles Properties – Summary Table			
Lifecycle Stage*	Particle Manufacture		
Technical or Commercial Name	DuPont™ Light Stabilizer 210 DuPont™ Light Stabilizer 220		
Common Form	Powder		
	Result	**Method**	**Remarks**
Chemical Composition			
Component 1: Titanium Dioxide	75-95%	ICP Spectroscopy	
Component 2: Aluminum Hydroxide	0-20%	ICP Spectroscopy	
Component 3: Amorphous Silica	0-25%	ICP Spectroscopy	
Component 4: Silane/Siloxane	0-5%	Leco – TCA	
Component 5: Polyol	0-5%	Leco - TCA	
Crystal Phase/Molecular Structure	Crystalline Rutile (major), Anatase (minor)	X-ray Diffraction	
Physical Form/Shape	Solid Powder/ Spherical to Polyhedral	SEM/TEM	
Size Distribution	D50 ~130-140 nm, GSD ~1.3-1.4	Dynamic Light Scattering (DLS) with sonication,	

		dispersed in water with TSPP	
Surface Area	30 – 60 m2/g	Nitrogen Adsorption (BET Method)	
Particle Density	3.8 g/cc	Helium pycnometry	
Solubility	Insoluble in water		
Bulk Density	~25-30 lb/ft3 (loose)		
Agglomeration/Aggregation State	Agglomerated in dry powder form	SEM/TEM	
Photoactivity	low/photopassivated	Phenol photooxidation	
Surface Charge (Zeta Potential)	DLS 210 IEP=7.7 Z.P. at 7.0 pH = 17	Zeta Potential Titration	
Porosity (Pore Size Dist. & Pore Vol.)	Avg Pore Dia=85-107A Pore Vol = 0.11 cc/g	Nitrogen porosimetry	
pH	4-8	10% aqueous dispersion in water	
Lifecycle Stage*	**Incorporated into Polymer matrix**		
Technical or Commercial Name	Various commercial names to be determined		
Common Form	Polymer composite		
	Result	**Method**	**Remarks**
Chemical Composition			
Component 1: Polymer (various)	70-99.5%		
Component 2: DuPont™ Light Stabilizer	0.5-30%		
Crystal Phase/Molecular Structure	Crystalline Rutile (major), Anatase (minor) in polymer		
Physical Form/Shape	Particles dispersed in solid polymer matrix		
Size Distribution	D50 ~130-140 nm, GSD ~1.3-1.4	SEM/TEM	
Surface Area	Not relevant[5]		
Solubility	Not relevant[5]		
Bulk Density	Not relevant[5]		
Agglomeration/Aggregation State	Dispersed in polymer	SEM/TEM	
Photoactivity	low/photopassivated		
Surface Charge (Zeta Potential)	Not relevant[5]		
Porosity (Pore Size Dist. & Pore Vol.)	Not relevant[5]		

[5] Encapsulated in a polymer matrix so that surface area, solubility, bulk density, surface charge and porosity are not measurable in this form.

Additional Notes:
These products are refractory oxides and their composition should not substantially change throughout the material's lifecycle.
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Step 2B – Develop Lifecycle Hazard Profile

Summary:

Human Health Hazard Summary
Based on hazard studies performed by DuPont, DuPont™ Light Stabilizer is a low toxicity compound. It has low acute oral and pulmonary toxicity, and is not a skin irritant or sensitizer. Detailed results can be found in David Warheit's paper listed below. Screening tests for mutagenicity and clastogenicity were negative. Chronic toxicity testing has not been conducted. Such testing is beyond the base set and the expected low level of exposure as well as the lack of adverse effects seen in acute studies do not indicate the need for chronic studies at this time. Should use of this product expand significantly, the need for such studies will again be considered.

DuPont has established an occupational health guideline or Acceptable Exposure Limit (AEL) to safeguard workers against inhalation of airborne DuPont™ Light Stabilizer. The AEL of 2 mg/m3 respirable dust was established by DuPont Haskell Laboratory after review of relevant literature data and subsequent internal toxicological testing results. An AEL of 2 mg/m3 over an 8-hour period is expected to be protective of workers. Details are outlined in DuPont internal document "Titanium Dioxide (Ultrafine)", D.B. Warheit, Haskell Laboratory.

Refer to papers in press "Development of a Base Set of Toxicity Tests Using Ultrafine TiO2 Particles as a Component of Nanoparticle Risk Management," D.B. Warheit, R.A. Hoke, C. Finlay, E.M. Donner, K.L. Reed, and C.M. Sayes , DuPont Haskell Laboratory for Health and Environmental Sciences, Newark, DE, USA in Toxicology Letters for a summary of the Base Set data.

Refer to paper "Pulmonary Toxicity Study in Rats with Three Forms of ultrafine-TiO2 Particles: Differential Responses Related to Surface Properties, David B. Warheit, Thomas R. Webb, Kenneth L. Reed, Scott Frerichs, and Christie M. Sayes, DuPont Haskell Laboratory for Health and Environmental Sciences, Newark, DE, USA in Toxicology (2007), 230, 90-104, Publisher: Elsevier Ltd.

Although some methods for skin penetration of ultrafine and nanoparticles have been developed, to the best of our knowledge, these methods have not been validated and broadly agreed upon for applications to nanomaterials. The only potential for skin contact to DuPont™ Light Stabilizer occurs during powder manufacturing and during polymer incorporation. Measures have been put in place to prevent skin contact in the workplace through engineering controls, personal protective equipment and procedures.

The product is contained in process equipment and is automatically packaged into plastic bags. Workers in areas where the product is manufactured, packaged or utilized use gloves as a preventative measure. Skin testing results reported in this section indicate DuPont™ Light Stabilizer is not a skin irritant or sensitizer. In our professional judgment, these engineering controls and personal protective equipment, combined with the apparent low toxicity of the product indicate that any potential risks are well managed. Because we expect the toxicity and exposure to be so low, no skin penetration testing was undertaken.

DuPont Light Stabilizer may be used as a component of polymers used as food and beverage containers, or in toys, which raises the possibility of ingestion should it somehow be extracted from the polymer. In this respect, it should be noted that titanium dioxide is classified by FDA as safe for use in food applications[6], although FDA has not specifically evaluated the material in nano form. We will continue to review literature and address any concerns that may arise.

Ecological Hazard Summary

DuPont™ Light Stabilizer has low acute toxicity to fish (test species is Rainbow trout) and invertebrates (test species is *Daphnia magna).* Test results with green algae showed medium toxicity, with a no-observed-effect-concentration (NOEC) of 10 mg/L. Green algae will be used as the most sensitive aquatic receptor for any quantitative assessment of risk.

Environmental Fate Data Summary

Titanium dioxide is a material that is naturally occurring and ubiquitous in the environment. These materials would ultimately be found in soil and sediments. Process water streams containing DuPont™ Light Stabilizer will be treated and material recycled. DuPont™ Light Stabilizer is insoluble in water and has a very high melting point and boiling point. It is a refractory inorganic material that will not photodegrade or transform and is stable in water. There are no established methods for differentiating naturally occurring titanium dioxide from titanium dioxide contained in DuPont™ Light Stabilizer in soil or sludge. There are no accepted methods for bioaccumulation potential screens for nanomaterials. These are areas where further methods development is required.

Safety Hazard Summary

The use of DuPont™ Light Stabilizer does not present safety concerns. It is not explosive, flammable, catalytically reactive or corrosive. It is a stable compound that has no known incompatibility with other materials.

Data needs and actions:

The commercially produced DuPont™ Light Stabilizer 210 will be included in a subsequent instillation study to confirm that pulmonary toxicity of the commercialized

[6] http://www.cfsan.fda.gov/~lrd/cfr73575.html.

formula is similar to previously tested pre-commercial materials. Plans call for full histopathology in this study.

Based on the results of Base Set Lifecycle Hazard Profile and the envisioned exposure potential for this material for the envisioned use, no additional tests, other than just noted, are planned at this time. Additional data needs will be re-examined during regular periodic reviews and any triggered reviews.

Table 2B. Nanomaterial Lifecycle Hazard Profile – Base Set		
Route	**Hazard** (characterization, e.g., low, moderate, high, and quantification if available, e.g., LOEL=x mg/kg)	**Source of Information** (e.g., report number)
Health Hazard Data		
1. Short-term Toxicity		
a. Pulmonary toxicity	Low toxicity, (NOEL = 5 mg/kg) DuPont AEL set at 2 mg/m3	DuPont Haskell Testing, Warheit et al., 2007[7]
b. Oral toxicity	Low toxicity (NOEL > 5000 mg/kg)	DuPont-20706
2. Skin irritation/sensitization	Not a skin irritant or sensitizer (Test dose = 0.5 g for irritation)	DuPont-20470,-20162
3. Skin penetration*	Measures put in place to prevent skin contact. No known validated method for nanoparticles (see text).	
Genotoxicity		
a. Gene mutation in prokaryotic cells	Negative	DuPont-20171
b. Chromosomal aberration	Negative	DuPont-20251
Environmental Hazard Data		
Aquatic Toxicity		
1. Fish (rainbow trout)	Low hazard, 96 hr (LC_{50}>100 mg/l)	DuPont-19375
2. Invertebrate (Daphnia)	Low hazard, 48 hr (EC_{50}>100 mg/l)	DuPont-19376
3. Aquatic Plant (green algae)	Medium concern, 72 hr (NOEC = 10 mg/l)	DuPont-19374
Terrestrial Toxicity (if significant release to terrestrial environments)		
1. Earthworms	No significant release (see step 2c)	
2. Plants	No significant release (see step 2c)	
Route	**Information**	**Source of Information** (e.g., report number)
Environmental Fate Data		
Environmental Fate (based on physical-chemical properties)		
Complete Physical and Chemical Properties	See Step 2A	See Step 2A

[7] "Pulmonary Toxicity Study in Rats with Three Forms of ultrafine-TiO2 Particles: Differential Responses Related to Surface Properties, David B. Warheit, Thomas R. Webb, Kenneth L. Reed, Scott Frerichs, and Christie M. Sayes, DuPont Haskell Laboratory for Health and Environmental Sciences, Newark, DE, USA

Water Solubility	Insoluble	
Vapor Pressure	A refractory solid, negligible at normal processing temperatures	m.p. = 1830-1850 C b.p. = 2500-3000 C
Adsorption / Desorption Coefficients in Release Medium (Soil/Sludge)	No established methods for differentiating naturally occurring titanium dioxide from titanium dioxide contained in DuPont™ Light Stabilizer in soil or sludge.	
Aggregation or disaggregation in applicable exposure medium		
Fate in porous media, such as groundwater aquifers, water treatment sand filtration systems and landfills (with soil cover).	Literature suggests nanomaterials are likely to be retained on porous media due to large diffusivity of small particles, combined with high ionic strength of these waters.	Wiesner et al., 2006 [8]
Fate in surface water, landfill leachate and wastewater treatment plants	Particles are expected to aggregate in aqueous environment and could form settleable colloids.	Wiesner et al., 2006
Fate in air	For Risk Assessment assume worst-case scenario of no aggregation, i.e., that particles remain completely dispersed and suspended in air compartment and are not removed via deposition.	
Persistence potential screen		
Biodegradability test (organic-based materials only)	Test is not applicable because this is an inorganic material that does not biodegrade. TiO2 is abundant in the environment.	
Photodegradability / Phototransformation	Refractory oxide – will not photodegrade or transform	
Stability in water (hydrolysis)	Fully oxidized, will not hydrolyze	
Bioaccumulation potential screen		
Octanol-Water Air/Water Partition Coefficient	Method not developed for nanomaterials.	
Bioconcentration Factor (BCF)	Method not developed	
Bioaccumulation Factor (BAF)	Method not developed	
Safety Hazard Data		
Flammability	Non-combustible	Fully oxidized
Explosivity	Non-explosive refractory oxide	Fully oxidized
Incompatibility	No known incompatibility	
Reactivity	Not catalytically active	
Corrosivity	Non-corrosive	

[8] Weisner, M. R., Lowry, G. V., Alvarez, P., Dionysiou, D., Biswas, P. 2006. "Assessing the Risks of Manufactured Nanomaterials". Enviro Sci Tech, July 15, 2006, p 4337.

Additional tests on an "as needed basis"

Nanomaterial Lifecycle Hazard Profile — Additional Tests As Needed		
Route	**Hazard** (e.g., low, moderate, high)	**Source of Information** (e.g., report number)
Health Hazard Data — Additional tests as needed		
Biological fate and behavior		
Chronic inhalation studies		
Chronic oral studies		
Chronic dermal irritation/sensitization studies		
Reproductive and developmental toxicity		
Neurotoxicity Studies		
More extensive genotoxicity studies		
Focused toxicity studies		
Environmental Hazard Data — Additional tests as needed		
ADME studies on aquatic organisms		
Chronic toxicity to soil microorganisms and sediment- and soil dwelling organisms		
Further testing for terrestrial toxicity		
Avian Toxicity		
Population/ecosystem level studies		
Environmental Fate Data — Additional tests as needed		
Activated sludge respiration inhibition		
Microorganism toxicity		
Persistence potential in relevant media		
Potential for transformations via oxidation-reduction reactions		
Safety Hazard Data — Additional tests as needed		
Stability		
Decomposition		
Polymerization		
Photoactivity		

* assumes valid method exists

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Step 2C – Develop Lifecycle Exposure Profile

The purpose of this Step is to assess potential for exposure from direct or indirect human contact or release to the environment at each stage of the lifecycle. The key deliverable is the **Exposure Characterization** – a summary and synthesis of the gathered exposure information.

Summary:
Exposure potential is expected to be low throughout the lifecycle (see Exposure Assessment 2.c.3 for additional information). Exposure potential is expected to be low under normal operating conditions in dry powder synthesis and packaging areas where the potential is the greatest. Exposure is low due to effective use of personal protective equipment, engineering controls, and effective work procedures. Personal protective equipment including safety glasses and gloves are used. Protective coveralls are available to workers. Half-mask cartridge respirators with P100 filters are used if AEL is exceeded. P100 cartridge filter media of the type used with the half-mask respirator have been tested by DuPont and the NOSH consortium and shown to be effective for filtering nanoparticles[9].

Personnel monitoring and area monitoring have been completed during production and handling of DuPont™ Light Stabilizer, including packaging tests, to assure exposure remains well below the acceptable exposure limit (AEL) (see section 2.c.3.1 for more information on monitoring). This AEL was set by experts from Haskell Laboratory after review of available data including published data. Personnel and area monitoring results are on record at the plant. Personnel monitoring and area monitoring will be completed during non-routine equipment clean-out procedures and spill cleanup.

DuPont has incorporated DuPont™ Light Stabilizer into polymers in processing equipment similar to that expected to be used in customer's polymer processing areas. Procedures and recommendations for safe handing have been developed. With use of proper procedures and personal protective equipment, exposure potential is expected to be low. Product use, storage and handling bulletins will be provided to customers and on-site consultation is available. Recommended acceptable exposure limits, personal protective equipment and engineering controls are provided in the bulletin.

Once incorporated into polymer DuPont™ Light Stabilizer is encapsulated by the polymer and exposure potential to workers and consumers is expected to be low.

Adequacy of personal protective equipment and workplace monitoring is an important concern that is being addressed by DuPont and others. DuPont is a founding member of the Nanoparticle Occupational Safety and Health (NOSH) consortium. The consortium includes international industrial, academic, government and non-governmental

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[9] Publication in preparation by NOSH consortium. NOSH work is described at http://www.aip.org/ca/2006/ostraat.html. Also see http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/101206/pdfs/1012_TRB%20Posters.pdf

organizations assembled for the purpose of obtaining information on occupational safety and health associated with aerosol nanoparticles and workplace exposure monitoring and protocols. The three main technical goals of the consortium are 1) the development of a method to generate a well-characterized aerosol of solid nanoparticles and to measure aerosol behavior as a function of time; 2) the development of an air sampling method that can be used on a day-to-day basis to conduct worker exposure assessments in workplace settings; and 3) the ability to measure barrier efficiency of commercially available filter media with respect to specific engineered aerosol nanoparticles. [10] Results from studies conducted by the NOSH consortium have been considered in specifying personal protective equipment used for the manufacture and handling of DuPont™ Light Stabilizers.

Further exposure summary information can be found in the **Exposure Characterization** on page 33.

Data needs and actions:

- Perform personnel monitoring and area monitoring during non-routine equipment clean-out procedures and during spill cleanup.
- Finalize documentation of spill procedures. (underway)
- Finalize documentation of recycle procedures, minimizing waste. (underway)
- Finalize recommended procedures for powder users by time of shipment of first samples to customers. (underway)

Area sampling and cleanout procedures are established and recorded in Standard Job Procedures (SJPs). Special procedures for spill cleanup, powder recycle, and powder waste disposal must be established and recorded in SJPs. Powder recycle is the preferred solution.

Potential for Direct Human Contact - Summary Table			
Lifecycle Stage*	**Particle Manufacture**		
Material Form	Powder		
Material	DuPont™ Light Stabilizer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
Synthesis	• Safety glasses • Gloves	• Enclosed process system	No potential for exposure during routine operation
Particle Conditioning	• Safety glasses • Gloves	• Enclosed process system • Aqueous slurry	Minor potential for dermal exposure during slurry

[10] See M. Ostraat in AIP Industrial Physics Forum, 2006 http://www.aip.org/ca/2006/ostraat.html

			sampling
Separations	• Safety glasses • Gloves	• Splash guards in place • Aqueous slurry	Potential for dermal exposure
Storage	• Safety glasses • Gloves	• Enclosed process system • Aqueous slurry	Minor potential for dermal exposure during slurry sampling
Processing	• Safety glasses • Gloves	• Enclosed process system • Aqueous slurry	Minor potential for dermal exposure during slurry sampling
Separation #1	• Safety glasses • Gloves	• Enclosed process system • Baghouse operates under negative pressure	Minor potential for inhalation exposure during sampling
Separation #2	• Safety glasses • Gloves	• Enclosed process system • Baghouse operates under negative pressure • Barometric Condenser (water spray)	Minor potential for inhalation exposure during baghouse sampling
Storage – Packer Bins	• Safety glasses • Gloves	• Enclosed process system • Packer bin operates under negative pressure	Minor potential for inhalation exposure during packer bin sampling
Packaging – Packaging Area	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available	• Local exhaust ventilation • Automatic packing	Potential for inhalation exposure during packing
Storage/Shipping	• Safety glasses • Gloves	• Bags are palletized and stretch-wrapped	
Maintenance	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available	• Local exhaust ventilation sometimes used	• Potential for inhalation exposure • Non-routine operations that happen infrequently
Quality Control Testing	• Safety Glasses • Nitrile Gloves available	• Local exhaust ventilation	• Limited potential for exposure
Slurry Spill Cleanup	• Safety Glasses • Gloves		Minor potential for dermal exposure
Powder Spill Cleanup	• Safety Glasses • Gloves • Half-mask respirator w/P100 cartridge if DuPont AEL		Potential for short-term inhalation exposure

	exceeded • Coveralls available		
Recycle/Waste disposal	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available		Estimated duration of exposure for bag recycling: 30 minutes per 12 hour shift,: 1 time per month No potential exposure for wastewater treatment operators.
Package Disposal	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available	•	Potential for short-term inhalation exposure

Lifecycle Stage*	**Polymer Concentrate Manufacturer or Polymer Compounder** - Incorporate into polymer matrix		
Material Form	Powder, Polymer Composite		
Material	DuPont™ Light Stabilizer, Polymer Resin		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
Product Receiving/Warehousing	• Safety glasses • Gloves	• Bags are palletized and stretch-wrapped	
Feed Hopper Loading	• Half-mask respirator w/P100 cartridge if if DuPont AEL exceeded • Safety glasses • Gloves • Coveralls	• Containment and local exhaust ventilation	Potential for inhalation exposure
Polymer Concentrate Manufacture - Compounding, Extrusion, Pellet Forming	• Safety glasses • Gloves		
Polymer Concentrate Packaging	• Safety glasses • Gloves		
Polymer Concentrate Warehousing	• Safety glasses • Gloves		
Maintenance – Feed Hopper or ventilation system	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available	• Local exhaust ventilation sometimes used	• Potential for inhalation exposure • Non-routine operations that happen infrequently
Powder Spill Cleanup/Disposal	• Safety Glasses • Gloves • Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Coveralls		Potential for short-term inhalation exposure

	available		
Packaging Disposal	• Half-mask respirator w/P100 cartridge if DuPont AEL exceeded • Safety Glasses • Gloves • Coveralls available		Potential for short-term inhalation exposure
Lifecycle Stage*	**Resin molders Film producers Extrusion producers**		
Material Form	Resin Pellets		
Material	DuPont™ Light Stabilizer incorporated into Polymer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
All steps in this stage			**De minimus exposure potential**
Lifecycle Stage*	**Original Equipment Manufacturers Packagers Customers for shapes, parts, films, fibers**		
Material Form	Parts		
Material	DuPont™ Light Stabilizer incorporated into Polymer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
All steps in this stage			**De minimus exposure potential**
Lifecycle Stage*	**Plastic Product Use**		
Material Form	Parts, Shapes, Films, Fibers, etc…		
Material	DuPont™ Light Stabilizer incorporated into Polymer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
Distribution			**De minimus exposure potential**
Use			**De minimus exposure potential**
Lifecycle Stage*	**Plastic Product Waste Management**		
Material Form	Used Parts, Shapes, Films, Fibers, etc…		
Material	DuPont™ Light Stabilizer incorporated into Polymer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**

Collection			**De minimus exposure potential**
Landfill		• Leachate collection and wastewater treatment	**De minimus exposure potential**
Incineration		• Baghouse fly ash collection, bottom ash collection	**De minimus exposure potential**

Lifecycle Stage*	**Plastic Product Recycle**		
Material Form	Used Parts, Shapes, Films, Fibers, etc…		
Material	DuPont™ Light Stabilizer incorporated into Polymer		
Step (e.g. process step, transfer step, …)	**Personal Protection Equipment (PPE)**	**Engineering Controls**	**Exposure Potential**
Collection			**De minimus exposure potential**
Sorting			**De minimus exposure potential**
Size Reduction			**De minimus exposure potential**
Remelt/pellet formation			**De minimus exposure potential**
Remolding			**De minimus exposure potential**

<u>Elaboration</u>

Lifecycle Stage: ***Particle Manufacture***
Step Name: ***Synthesis/Separation***
Material Form: *Aqueous solution and dry powder*
Number of People Potentially Exposed: *There is little potential for exposure during particle synthesis and separation as the material is contained in enclosed processing equipment. Normally one or two operators may be present in the process area during manufacturing.*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*
Personal Protection Equipment: *Safety glasses, leather gloves, hard hat, long pants, half-mask respirator w/P100 cartridge if AEL is exceeded. Coveralls available. (see section 2.c.3.1)*
Engineering Controls: *Enclosed process system.*
Procedures: *Area sampling and cleanout procedures are established and recorded in Standard Job Procedures (SJPs). Special procedures for spill cleanup, powder recycle, and powder waste disposal must be established and recorded in SJPs. Powder recycle is the preferred solution.*

Estimated Exposure and Dose: *No potential for exposure under normal conditions. Exposure possible during sampling and cleanout but personal protective equipment is provided and area monitoring is done to assure exposure below acceptable exposure levels listed on MSDS sheet.*
Unknowns and Uncertainties: *Sampling and cleanout monitoring to be completed.*

Lifecycle Stage: ***Particle Manufacture***
Step Name: ***Powder packaging***
Material Form: *dry powder*
Number of People Potentially Exposed: *one per shift*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*
Personal Protection Equipment: *safety glasses, leather gloves, hard hat, long pants, half-mask respirator w/P100 cartridge if AEL is exceeded. Coveralls available.*
Engineering Controls: *contained in equipment, bins and automatic bag packer*
Procedures: *Procedures are established and recorded in Standard Job Procedures (SJPs) available on the plant computer system. Special procedures for spill cleanup, powder recycle, and powder waste disposal must be established and recorded in SJPs. Powder recycle is the preferred solution.*
Estimated Exposure and Dose: *Area and personnel monitoring has been performed to assure that exposure remains below the acceptable exposure limit listed on the MSDS sheet.*
Unknowns and Uncertainties: *Spill cleanup monitoring to be completed.*

Lifecycle Stage: ***Particle Manufacture***
Step Name: ***Equipment Maintenance***
Material Form: *dry powder*
Number of People Potentially Exposed: *two per shift*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*
Personal Protection Equipment: *safety glasses, leather gloves, hard hat, long pants, half-mask respirator w/P100 cartridge if AEL exceeded, coveralls available.*
Engineering Controls: *local exhaust ventilation sometimes used.*
Procedures: *Procedures are established and recorded in Standard Job Procedures (SJPs) available on the plant computer system. Special procedures for spill cleanup, powder recycle, and powder waste disposal must be established and recorded in SJPs. Powder recycle is the preferred solution.*
Estimated Exposure and Dose: *Area and personnel monitoring will be performed to assure that exposure remains below the acceptable exposure limit listed on the MSDS sheet.*
Unknowns and Uncertainties: *Spill cleanup monitoring to be completed.*

Lifecycle Stage: ***Particle Manufacture or Customer powder handling***
Step Name: ***Spill Cleanup***
Material Form: *dry powder*
Number of People Potentially Exposed: *one to two*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*

Personal Protection Equipment: S*afety glasses, gloves, hard hat, long pants, half-mask respirator w/P100 cartridge if AEL exceeded, coveralls available.*
Engineering Controls: *local exhaust ventilation sometimes in area*
Procedures: *DuPont procedures are established and recorded in Standard Job Procedures (SJPs) available on the plant computer system. Special procedures are being established for spill cleanup, powder recycle, and powder waste disposal and recorded in SJPs. Powder recycle is the preferred solution. Dampening powder with water will agglomerate the powder and reduce inhalation potential. Recommended procedures will be conveyed to customers.*
Estimated Exposure and Dose: *Personnel monitoring to be been performed in DuPont facilities to assure that exposure remains below the acceptable exposure limit listed on the MSDS sheet. Personnel monitoring should be performed by customers handling the material.*
Unknowns and Uncertainties: *Customer current engineering controls and procedures.*

Lifecycle Stage: ***Polymer Concentrate Manufacturer or Polymer Compounder***
Step Name: *Powder incorporation into polymer matrix*
Material Form: *dry powder transformed to polymer composite*
Number of People Potentially Exposed: *to be determined, typically one per shift in similar DuPont facilities.*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*
Personal Protection Equipment: *Recommended safety glasses, leather gloves, hard hat, long pants, Coveralls available, recommend that respirator w/P100 cartridge be worn during powder pouring into feed bins.*
Engineering Controls: *Recommend local ventilation systems*
Procedures: *Procedures for minimizing dusting during material transfer will be provided to customers. Recommend that procedures for spill cleanup, powder recycle, and powder waste disposal be established and recorded in SJPs. DuPont recommendations will be provided. Powder recycle is the preferred solution.*
Estimated Exposure and Dose: *Area monitoring will be recommended so that customers can assure that exposure remains below the acceptable exposure limit listed on the MSDS sheet.*
Unknowns and Uncertainties: *Customers may have existing procedures for handling ultrafine powders such as fumed silica, colored pigments and carbon black.*

Lifecycle Stages: ***Resin Manufacture, Plastic Product Fabrication, Plastic Product Distribution, Plastic Product Use***
Once incorporated into a polymer matrix potential for human contact is expected to be de minimus. In the absence of a standard test, DuPont has performed internal grinding studies with other nanomaterials incorporated into polymer matrices. These studies show that for the materials tested grinding and abrasion of the polymer does not release nanoparticles.[11] Limited chemical extraction studies of pigmentary TiO2 also shows particles were not released under the conditions tested (see 2.c.3.3). The exposure potential from such release, if it were to occur, would be very low due to the low concentrations in the polymers and the low amount of material that could be released, if it

[11] K. Swain and D. Warheit, DuPont internal grinding study, 2006.

were possible. However, we are making a recommendation to repeat this test for DuPont™ Light Stabilizer (see Step 4).

Lifecycle Stage: ***Plastic Product Waste Management - Incineration***
Step Name: *Incineration*
Material Form: *Plastic composite*
Number of People Potentially Exposed: *one per shift*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal): *inhalation, dermal*
Personal Protection Equipment: *No special equipment is required other than that normally worn during these operations.*
Engineering Controls: *Bottom ash and flyash baghouse collection systems*
Procedures: *Procedures should be implemented for minimizing dusting during ash transfer because of the general dustiness of these materials.*
Estimated Exposure and Dose: *The concentration of material in a polymer part is low (<3%) and the number of parts containing this material in any given load of waste to be combusted is low. Material will be retained in bottom ash and in flyash captured by baghouses and will be at very low concentration.*
Unknowns and Uncertainties: removal efficiency

Lifecycle Stage: ***Plastic Product Waste Management - Landfill***
Step Name: *Landfill*
Material Form: *Plastic composite*
Number of People Potentially Exposed: *no potential for exposure*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal):
Personal Protection Equipment: *No special equipment is required other than that normally worn during these operations.*
Engineering Controls: *Leachate collection systems and wastewater treatment*
Procedures: *No special procedures are required*
Estimated Exposure and Dose: *No exposure to particles in nano form is anticipated. The concentration of material in a polymer part is low (<3%) and the number of parts contained in any given load of waste and any given landfill will be small. Further the material is encapsulated in plastic. Chemical extraction studies of pigmentary TiO2 also shows particles were not released (see 2.c.3.3). The exposure potential from such release, if it were to occur, would be very low due to the low concentrations in the polymers and the low amount of material that could be released, if it were possible. However, we are making a recommendation to repeat this test for DuPont™ Light Stabilizer (see Step 4).*
Unknowns and Uncertainties: *Extraction potential under acidic conditions mimicking landfill leachate has not been studied but based on the propensity for nanoparticles to be filtered out in porous environments, free particles are not expected to be present in the landfill (see 2.c.3.1)*

Lifecycle Stage: ***Plastic Product Recycle***
Step Name: *Collection, Sorting, Size Reduction (e.g. grinding), Remelt with Pellet Formation, Remolding*
Material Form: *Plastic composite*

Number of People Potentially Exposed: *no potential for exposure*
Potential Routes for Exposure (e.g. inhalation, ingestion, eye, dermal):
Personal Protection Equipment: *No special equipment is required other than that normally worn during these operations.*
Engineering Controls: *no special engineering controls required*
Procedures: *No special procedures are required*
Estimated Exposure and Dose: *No exposure to particles in nano form is anticipated. The material is fully encapsulated in the plastic. The concentration of material in a polymer part is low (<3%) and the number of parts contained in any given load of recycle material is small. Further, DuPont studies with other nanomaterials incorporated into polymer matrices shows that grinding and abrasion of the polymer does not release those nanoparticles.*[11]
Unknowns and Uncertainties: Exposure is expected to be sufficiently low that remaining uncertainties would not have an impact on the potential risk profile.

Potential for Environmental Release – Summary Table			
Lifecycle Stage*	**Particle Manufacture**		
Material Form	Powder		
Material	DuPont™ Light Stabilizer		
Step **(e.g. process step, transfer step, …)**	**Potential Release Medium (e.g., Air, Water, Soil)**	**Engineering Controls**	**Release Potential**
• Filtration Area filtrate • Barometric Condenser water • Process area wash water • Area stormwater	Water	Goes to wastewater treatment system for flocculation, settling and separation	Low discharge potential from treatment system to surface water (see elaboration)
• Separation #1	Air	Air is pretreated through baghouse filtration	Low discharge potential from stack to ambient air (see elaboration)
• Separation #2	Air	Filtration with total condenser and closed loop system	Negligible potential for air emissions
• Packaging – Packing Area	Air	Packing bins have dust collector, packing machine currently being used has no secondary dust collection.	Low discharge potential to ambient air confirmed by area monitoring
• Waste Disposal • Used Package Disposal	Land	Permitted Municipal Landfill with daily cover, leachate capture and treatment	Low discharge potential
• Wastewater Treatment Solids	Land	Permitted onsite landfill with leachate capture and onsite treatment	Low discharge potential

Lifecycle Stage*	**Polymer Concentrate Manufacture**		
Material Form	Powder, Pellets		
Material	DuPont™ Light Stabilizer, resin pellets		
Extrusion Compounding	Air	Containment, Ventilation	Potential should be determined on a case-by-case basis depending on equipment and controls

<u>Elaboration - Water</u>

Lifecycle Stage: *Particle Manufacture*
Step Name: *Filtration Area Filtrate, Barometric Condenser, Process Area Wash Water, Area Stormwater*
Material Form: *Aqueous dispersion*
Potential Release Medium (i.e., routes of entry) : *Water*
Engineering Controls: *Filtration, flocculation, separation*
Procedures: *Material is contained within process vessels and piping and no special operating procedures are required.*
Release Potential*: There is low discharge potential from treatment system to surface water. Effort is made to minimize loss of material during the manufacturing step. Small amounts of material will be present in certain aqueous process streams. These streams go to a wastewater treatment system where solids in these streams are effectively removed in a lamella using polymer flocculant addition. Testing of the engineering control device shows that it provides 99.3% removal efficiency. Solids recovered from this step are recycled back to the process. Subsequent separation steps provide additional removal. Solids removal by flocculant has been studied and reported in lab notebooks. These data serve as input to the Risk Assessment.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. For the extremely small concentrations that may enter surface water, the potential exists for settling into sediments.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Risk Assessment, Step 3.*
Unknowns and Uncertainties: *Uncertainties are low, estimated exposure is based on actual site waste water treatment test data and is documented in the risk assessment*

<u>Elaboration - Air</u>

Lifecycle Stage: *Particle Manufacture*
Step Name: *Separation* #1
Material Form: *dry powder*
Potential Release Medium (i.e., routes of entry) : *Air*
Engineering Controls: *Filtration*

Procedures: *Preventive maintenance is schedule for the baghouse to assure proper functioning of this equipment.*
Release Potential*: There is low discharge potential from stack to ambient air. Bag material selection has been made to assure maximum collection of product. Stack sampling showed that collection efficiency is greater than 99.98%.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. Material will likely enter surface water and land in extremely low concentrations.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Exposure Characterization below and in the Risk Assessment, framework Step 3.*
Unknowns and Uncertainties: *Uncertainties are low, estimated exposure based on actual site test data.*

Lifecycle Stage: *Particle Manufacture*
Step Name: *Separation #2*
Material Form: *dry powder*
Potential Release Medium (i.e., routes of entry) : *Air, water*
Engineering Controls: *Filtration to capture product followed by total condensation of filtrate stream and closed loop recirculation system.*
Procedures: *Material is contained, no special operating procedures are required.*
Release Potential*: There is negligible potential for air emissions. Water from the total condenser recirculates. Any time this recirculating water is replaced, the used water goes to the wastewater treatment facility for solids capture.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. For the very small concentrations that may enter surface water, the potential exists for settling into sediments.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Risk Assessment, Step 3.*
Unknowns and Uncertainties: *Uncertainties are low, estimated exposure based on actual site test data.*

Lifecycle Stage: *Particle Manufacture*
Step Name: *Packing Area*
Material Form: *dry powder*
Potential Release Medium (i.e., routes of entry) : *Air, water*
Engineering Controls: *Packing bins have dust collectors. Packing machine currently being used does not have secondary dust collection.*
Procedures: *If engineering controls are not adequate to keep exposure below the Acceptable Exposure Limit then additional personal protective equipment is mandated.*
Release Potential*: There is low discharge potential to ambient air confirmed by area monitoring.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. Material is contained within a building.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Risk Assessment, Step 3.*

Unknowns and Uncertainties: *Uncertainties are low, estimated exposure based on actual site test data.*

<u>Elaboration - Land</u>

Lifecycle Stage: *Particle Manufacture*
Step Name: *Waste disposal, Used package disposal*
Material Form: *powder, wet powder, largely agglomerated*
Potential Release Medium (i.e., routes of entry) : *Land*
Engineering Controls: *Permitted municipal landfill with daily cover, leachate capture and treatment.*
Procedures:
Release Potential*: There is low discharge potential from landfill. The material, when damp is very agglomerated. Further landfill has daily cover and leachate capture.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. Solids are likely to remain in the landfill solids.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Risk Assessment, Step 3.*
Unknowns and Uncertainties: *Uncertainties are low.*

Lifecycle Stage: *Particle Manufacture*
Step Name: *Wastewater treatment solids*
Material Form: *Wet agglomerated solids*
Potential Release Medium (i.e., routes of entry) : *Land*
Engineering Controls: *Permitted on-site landfill with leachate capture and onsite treatment.*
Procedures:
Release Potential*: There is low discharge potential from landfill. The material, when damp is very agglomerated. Further landfill has leachate capture.*
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): *Material will not degrade or transform. Material is likely to remain in the landfill solids.*
Estimated Exposure and Dose: *Estimates of exposure and dose can be found in the Risk Assessment, Step 3.*
Unknowns and Uncertainties: *Uncertainties are low.*

Exposure Data – Summary Table	
Nanomaterial Manufacture	
	Information
Stage of Development	Ready for commercial launch
Number and Location of Manufacturing Sites	1
Annual Production Volumes (current & expected)	Confidential – manufactured in relation to demand. Production will ramp up depending on customer demand. Production rate, ramp up rate and ultimate production are Confidential Business Information.
Manufacturing Site's NAICS code	325131
Manufacturing Method	DuPont Confidential Process
Number of workers exposed at the manufacturing site	Engineering controls and personal protection equipment are in place and exposure is minimized. Automatic packing equipment is used. 1 employee tends this auto packer in addition to several others auto packers. Equipment cleanout – up to 2 employees during equipment cleanout

Industrial Functions (e.g., adhesive, coloring agent, etc…)	Percent of Production	Physical Form & Concentration
Function 1: Light Stabilizer	100%	Composite material typically at <3% concentration
Function 2: tbd		
Function 3:		
Function n:		

Material Processing	
Type of downstream industrial processing or use	Polymer processing
Number of processing or commercial use sites	To be determined, thought to ultimately be <250 polymer processing sites worldwide (estimated)
NAICS code of processors	325211

Industrial Functions	Percent of Production	Number of Sites	Numbers of Workers at Site	Number of Workers Exposed
Function 1: Light stabilizer	100%	<250 (estimated)	tbd	1/site/shift (estimated)
Function 2: tbd				
Function 3:				
Function n:				

Material Use					
Commercial or Consumer Product Types	Percent of Production	Setting for Use (homes, outdoors)	Concentration in Product	Released during Use?	Est. Number of Exposed Users
Product Type 1: Plastic Articles	100% initially	Many uses: business, home, indoor outdoor	<3%	no	No exposure, encapsualted in plastic

Product Type 2: tbd					
Product Type 3:					
Product Type n:					

Distribution/Storage		
Methods of Delivery & Storage		
Manufacture	Plastic bags/pallets/trucks/warehouse	
Processors	Plastic bags/pallets/trucks/warehouse	
Distributors	Bound in various polymer products	
Retailers	Bound in various polymer products	
Consumers	Bound in various polymer products	
Post-Use Management		
	Expected disposal methods	**Expected Recovery/Reuse/Recycle Methods**
Manufacturer	Lined landfill	Recycle with reprocessing to product
Processors	Lined or municipal landfill	Recycle with reprocessing to product
End-Users	• municipal landfills (majority) • incineration	Recycle with reprocessing to other plastic products

Elaborate on the types of employees, handling practices, and environmental containment and control equipment used to mitigate exposure potential at the manufacturing site(s) and the downstream processing site(s).

Manufacturing Site

This material will be contained within process equipment throughout the manufacturing process. Manufacturing operators will monitor and control the manufacturing process. The material is in dry powder form for only a limited portion of the manufacturing process and while dry is still contained in process equipment. Any spill of material from the process equipment and cleaning of process equipment will be collected by manufacturing operators and these operators will be wearing prescribed personal protective equipment to minimize exposure.

Packaging will be done by automatic packing machines. Plastic bags will be used and these bags will be automatically palletized and stretch wrapped for warehouse storage and shipment. Packaging and storage spills will be cleaned up by operators and these operators will be wearing prescribed personal protective equipment to minimize exposure. Spilled material will be recycled where possible, and where not possible placed in sealed containers for disposal in a lined landfill.

Polymer Processing Sites

This material will be consumed by discharging from plastic bags into hoppers of polymer processing equipment. At DuPont's polymer processing site worker exposure will be minimized through 1) engineering controls including dust collection from the feed bin area, and 2) prescribed personal protective. Spilled material will be recycled where possible and where not possible placed in sealed containers for disposal. DuPont recommends similar procedures be followed at non-DuPont facilities.

Elaborate on the use the material in commercial and/or consumer products. Is there potential for exposure to the nanomaterial? If so, describe the circumstances. Describe any recommended controls for use. Describe recovery or recall techniques. Are the products intended to be used by children or other sensitive populations?

Potential for exposure in commercial and consumer product is low. The material is encapsulated in a polymer matrix and is no longer available as a free material. In this form there is no exposure to anyone using the product. No special controls are necessary for use in this form.

Elaborate on the Post-Use Management of the material across the Lifecycle:

The material is encapsulated in a polymer matrix and is no longer available as a free material. The material will typically be used at 3% or less concentration in selected plastics. The amount of plastic material being recycled or disposed of at any one time that contains this material will be very small. Plastics containing this material will be recycled or largely go to landfill. As with any plastic material, a portion will go to incineration.

- -

Exposure Characterization

In preparation for the Risk Evaluation of Step 3, an Exposure Characterization must be performed. Risk is based on both potential for exposure and hazard of the material. Toxicity tests performed in Step 2B to characterize the Lifecycle Hazard Profile indicate that DuPont™ Light Stabilizers are low toxicity materials. The Exposure Characterization identifies and characterizes the potential for human and environmental exposures throughout the product lifecycle. For each of the lifecycle profile stages shown in Figure 2, the potential for release was assessed in a detailed fashion. The results of this assessment were captured in a template which is included in the DuPont internal document "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer" and summarized in the following sections. Assumptions used in assessing exposure are described throughout the assessment discussion.

2.c.1 General Information on Use

The majority of titanium dioxide produced and marketed globally today is pigmentary titanium dioxide used to impart whiteness into paints, plastics, and paper. Pigmentary titanium dioxide has a median particle size in the range of 250 –350 nm, which is more than two times larger in size than DuPont™ Light Stabilizer. Over 11 billion pounds of titanium dioxide are produced and consumed each year. Ultrafine TiO_2 has been sold commercially for over 30 years and has been approved for use in sunscreens for over a decade. Global production of ultrafine TiO_2 is thought to be less than 0.25% of all titanium dioxide produced. DuPont's intended ultimate production represents <0.1% of the global production of all titanium dioxide.

2.c.2 Conceptual Exposure Model

A conceptual exposure model aids with visualizing the potential exposures to a material that may result during its production and use. At each lifecycle stage, the conceptual model provides a graphic representation of the exposure pathways (combinations of sources, exposure media, and exposure routes) and potentially exposed populations (called receptors) for a given chemical. The model also includes documentation of which exposure pathway-receptor combinations do not lead to exposure, which pathways are inconsequential due to insignificant release of material, which pathways are evaluated qualitatively, and which pathways are evaluated quantitatively. The conceptual exposure model for DuPont™ Light Stabilizer is shown in Figure 3 and is based on information in the document "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer".

Figure 3 - Conceptual Exposure Model

Potential Pathways				Potential Receptors			
Lifecycle Stage	**Emission Source**	**Exposure Medium**	**Exposure Route**	**Production Workers**	**Community Members**	**Consumers**	**Aquatic Organisms**
Materials Manufacture and Packaging	Process Operations	Indoor Air	Inhalation	+	O	O	O
	Stack emissions	Outdoor Air	Inhalation	#	+	O	O
	Process wastewater	Surface Water	Ingestion	O	+	O	+
	Solid waste that is landfilled	Landfill Leachate	Ingestion	O	X	O	X
Product Fabrication	Process Operations	Indoor Air	Inhalation	U	O	O	O
	Stack emissions	Outdoor Air	Inhalation	#	O	O	O
	Process Wastewater	Surface Water	Ingestion	O	X	O	X
	Solid Waste that is landfilled	Landfill Leachate	Ingestion	O	X	O	X
Consumer Article Use	Weathered articles	Indoor or outdoor air	Inhalation	O	O	X	O
Post-Consumer Disposal-Landfill	Municipal Landfill	Landfill Leachate	Ingestion	O	X	O	X
Post-Consumer Disposal - Incinerator	Municipal Incinerator	Stack emissions	Inhalation	O	X	O	O
	Bottom Ash that is landfilled	Landfill Leachate	Ingestion	O	X	O	X

+ Pathway is evaluated quantitatively

O Receptor is not exposed to this emission source

 # Another complete pathway for the same receptor group would be expected to result in greater exposures

U Pathway is evaluated qualitatively; exposure is inconsequential if recommended worker practices are followed
X Inconsequential exposure due to insignificant release of material

2.c.3 Exposure Assessment

2.c.3.1 Particle Manufacturing, Packaging and Distribution

This lifecycle stage includes DuPont's ultrafine TiO2 particle manufacture.

Occupational Exposure

Particle manufacture takes place at a single DuPont facility with several workers per shift in the area. The manufacture of DuPont™ Light Stabilizer is primarily conducted in a closed process within process vessels and piping. The material is in wetted form when the material is open to the atmosphere, except in the case of packaging and some maintenance activities. Airborne material may be generated as a result of packaging, handling the packaged product, or from maintenance and cleanup activities. Airborne material is not expected to transform or react. Only a portion of DuPont™ Light Stabilizer is in the nano size range and this material agglomerates. For purposes of this assessment 100% of the material was assumed to be present in the nano-range and to resist agglomerating to larger particle sizes (worst case assumption). Manufacturing areas are equipped with mechanical ventilation. Air monitoring has been conducted in various operating areas, and results show air concentrations are less than 2 mg/m^3 and in most cases are not above the detectable limit of 0.3 mg/m^3 [12]. Indoor air monitoring is conducted frequently to ensure area concentrations are controlled. In preparation for commercial production, air monitoring was done for every packing test. Personnel are provided with safety glasses, coveralls, gloves and respirators in areas where there is a potential for higher airborne material. P100 cartridge filter media of the type used with the half-mask respirator has been tested and shown to be effective for filtering nanoparticles[13].

In summary, DuPont's particle manufacturing is a predominantly closed process. The material is in wetted form, eliminating dusting, when the process is open to the atmosphere, except in the case of packaging and some maintenance activities. Packaging areas are equipped with local exhaust ventilation and workers are provided with equipment to prevent dermal, optical and inhalation exposures. The potential for worker exposure to DuPont™ Light Stabilizer is minimal.

Community Exposure

DuPont manufacturing emissions from air and wastewater treatment facilities and waste disposal units have been considered for their potential for exposure to human receptors in the surrounding community. These emissions and the potential for community exposure are summarized in Table 5.

- Air emissions are treated in a baghouse for particulate removal prior to discharge from a single process stack. Stack tests were conducted to characterize emission rates during DuPont™ Light Stabilizer production.

[12] DuPont Facilities Services (DFS) 2006. "Industrial Hygiene Air Monitoring Report". DFS Industrial Hygiene Group, file # ES-06-182.

[13] Publication in preparation.

Stack emissions were used in a screening level air dispersion model using worst-case meteorological conditions to provide an estimate for community air concentrations, as shown in Table 5. (Reference document "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer", Appendix B containing the screening level modeling report.)

- Process wastewater containing DuPont™ Light Stabilizer is pre-treated for particle removal by a lamella settling unit prior to being treated in a series of wastewater settling basins where it is further removed prior to discharge from the permitted outfall. Treated effluent and cooling water are discharged to a river. The concentration of DuPont™ Light Stabilizer in the river is estimated to be 20 ug/L (20 ppb).

- Settling basin solids are disposed of in an on-site landfill. Leachate from the landfill is recycled back to the settling basin, which is already considered in this assessment.

- Solid waste from the process is disposed of at a local permitted landfill. Based on the propensity for nanoparticles to be filtered out in porous environments such as landfills (see Table 2B), DuPont™ Light Stabilizer is not expected to be present in the landfill leachate. In the unlikely event that DuPont™ Light Stabilizer was to enter the leachate, it is expected to be removed or rendered to undetectable concentrations in the municipal wastewater treatment plant where the landfill leachate is sent for treatment.

Table 5 Potential Community Exposure from Manufacturing

Emission Source	Release Medium	Media Concentration	Exposure Route
Stack Emission from Baghouse Treatment	Ambient Air	0.2 ug/m^3 in ambient air at fence line	Inhalation
On-Site Wastewater Settling Basins	Aqueous Effluent	20 ug/L in surface water receiving stream	Ingestion
On-Site Wastewater Settling Basins	Wastewater Settling Basin Solids	No release – solids to on-site landfill	No exposure potential
On-Site Landfill	Leachate	No release – leachate to on-site settling basins	No exposure potential
Municipal Landfill	Leachate	Insignificant – Low leachate volume to high volume municipal wastewater treatment plant.	No exposure potential

Environmental Exposure (Aquatic Organisms)

Discharge of treated effluent to the receiving stream was assessed for impact on aquatic organisms. The concentration in effluent is very low due to several stages of water treatment prior to discharge. Based on environmental fate and transport data collected in Table 2B, any ultrafine TiO2 particles inadvertently introduced to a surface water have the potential to agglomerate and settle. Titanium dioxide is a naturally occurring mineral commonly found in soils and sediments. The exposure assessment performed here assumes that all DuPont™ Light Stabilizer particles entering the surface water remain suspended and available to aquatic organisms, which is a worst case assumption. Therefore, the surface water concentrations calculated in Table 5 will be used as the exposure concentration for aquatic organisms. Further consideration will be given to assessing the potential for exposure of benthic or filter-feeding organisms.

2.c.3.2 Materials Incorporation, Packaging and Product Fabrication

This lifecycle stage includes both the production of polymer resin concentrates and intermediates containing DuPont™ Light Stabilizer and the various ways of processing resin pellets to fabricate a final product containing DuPont™ Light Stabilizer as a light stabilizer.

Occupational Exposure

The production of polymer resin intermediates containing DuPont™ Light Stabilizer involves blending dry powder into molten polymer to produce resin pellets. Product fabrication could include extrusion or various types of high temperature molding. The polymer can be processed into sheets, films parts, fibers or coatings. While these processes are conducted at elevated temperatures, temperatures are well below the melting and boiling points of TiO2. Therefore, it is not expected to liquefy, volatilize or otherwise transform during intermediate or final product fabrication. While the production of polymer resin and final products are usually not DuPont processes, DuPont does provide extensive technical information to its downstream customers as a part of its formal Product Stewardship program. At minimum, Material Safety Data Sheets (MSDS) and Product Use Storage and Handling (PUSH) documents are provided, and on-site consultation is available.

Due to lack of monitoring data during product fabrication, a quantitative assessment of occupational exposure is currently not available for this lifecycle stage. However, resin intermediate and product fabricators, while not DuPont sites, are provided with appropriate technical guidance from DuPont and are anticipated to protect their workers as recommended by DuPont's Product Stewardship guidance. The potential for worker exposure to DuPont™ Light Stabilizer is minimal if DuPont's technical guidance is followed.

Community Exposure

No information is currently available for emissions generated by polymer resin manufacturers or final product fabricators. However, because a) limited quantities are used relative to other materials at these site, and b) modest quantities of DuPont™ Light Stabilizer are contained in the polymer resin (<3% in final products), c) because the DuPont™ Light Stabilizer is captured by the polymer resin during processing, and d) and because the resin is not heated above the melting or boiling point of TiO2 during intermediate or final product fabrication, DuPont™ Light Stabilizer particles are expected to remain embedded in the polymer matrix and unavailable for release into the environment through air, water or solid waste disposal. It is unlikely that significant quantities would be released to the environment during incorporation and product manufacture.

Environmental Exposure (Aquatic Organisms)
This scenario cannot be evaluated quantitatively, due to lack of actual emissions data. However, because a) limited quantities are used relative to other materials at these site, and b) modest quantities of DuPont™ Light Stabilizer are contained in the polymer resin (<3% in final products), c) because the DuPont™ Light Stabilizer is captured by the polymer resin during processing, and d) and because the resin is not heated above the melting or boiling point of TiO2 during intermediate or final product fabrication, DuPont™ Light Stabilizer is expected to remain embedded in the polymer matrix and unavailable for release into the environment through air, water or solid waste disposal.

2.c.3.3 Consumer Article Use

DuPont™ Light Stabilizer can be incorporated into a variety of end products, including automotive interior parts, sporting goods, and films. For this assessment, outdoor furniture was selected as a surrogate consumer article because of its use in a residential setting. The potential exposure pathway to explore is the release of DuPont™ Light Stabilizer from the article as it weathers over time.

The maximum amount of DuPont™ Light Stabilizer in the end polymer product is usually 3% or less, so very little of the product is present in consumer article and available for release. The product is encapsulated in the polymer and weathering takes place over years. The combination of a low rate of release and expected low toxicity indicates that this pathway is unlikely to pose any significant risk.

Extraction studies were conducted to determine the potential migration of titanium dioxide from two types of polymer[14]. These test materials contained a similar alumina surface coating on pigment grade titanium dioxide with a particle size approximately three times that of the median size for DuPont's ultrafine TiO2. Because only 20% or less of DuPont's ultrafine TiO2 is actually nano-sized material, results from pigment grade extraction studies are one way to explore the migration of DuPont™ Light Stabilizer. Polymers were extracted at elevated temperatures with ethanol from 1 to 10 days, and the extract was analyzed for aluminum and titanium that may have leached from the polymer. All aluminum and titanium values were less than the limit of detection of 0.5 $\mu g/in^2$. DuPont is not suggesting that ethanol extraction studies should be standard protocol for simulating weathering of consumer articles, however these results are one indication of the integrity of encapsulation of DuPont™ Light Stabilizer in the polymer. .

[14] Hazelton Wisconsin, Inc., 1994. "Determination of Potential Migration from Low Density Polyethylene in Food-Simulating Solvents". HWI Study No. 6324-125, Madison, Wisconsin, November 30, 1994.

These test results, in addition to the low concentration of DuPont™ Light Stabilizer present in consumer articles and the fact the product is encapsulated in polymer, suggest that consumer articles are an unlikely source of exposure.

2.c.3.4 Post-Consumer Disposal

Post-consumer disposal of articles containing DuPont™ Light Stabilizer will be either in a municipal landfill or in a municipal incinerator. As discussed in the previous section on Consumer Article Use, DuPont™ Light Stabilizer is not expected to migrate from the polymer matrix., Extraction tests using ethanol are one indication of the integrity of encapsulation of the product in a polymer. These test revealed no detectable titanium. The low concentrations of DuPont™ Light Stabilizer in products, the likelihood that a low number of products containing DuPont™ Light Stabilizer will be present in any given landfill and the difficulty in extracting DuPont™ Light Stabilizer from polymer matrices suggest that release rates will be very low. In the unlikely event that material were released, literature suggests it is likely to be retained on porous media such as soil in the landfill.[15] Even so, most leachate from permitted municipal facilities is treated, where any DuPont™ Light Stabilizer would be rendered undetectable and/or removed through treatment. No environmental releases are expected from disposing of used consumer articles or end products in a municipal landfill.

Incineration of polymer containing DuPont™ Light Stabilizer is likely to combust the polymer; however the TiO2 will not be thermally degraded because incineration temperatures are below the melting and boiling points of the TiO2. Literature describing the fate of titanium dioxide in incinerators has shown that approximately 50% of the titanium dioxide will go to fly ash (entrained in offgas) and 50% will go to bottom ash (residual solids)[16].

While actual data are not available for a quantitative assessment, based on a weight-of-evidence approach, it is concluded that DuPont™ Light Stabilizer is unlikely to be a significant exposure concern in incinerator emissions. Most municipal incinerators are equipped with particulate removal equipment, such as a baghouse or electrostatic precipitator which would capture some, if not all, of the TiO2 in the fly ash. A baghouse has been used effectively for treatment of DuPont™ Light Stabilizer at the DuPont manufacturing site effectively removing >99.98%, lending support to the probability that particulate removal equipment in municipal incinerators would effectively capture any DuPont™ Light Stabilizer. Residual solids are expected to be contained in a landfill, which is not an exposure pathway of concern, as discussed earlier. It should also be noted that ultrafine TiO2 is not a new ingredient in consumer products having been included in sunscreens and wood coatings in the past. Based on current use rates for

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[15] Weisner, M. R., Lowry, G. V., Alvarez, P., Dionysiou, D., Biswas, P. 2006. "Assessing the Risks of Manufactured Nanomaterials". Enviro Sci Tech, July 15, 2006, p 4337.

[16] Fujimori, E., Iwata, S., Minamoto, K., Lee, K.-H., Itoh, A., Chiba, K., Haraguchi, H., 2004. "Partitionings and Kinetic Behaviors of Major-to-Ultratrace Elements between Industrial Waste Incineration Fly and Bottom Ashes as Studied by ICP-AES and ICP-MS". *Analytical Sciences*, 20 (1) p 189-194.

ultrafine TiO_2, DuPont will not be adding measurably to existing municipal incinerator loadings.

Thus, while the possibility that DuPont™ Light Stabilizer could be present in municipal incinerator emissions cannot be ruled out, it is expected that levels will be extremely small or non-detectable and thus not be of concern to the surrounding community. This conclusion is based on the relatively small DuPont contribution to existing loading, in addition to the likelihood that existing particulate removal systems will abate emissions to an acceptable degree. The potential for release to the environment and associated community exposure is low.

2.c.3.4.1 Exposure Assessment Summary

Exposure to DuPont™ Light Stabilizer used in a light stabilizing application is minimal throughout its product lifecycle because:
(1) Potential worker exposure is well-managed in industrial settings.
(2) Due to the low production, use of engineering controls, and inherently low volatility and low solubility, releases to the environment are expected to be low with respect to levels of human health or ecological concern, from manufacturing through waste disposal.
(3) The ultimate sink is a polymer matrix (end product) where it is retained unless incinerated. Environmental releases from incineration of polymer are not expected to be significant.

Inhalation is the primary potential exposure pathway for humans, although the potential for oral ingestion bears consideration. Dermal exposure is not a significant route of exposure for envisioned light stabilizing applications.

The exposure assessment for DuPont particle manufacture is robust considering the availability of indoor air monitoring data and measured emissions data. Uncertainties in the remainder of the exposure assessment stem from the lack of data for downstream manufacturers and municipal incinerators. However, information from literature and engineering calculations using conservative assumptions helped to reduce the uncertainty.

Step 3 – Evaluate Risks

A synthesis of information collected in Step 2 to produce a ***Risk Evaluation*** - estimates of the nature, likelihood, and magnitude of adverse effects on human health and the environment.

Summary:

3.a Human Health Risk

The risk assessment showed that human health risk is low. Based on a review of DuPont™ Light Stabilizer flow through commerce, there are limited opportunities for human exposure. Exposure to DuPont™ Light Stabilizer could occur during particle manufacture, potentially resulting in occupational exposures and community exposure from manufacturing emissions. These exposures were considered for risk characterization using the following health guidelines:

• For occupational exposures the acceptable exposure limit for inhalation is 2 mg/m3 for DuPont™ Light Stabilizer.

• For community inhalation, a calculation was performed to adjust the occupational acceptable exposure limit for extended exposure duration and uncertainty (in addition to uncertainties already included in the occupational exposure limit). This resulted in a long-term acceptable community exposure value of 0.048 mg/m3.[17]

• For ingestion, a No Observed Effect Level (NOEL) of 5000 mg/kg will be used as a point of comparison, taken from acute oral toxicity studies with rats.

3.a.1 Occupational Risk from Production

Occupational risk from manufacturing operations is a low potential risk. DuPont™ Light Stabilizer levels in working environments typically do not exceed 0.3 mg/m3 based on work area monitoring and personnel monitoring studies conducted by DuPont. These levels are well below the 2 mg/m3 AEL for DuPont™ Light Stabilizer.

3.a.2 Community Risk from Manufacturing Emissions

Community exposure from manufacturing air emissions is a low potential risk. Maximum DuPont™ Light Stabilizer levels in ambient air were estimated to be 0.0002 mg/m3, based on conservative air dispersion modeling. These levels are well below the 0.048 mg/m3 community inhalation benchmark derived for DuPont™ Light Stabilizer.

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[17] Following practices used by the Minnesota Department of Health, the 8-hour worker exposure benchmark was converted to a chronic benchmark by applying a factor of 4.2 to account for 7 days a week and 24 hours a day of exposure, as opposed to 5 days a week, 8 hours a day (http://www.health.state.mn.us/divs/eh/risk/guidance/essievs.html). An additional 10-fold uncertainty factor was applied to account for potentially sensitive populations in the community as per EPA's Framework for Assessing Health Risks for Environmental Exposures to Children (EPA/600/R-05/093F, Sept 2006, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363).

Surface water concentrations in the receiving stream adjacent to the manufacturing site were estimated to be 20 ug/l (ppb). In the unlikely event surface water was ingested on a daily basis, a daily intake of 5.7x10-4 mg/kg/day was calculated. This calculated dose can be compared to the ingestion NOEL of 5000 mg/kg/day to develop a margin of exposure (MOE) or safety factor. The calculated MOE for ingesting surface water is over 8,000,000 . EPA often uses a range of 100 to 1000 as being an acceptable MOE. Community risk from surface water ingestion is a low potential risk, based on the MOE approach.

3.b Ecological Risk

Surface water concentrations can be compared to the NOEC of 10 mg/L for green algae, which was the most sensitive ecological species tested with DuPont™ Light Stabilizer. The calculated concentration in the effluent prior to discharge is 3 mg/L, which is more than 3 times below the NOEC (No Observable Effect Concentration) before any mixing with the river. Once the discharge enters the river, mixing and dilution will lower the concentration in the river. Based on minimum river flow rate and maximum plant discharge flowrate the calculated surface water concentrations were 200 times below the ecological level of concern; thus risk to aquatic organisms from DuPont™ Light Stabilizer manufacture is low.

3.c Conclusions

Results of the risk characterization are summarized in Table 6. DuPont™ Light Stabilizer is a low toxicity compound with low acute oral or pulmonary toxicity, and is not a skin irritant or sensitizer. The primary exposure route of interest is inhalation. Risk of adverse occupational health effects during manufacturing and processing is low. If exposure monitoring shows levels above the AEL then recommended industrial hygiene measures and engineering controls are necessary. Estimated community exposures to manufacturing emissions are well below levels of concern in air and water. Further, the intended use of commercial or consumer products containing DuPont™ Light Stabilizer presents no substantive adverse health risk, based on tests which showed titanium dioxide is not expected to migrate from end products during use. The ultimate sink for DuPont™ Light Stabilizer is a polymer matrix (end product) where it is retained unless incinerated. Environmental releases from incineration of polymers are not expected to be significant, Finally, DuPont™ Light Stabilizer is not expected to be present at concentrations approaching concern in ecosystems. Based on a review of DuPont™ Light Stabilizer flow through commerce, this assessment concludes that there are no potentially substantive adverse health or environmental risk issues associated with its manufacture, processing, use or disposal.

Table 6. Risk Characterization Results

Potential Pathways				Potential Risk to Receptor			
Lifecycle Stage	Emission Source	Exposure Medium	Exposure Route	Production Workers	Community Members	Consumers	Aquatic Organisms
Materials Manufacture and Packaging	Process Operations	Indoor Air	Inhalation	Low	Not Applicable	Not Applicable	Not Applicable
	Stack emissions	Outdoor Air	Inhalation	Low	Low	Not Applicable	Not Applicable
	Process wastewater	Surface Water	Ingestion	Not Applicable	Low	Not Applicable	Low
	Solid waste that is landfilled	Landfill Leachate	Ingestion	Not Applicable	Low	Not Applicable	Low
Product Fabrication	Process Operations	Indoor Air	Inhalation	Low	Not Applicable	Not Applicable	Not Applicable
	Stack emissions	Outdoor Air	Inhalation	Low	Not Applicable	Not Applicable	Not Applicable
	Process Wastewater	Surface Water	Ingestion	Not Applicable	Low	Not Applicable	Low
	Solid Waste that is landfilled	Landfill Leachate	Ingestion	Not Applicable	Low	Not Applicable	Low
Consumer Article Use	Weathered articles	Indoor or outdoor air	Inhalation	Not Applicable	Not Applicable	Low	Not Applicable
Post-Consumer Disposal-Landfill	Municipal Landfill	Landfill Leachate	Ingestion	Not Applicable	Low	Not Applicable	Low
Post-Consumer Disposal - Incinerator	Municipal Incinerator	Stack emissions	Inhalation	Not Applicable	Low	Not Applicable	Not Applicable
	Bottom Ash that is landfilled	Landfill Leachate	Ingestion	Not Applicable	Low	Not Applicable	Low

Data needs and actions:
Data needs and actions outlined in previous sections may be pertinent to the Risk Assessment. Our current assessment suggests that the material is well-managed, given current management practices. As further information is obtained, the Risk Assessment will be refined to include this new information.

Risk Evaluation – Summary Table*		
Risk Type	**Nature, Magnitude, and Probability**	**Source(s) of Risk Assessment**
Human		
Respiratory	Nature: Inhalation of airborne material in a manufacturing setting and from municipal incinerator. Magnitude: Below levels of health concern Probability: Potential for risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"
Dermal	Nature: Worker contact with material in a manufacturing setting. Magnitude: Low Probability: Potential for risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"
Ingestion	Nature: If material in surface water eventually was used as drinking water source. Magnitude: Low Probability: Potential for risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"
Environmental		
Aquatic	Nature: Surface water Magnitude: Low Probability: Potential for risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"
Terrestrial	Nature: Land Magnitude: Low Probability: Potential for exposure and risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"
Additional		
Eye irritation	Nature: Eye irritation in a manufacturing environment Magnitude: Low Probability: Potential for risk to receptors is low	DuPont internal Risk Assessment - "Environmental, Health and Safety Assessment, DuPont™ Light Stabilizer"

Step 4 – Assess Risk Management

Determine how to minimize or eliminate any potential adverse impacts throughout the product's lifecycle. The key deliverable from Step 4 is the ***Plan for Risk Management*** – a summary of the gathered exposure information and a plan for risk management, monitoring, compliance and reporting.

Summary:

Based on a review of DuPont™ Light Stabilizer flow through commerce, the Risk Assessment in Step 3c concludes that there are no substantive risk issues associated with its manufacture, processing, use or disposal.

Site personnel associated with this product have been informed of the Acceptable Exposure Limit and practices for managing potential exposure. Results of personal monitoring have been shared with these work groups. Broader communications to all site personnel will be accomplished before commercialization of this product.

The community will be apprised of this project through the Community Advisory Panel.

Data needs and actions:

- A study of migration of DuPont™ Light Stabilizer 210 from polymers will be performed to assure that this material behaves similarly to pigmentary titanium dioxide.
- DuPont™ Light Stabilizer 210 will be included in a subsequent pulmonary instillation study to confirm pulmonary toxicity of the commercialized formula is similar to previously tested pre-commercial materials. Plans call for full histopathology in this study.
- Perform personnel monitoring and area monitoring during non-routine equipment clean-out procedures, area sampling, and during spill cleanup. If monitoring data is above AEL, special procedures must be established and recorded in Standard Job Procedures (SJPs). Powder recycle is the preferred solution for spills.
- Develop and document recycle procedures, minimizing waste.
- Recommended procedures for powder users. Issue these as "Product Use, Storage and Handling" (PUSH) bulletins.
- Packaging area and personnel monitoring will be repeated every 3 years or after a significant change occurs in the packaging process.

Review Cycle and Conditions:

- The next product stewardship review will be performed after 2 years of commercial sales.
- The subsequent product stewardship review cycle is 4 years maximum

- Triggers for an additional review include any significant change in production, processing or use pattern, any significant new exposure scenario, or any significant new hazard data.
- Process Hazards Analyses for manufacturing processes are performed on a 5 year frequency.

Plan and Timeline for Risk Management, Monitoring, Compliance and Reporting:

Material Safety & Handling – Nanomaterial Manufacturer		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Processing	• Perform personnel monitoring and area monitoring during non-routine equipment clean-out procedures . If above acceptable exposure limit implement additional engineering controls or personal protective equipment. • Establish non-routine equipment clean-out procedures and record in standard job procedures. Include procedure in Product Use, Storage and Handling bulletin. Assure workers are trained in procedures.	• Engineering controls or personal protective equipment would reduce exposure to below the acceptable exposure limit (AEL). • If Standard Job Procedures are followed exposure should be below AEL.
Storage	No action necessary	
Handling	• Record product handling procedures in standard job procedures and include procedure in Product Use, Storage and Handling bulletin. • Assure workers are trained in procedures.	• If product handling procedures are followed exposure should be below AEL.
Spills	• Perform personnel monitoring and area	• Engineering controls or personal protective

	monitoring during spill cleanup. . If above acceptable exposure limit implement additional engineering controls or personal protective equipment. • Establish cleanup procedures and record in standard job procedures. Include procedure in Product Use, Storage and Handling bulletin. • Assure workers are trained in procedures.	equipment would reduce exposure to below the acceptable exposure limit (AEL). • If Standard Job Procedures are followed exposure should be below AEL.
Transport	No action necessary	
Fire	No action necessary	
Packaging	• Record product handling procedures in standard job procedures. • Assure workers are trained in procedures.	• If product handling procedures are followed exposure should be below AEL.
Use	• Produce a Product Use, Storage and Handling bulletin.	• If product handling procedures are followed exposure should be below AEL.
Disposal (including packaging materials)	•	• If product handling procedures are followed exposure should be below AEL.
Other:		

Material Safety & Handling – Nanomaterial User		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Processing	See recommendations in Product Use, Storage and Handling bulletin.	If product handling procedures are followed exposure should be below AEL.
Storage	No action necessary	
Handling	See recommendations in Product Use, Storage and Handling bulletin.	If product handling procedures are followed exposure should be below AEL.
Spills	See recommendations in Product Use, Storage and Handling bulletin.	If product handling procedures are followed exposure should be below AEL.
Transport	No action necessary	
Fire	No action necessary	
Packaging	No action necessary	
Use	No action necessary	
Disposal (including packaging materials)	See recommendations in Product Use, Storage and Handling bulletin.	If product handling procedures are followed exposure should be below AEL.
Other:		

Material Safety & Handling – End Product User		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Storage	No action necessary	
Handling	No action necessary	
Spills	No action necessary	
Transport	No action necessary	
Fire	No action necessary	
Packaging	No action necessary	
Use	No action necessary	
Disposal (including packaging materials)	No action necessary	
Other:		

Material Safety & Handling (end of life)		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Processing	No action necessary	
Storage	No action necessary	
Handling	No action necessary	
Spills	No action necessary	
Transport	No action necessary	
Fire	No action necessary	
Packaging	No action necessary	
Use	No action necessary	
Disposal (including packaging materials)	No action necessary	
Other:		

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Step 5. Decide, Document and Act

Cross functional review team critically examines compiled information, analyzes the options, documents the resulting analysis, makes decisions and takes appropriate actions.

A cross-functional decision-making review team was assembled in June 2007 to critically review the compiled DuPont™ Light Stabilizer framework worksheet information, discuss the information with the product stewardship team, analyze the options, and to deliberate on any additional data needs or actions. The review team accepted the recommendation made in Step 4 for additional data needs and actions and approved moving forward to product announcement and subsequent commercial introduction.

Go/no-go/redirect decision and rationale: Approval to proceed to product announcement and subsequent commercial introduction.
Additional data needs: Data needs as recorded in Step 4
Additional data collection assignments: Data needs as recorded in Step 4 are to be followed by the product stewardship team.
Product steward: Gary Whiting
Review team: Product Steward, Product Stewardship Manager, Workforce Representative, Manufacturing Lead, Administrative Decision maker, Safety Officer, Legal Counsel
Product Review Cycle: Regular review 3Q2009, every 4 years thereafter
Needed Actions and Responsible Persons: Questions remaining after the meeting and requests for clarification have been addressed by the Product Stewardship team.

Step 6. Review and Adapt

User implements a series of periodic and as-needed reviews to ensure that the information, evaluations, decisions, and actions of the previous steps are kept up-to-date.

DuPont has scheduled reviews of DuPont™ Light Stabilizer 210 first in 3Q2009 and subsequently every 4 years thereafter. Additional "as-needed" risk reviews will be triggered by events such as applications in new market segments, significant changes in hazard or exposure information, or production volume beyond that anticipated in the current document.

List of reviews held (dates): Next regular review is scheduled for 3Q2009.
Conditions that triggered review(s): future action, to be determined
Changes made in report and rationale (e.g., changes to lifecycle profiles): future action, to be determined
Actions taken and rationale (e.g., revised risk management practices): future action, to be determined

Additional References: