DuPont™ Crystar® 6920 PET *poly-(ethylene terephthalate)* Resin with Sepiolite Clay, Pangel S-9 as an encapsulated nanodispersed filler

NANO RISK FRAMEWORK OUTPUT WORKSHEET
July 23, 2008 (GJS)

Nanomaterial Risk Assessment Document — [Sepiolite Clay, Pangel S-9]

Section 1: Describe Material and Its Applications

Develop basic descriptions — general overviews — of the nanoscale material and its intended uses.

General Overview:[1]

This Risk Assessment is based on the current Pre-Commercial stage of development for the nanoscale material application. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed will be obtained to facilitate the risk management process. Sepiolite (aka, DNM-1, by DuPont internal naming) is an existing TSCA listed substance. The Sepiolite is incorporated into DuPont's ***poly-(ethylene terephthalate)*** *(PET) resin, commercially known as Crystar®, via an in-situ polymerization process. The DNM-1 is added early in the process just after monomer formation and before the part of the process where molecular weight is further increased. The DNM-1 exfoliates in this early part of the process, going from an agglomerated particle nominally from 1µm to about 5µm in size to an exfoliated particle, in most cases, measuring approximately 20 nm by 200 nm.*
The DNM-1 does not react with or become part of the polymer chain. The DNM-1 is encapsulated within the polymer resin. Work at the DuPont Experimental Station and at DuPont Haskell Labs has been unsuccessful in creating, isolating, or detecting any release of DNM-1 particles from the polymer matrix. Incineration has yielded the same agglomerates of particles as found in nature and the original sepiolite as received from the supplier. Thus, the only nano-size material is found encapsulated within the polymer matrix where it poses no potential for direct or indirect contact.

Material Description: Sepiolite Clay, Pangel S-9

Material source or producer: *grade: Pangel S-9, Tolsa SA; Distributed by E. M. Sullivan*
Manufacturing process: *Mined as sepiolite clay with proprietary purification at the mine site, and then bagged (20# each).*
Appearance: *light cream, flocculent powder or pellets (ref: supplier MSDS)*
Chemical composition: *Primarily hydrated magnesium silicate with various mineral impurities. Less than 1% Quartz.*
Physical form/shape: *gross form is a flocculent, agglomerated powder; the agglomerate particles are on the order of about 1-5 microns (skewed toward the*

[1] The general overview should contain descriptions sufficient to guide development of more detailed profiles of the material's properties related to hazard and exposure potential at various lifecycle stages (such as manufacture, use, and end-of-life). This overview should be developed from information in the possession of the user or available in the literature.

upper size distribution) with clusters of 20nm by 200 nm (nominal) needles. There are few to no free needles.
Concentration: *nominal 99+%*
Size distribution: *average flocculent (or agglomerated) particle: 1-5 microns; the needles that make up the agglomerated clusters: est. 20 x 50 - 200 nm*
Solubility*: water: barely; organic solvents: insoluble*
State of aggregation or agglomeration: *very high in the neat state. low to moderate in polymer. There are some areas with high agglomeration due to processing limitations.*

Material CAS number (if applicable):

Material	CAS Number	Composition
Sepiolite clay (Mg silicate hydrated)	63800-37-3	99+%
Quartz (crystalline silica)	14808-60-7	<1%

Main applications (current or expected):

The application being considered here is using the sepiolite (Tolsa's Pangel S-9) as an additive in the resin that goes into CPET (Crystar® - poly-(ethylene terephthalate)), dual-ovenable, frozen food trays.

Sepiolite clay is commonly used in kitty litter and oil well drilling mud either in the neat form or pelletized with a simple binder. Some applications may use it as a prepared slurry. Sepiolite is also used in various applications as a rheological additive, as a polymer additive, and some pharmaceutical compounding in Europe.

Stage of development:

Pre-Commercial Development and Testing. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed will be obtained to facilitate the risk management and product stewardship process.

General physical and mechanical properties of this material:

In PET poly-(ethylene terephthalate), an increase in Heat Deflection Temperature (HDT) of near 20% in formed parts has been found with reduced creep and improved

tensile properties. This application was primarily for engineered or molded parts in moderate to high heat service where incumbent materials did not quite meet the demands of the application either due to price or performance.

Past experience with this material or a similar material:

DuPont Central Research and Development introduced this as a prospective polymer additive in 2004. In 2005 it was brought to DuPont Crystar® to be added to PET to examine the commercial production viability and produce resin for extended testing in an existing application under development. Other applications are under development.

Customers have been sampled for use in dual-ovenable, frozen food trays. Development work and the search for other opportunities of use continues.

Potential benefits/positives of the material:

The filled resin allows extended temperature use ranges and a more rigid article. This would extend the useful temperature range and safety in handling hot food trays. The sepiolite also has a notable effect of reducing combustibility (flame retardant) of final, formed articles made of PET.

Potential risks/negatives of the material:

Health: ***For the dual-ovenable, frozen food trays there are no recognized or perceived health issues for the PET articles. The sepiolite as raw material may pose an inhalation problem within the workplace operations if proper containment and controls with personnel protective equipment is not taken.***

Environmental*: The use of necessary fillers in plastics limits the recyclability since applications that are sensitive to extraneous fillers are excluded. Sepiolite is considered an inorganic clay and, by default, is considered bio-persistent. However, it is not considered deleterious to the environment.*

Sources of additional information:

The DuPont MSDS for Crystar® 6920 poly-(ethylene terephthalate) resin is readily available.

The MSDS for Pangel S-9, hydrated magnesium silicate with various mineral impurities. Less than 1% Quartz Tolsa SA; distributed by E. M. Sullivan is readily available.

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The open literature has quite a bit of information concerning sepiolite properties, applications, and sources. There is also a fair amount of information on the safety and health effects of sepiolite.

The resin, Crystar® 6920 and other synonyms of this composition, are determined to be compliant with Food Contact Notification(s) by DuPont Regulatory Affairs.

The DuPont Nanotechnology Advisory Team (DNAT) has advised that this material under the conditions of handling and application can be used safely. Any changes will be communicated by the discovering organization and a review will be necessary.

Discussions with DuPont Corporate Safety, Health, and Environmental experts, DNAT, and the Applied BioSciences Product Stewardship consultants indicate that the handling of sepiolite in the workplace-operations is a potential hazard when it is present as a free material, as received from vendors. The hazard is primarily inhalation if an aerosol is generated. Layers of protection incorporating administrative/procedural controls, engineering controls, and personnel protective equipment are in place to minimize the potential for exposure to the sepiolite particles. Each of these meets or exceeds manufacturer recommendations.

The safe handling and transport of the sepiolite as received from the supplier is not different from normal safe handling and transport in any other, existing application. It is important to note that stringent controls in handling have been, and will continue to be, enforced.

Section 2: Profile Lifecycles

Define and catalog the known and anticipated activities in a material's lifecycle in the following table, detailing both the product form and the operations and activities that occur at that stage of the product lifecycle. Include activities within the user's control as well as those activities upstream or downstream of the user.

Lifecycle Profile		
Material Lifecycle Stage	**Material Form(s)**	**Operations and Activities**
Material Sourcing (e.g., producer, supplier)	***Free mineral as received from the supplier in 20# bags or other containers as needed.***	***Raw Material – purified form of sepiolite as received from the supplier***
Manufacturing Level I (e.g., processor)	***Free mineral is slurried, then encapsulated into the polymer. No free sepiolite particles exist.***	***Sepiolite is slurried and introduced into polymerization process. The final polymer is produced as pellets with sepiolite dispersed and encapsulated within the polymer.***
Manufacturing Level II (e.g., product fabrication)	***Solid Polymer with various additives. The sepiolite is encapsulated in the PET poly-(ethylene terephthalate) resin.***	***The polymer is compounded with other additives and extruded to give a final product of dual-ovenable trays. These trays are inspected, trimmed, packaged, and shipped to food processors.***
Manufacturing Level III (e.g., filling/packaging)	***Solid Polymer with various additives. As described above.***	***Trays are filled with the food of choice, sealed, labeled, and put into final bulk packaging. Pasteurization or retort may be done as part of this process. The Bulk packages will be frozen and shipped to distribution.***
Distribution (e.g., retailer)	***Solid Polymer with various additives. As described above.***	***Commercial or retail food sales will receive the packaged food product and sell directly to the consumer or institutional users.***
Use/Reuse/Maintenance (e.g., consumer)	***Solid Polymer with various additives. As described above.***	***The product is unwrapped according to instructions, depending on microwave or convection cooking and prepared accordingly. Typically, the packaging is***

		not kept or reused.
End of Life (e.g., recycling, disposal)	***Solid Polymer with various additives, as above.***	***The trays will typically be sent to refuse pick-up and then to a landfill.***

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Section 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:
Sepiolite, Pangel S-9 with particle distribution of 1-5um's is produced by the manufacturer in a proprietary process. The sepiolite is received by DuPont as a flocculent, agglomerated powder in 20# bags. The sepiolite material is added to process equipment with poly-(ethylene terephthalate) (PET) resin, where the sepiolite produces nanoscale particles within the polymer resin through melt processing. The product of this process is polymer pellets where the Sepiolite nanoscale particles (20-50nm x200nm) are encapsulated by the PET resin. The pellets are used by targeted manufacturers of engineered or molded parts to produce dual-ovenable frozen food trays.
Data needs and actions:
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Lifecycles Properties — Summary Table			
Lifecycle Stage* ***Pre-Commercial Development***	***Raw Material***		
Technical or Commercial Name	***Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***		
Common Form	***Powder***		
	Result	***Method***	***Remarks******
Chemical Composition (including surface coatings)			
Component 1:***Sepiolite Clay***	***>99% by weight***		***MSDS***
Component 2:***Total quartz (Total Crystalline Silica)***	***<1% by weight***		***MSDS IARC:1, NTP:X***

			ACGIH:A2
Component n:			
Crystal Phase/Molecular Structure			
Physical Form/Shape	***Powder or pellets***		***MSDS***
Particle Size and Size Distribution	***1-5um***		***MSDS***
Surface Area	***320m^2/g***	***BET***	***MSDS***
Particle Density			
Solubility in water	***insoluble***		***MSDS***
Bulk Density	***60+/-30 gr./l***		***MSDS***
Agglomeration/Aggregation State	***Agglomerated powder (particles of 1-5um, w/clusters of 0.02X0.05-0.2um needles)***		***MSDS***
Porosity			
Surface Charge			

Lifecycles Properties — Summary Table			
Lifecycle Stage* ***Pre Commercial Development***	***Polymer matrix via processing***		
Technical or Commercial Name	***Crystar® - poly-(ethylene terephthalate) (DNM-1 Masterbatch) and Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***		
Common Form	***Pellets***		
	Result	**Method**	**Remarks*****
Chemical Composition (including surface coatings)			
Component 1: ***Crystar® - poly-(ethylene terephthalate)***	***>68%***		***MSDS***
Component 2: ***Unregulated Additives (Sepiolite Clay, Pangel S-9)***	***<31%***		***Confidential Business Information, MSDS***
Component n: ***Crystalline Silica***	***<0.3%***		***MSDS IARC:1, NTP:X ACGIH:A2***
Crystal Phase/Molecular Structure			
Physical Form/Shape	***Pellets***		***MSDS***

Particle Size and Size Distribution	***0.01 – 0.02um width X 100 – 200um length***		***Confidential Business Information - Particles encapsulated in the resin***
Surface Area			
Particle Density			
Solubility in water	***Insoluble***		***MSDS***
Bulk Density			
Agglomeration/Aggregation State			
Porosity			
Surface Charge			

Section 2B: Develop Lifecycle Hazard Profile
Gather information and characterize the material's potential health, environmental, and safety hazards over the entire lifecycle.

Summary:
This Risk Assessment is based on the current Pre-Commercial Stage of Development for the nanoscale material application. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed will be obtained to facilitate the risk management process.

Data needs and actions:
DuPont Haskell pulmonary bioassay screening study with Sepiolite – Hydrated Magnesium Silicate CAS # 63800-37-3 and Sepiolite Nanoclay – Organically Modified Hydrated Magnesium Silicate was conducted in rats. The histopathology results indicated that lung exposures to sepiolite particles produced evidence of multinucleate giant cells in airspaces and patchy evidence of minimal septal lung tissue thickening, suggesting the development of early phase lung fibrosis. Biological significance to be determined w/follow-up study.

Nanomaterial Lifecycle Hazard Profile — Base Set		
Route	**Hazard** (characterization [e.g., low, moderate, high] and quantification if available [e.g., LOAEL=x mg/kg])	**Source of Information** (e.g., report number)
Health Hazard Data		
1. Short-term Toxicity		
a. Pulmonary toxicity	***DuPont Haskell pulmonary***	***DuPont Haskell Pulmonary***

	bioassay screening study with Sepiolite – Hydrated Magnesium Silicate CAS # 63800-37-3 and Sepiolite Nanoclay – Organically Modified Hydrated Magnesium Silicate was conducted in rats. The histopathology results indicated that lung exposures to sepiolite particles produced evidence of multinucleate giant cells in airspaces and patchy evidence of minimal septal lung tissue thickening, suggesting the development of early phase lung fibrosis. Biological significance to be determined w/follow-up study.	***Bioassay screening study, TSCA 8(e) submittal***
b. Oral toxicity		
2. Skin sensitization/irritation		
3. Skin penetration*	***Exposure prevention measures put in place to prevent skin contact. No known validated method for nanoparticles.***	
4. Genotoxicity		
a. Gene mutation in prokaryotic cells		
b. Chromosomal aberration		
Environmental Hazard Data		
Aquatic Toxicity		
1. Fish (fathead minnow or trout)		
2. Invertebrate (Daphnia)		
3. Aquatic Plant (algae)		
Terrestrial Toxicity (if significant release to terrestrial environments)		
1. Earthworms		
2. Plants		
Environmental Fate Data		
Water Solubility	***Insoluble***	
Vapor Pressure		
Adsorption/Desorption Coefficients in Release Medium (Soil/Sludge)		

Persistence potential screen		
Bioaccumulation potential screen		

Base Set of Safety Hazard Data		
Flammability	***Non-flammable***	***MSDS***
Explosivity	***Not applicable***	***MSDS***
Incompatibility	***None known***	***MSDS***
Reactivity	***Stable in normal conditions***	***MSDS***
Corrosivity	***Not expected***	***MSDS***

Additional tests on an "as needed" basis

Nanomaterial Lifecycle Hazard Profile — Additional Tests		
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		

Section 2C: Develop Lifecycle Exposure Profile

Assess potential for exposure from direct human contact or release to the environment at each stage of the lifecycle. The key deliverable from Step 2C is the ***Exposure Characterization*** — a summary and synthesis of the gathered exposure information.

Summary:
Exposure potential is expected to be low throughout the lifecycle. Exposure potential is expected to be low under normal operating conditions in processing and packaging areas, where containment and control measures are implemented. Personnel monitoring and area monitoring of masterbatch preparation (Crystar® - poly-(ethylene terephthalate) (DNM-1 Masterbatch) and Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3) with particle counting industrial hygiene equipment have been completed and results indicate that exposure potential is low for inhalation and skin contact or environmental release to the air.

Data needs and actions:
If the product advances to Commercialization, additional safety, health and environmental data will be obtained to facilitate the risk management process.

Potential for Direct Human Contact — Summary Table			
Lifecycle Stage* ***Pre-Commercial Development***	***Polymer matrix via processing***		
Material Form	***Sepiolite agglomerated powder and PET polymer pellets***		
Material	***Sepiolite Clay, Pangel S-9 and Crystar® poly-(ethylene terephthalate)***		
Step (e.g. process step, transfer step, cleanup/disposal	**Engineering Controls**	**Personal Protection Equipment (PPE)**	**Exposure Potential**

procedures)			
Receiving/Storage	***General ventilation***	• ***Safety Glasses w/side shields*** • ***Gloves***	***None expected***
Processing	***Local exhaust ventilation, ventilated enclosure, HEPA vacuum cleaner for contamination control***	• ***Safety Glasses w/side shields*** • ***Gloves*** • ***Half-mask respirator w/N100 or P100 HEPA filter if Acceptable Exposure Limit is exceeded.***	***Low***
Housekeeping/cleanup	***Local exhaust ventilation, HEPA vacuum cleaner***	• ***Safety Glasses w/side shields*** • ***Gloves*** • ***Half or full mask respirator w/N100 or P100 HEPA filter based upon level of contamination.***	***Low***
Spills	***Local exhaust ventilation, HEPA vacuum cleaner***	• ***Safety Glasses w/side shields*** • ***Gloves*** • ***Half-mask respirator w/N100 or P100 HEPA filter if spill is large and/or Acceptable Exposure Limit is exceeded.***	***Low***

Storage	***General ventilation***	• ***Safety Glasses w/side shields*** • ***Gloves***	***None expected***
Maintenance	***Local exhaust ventilation where there is exposure potential***	• ***Safety Glasses w/side shields*** • ***Gloves*** • ***Half-mask respirator w/N100*** • ***or P100 HEPA filter if Acceptable Exposure Limit is exceeded.***	***Exposure based on activity. Low to moderate exposure potential***
Quality Control	***General ventilation***	• ***Safety Glasses w/side shields*** • ***Gloves***	***None expected to Low***
Recycle/Waste Disposal	***General ventilation***	• ***Safety Glasses w/side shields*** • ***Gloves***	***None expected to Low***
Package Disposal	***General ventilation***	• ***Safety Glasses w/side shields*** • ***Gloves***	***None expected***

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Receiving/Storage
Material Form: Sepiolite powder and polymer resin pellets
Number of People Potentially Exposed: Two
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): None expected
Personal Protection Equipment: Safety Glasses w/side shields, Gloves
Engineering Controls: General ventilation
Procedures: Receiving and storage, spill response
Exposure Potential: None expected
Estimated Exposure and Dose: None expected
Unknowns and Uncertainties:

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Processing
Material Form: Sepiolite powder or polymer resin pellets or composite resin pellets
Number of People Potentially Exposed: Three
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment:

- ***Safety Glasses w/side shields***
- ***Gloves***
- ***Half-mask respirator w/N100 or P100 HEPA filter if Acceptable Exposure Limit is exceeded.***

Engineering Controls: Local exhaust ventilation, Ventilated enclosure, HEPA Vacuum cleaner for contamination control
Procedures: Standard Operating Procedures
Exposure Potential: Low
Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties: Quantitative exposure and dose assessment data for the nanoscale material of interest/use.

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Housekeeping/cleanup
Material Form: Sepiolite powder or polymer resin pellets or composite resin pellets
Number of People Potentially Exposed: Three
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment: Safety Glasses w/side shields, Gloves. Based upon the level of potential contamination and/or if Acceptable Exposure Limit is exceeded – Half or full mask respirator w/N100 or P100 HEPA filter.
Engineering Controls: Local exhaust ventilation, HEPA vacuum cleaner
Procedures: Standard Operating Procedures
Exposure Potential: Low
Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties: Quantitative exposure and dose assessment data for the nanoscale material of interest/use.

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Spills
Material Form: Sepiolite powder or polymer resin pellets or composite resin pellets
Number of People Potentially Exposed: Three

Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment:

- ***Safety Glasses e/side shields***
- ***Gloves***
- ***Hal or full f-mask respirator w/N100 or P100 HEPA filter if spill if large and/or Acceptable Exposure limit is exceeded.***

Engineering Controls: Local exhaust ventilation, HEPA vacuum cleaner
Procedures: Standard Operating Procedures
Exposure Potential: Low
Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties: Quantitative exposure and dose assessment data for the nanoscale material of interest/use.

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Storage of composite resin
Material Form: Composite resin pellets (Crystar® - poly-(ethylene terephthalate) resin encapsulating Sepiolite Clay, Pangel S-9)
Number of People Potentially Exposed: Two
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): None expected
Personal Protection Equipment: Safety Glasses w/side shields, Gloves
Engineering Controls: General ventilation
Procedures: Standard Operating Procedures
Exposure Potential: None expected
Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties:

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Maintenance
Material Form: Sepiolite powder, PET polymer resin pellets, composite resin pellets
Number of People Potentially Exposed: Two
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment:

- ***Safety Glasses w/side shields***
- ***Gloves***
- ***Half-mask respirator w/N100 or P100 HEPA filter if Acceptable Exposure Limit is exceeded.***

Engineering Controls: Local exhaust ventilation where there is exposure potential
Procedures: Standard Operating Procedures
Exposure Potential: Exposure based on activity. Low to moderate exposure potential

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Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties: Quantitative exposure and dose assessment data for the nanoscale material of interest/use.

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Quality Control
Material Form: Composite resin pellets (Crystar® - poly-(ethylene terephthalate) resin
Number of People Potentially Exposed: Two
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Dermal
Personal Protection Equipment: Safety Glasses w/side shields, Gloves
Engineering Controls: General ventilation
Procedures: Standard Operating Procedures
Exposure Potential: None expected to low
Estimated Exposure and Dose: Non detectable – below acceptable exposure limits
Unknowns and Uncertainties:

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Recycle/Waste Disposal
Material Form: Sepiolite powder and polymer resin pellets, composite resin pellets
Number of People Potentially Exposed: Three
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment: Safety Glasses w/side shields, Gloves
Engineering Controls: General ventilation
Procedures: Standard Operating Procedures
Exposure Potential: None expected to Low
Estimated Exposure and Dose: None expected to Low
Unknowns and Uncertainties:

Elaboration

Lifecycle Stage: Pre-Commercial Development – Polymer Matrix via processing
Step Name: Package Disposal
Material Form: Sepiolite powder and polymer resin pellets, composite resin pellets
Number of People Potentially Exposed: Three
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): Inhalation, dermal
Personal Protection Equipment: Safety Glasses w/side shields, Gloves
Engineering Controls: General ventilation
Procedures: Standard Operating Procedures
Exposure Potential: None expected to Low

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Estimated Exposure and Dose: None expected to Low
Unknowns and Uncertainties:

Potential for Direct Human Contact — Summary Table			
Lifecycle Stage* ***Pre Commercial Development***	***Customers who produce engineered or molded parts, e.g. dual – ovenable frozen food trays***		
Material Form	***Pellets***		
Material	***Resin of Crystar® poly-(ethylene terephthalate) and encapsulated Sepiolite Clay, Pangel S-9***		
Step (e.g. process step, transfer step, cleanup/disposal procedures)	**Engineering Controls**	**Personal Protection Equipment (PPE)**	**Exposure Potential**
All steps in this stage of development	***Exhaust ventilation for off gasses from the PET polymer melt process and recommend customers workplace safety protocols.***	***Specific to PET polymer processing., recommend;*** • ***Safety Glasses w/side shields*** • ***Gloves*** • ***Respirator w/appropriate filter if Acceptable Exposure Limit is exceeded.*** ***and also recommend customers workplace safety protocols.***	***De minimus exposure potential to nanoscale material.***

Elaboration

Lifecycle Stage: Pre-Commercial Development – Customers who produce engineered or molded parts, e.g. dual – ovenable frozen food trays
Step Name: All steps
Material Form: Resin pellets
Number of People Potentially Exposed: To be determined, typically one to two people per shift

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Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): polymer inhalation and dermal contact to resin
Personal Protection Equipment: Recommend

- ***Safety Glasses w/side shields***
- ***Gloves***
- ***Respirator w/appropriate filter if Acceptable Exposure Limit is exceeded.***

Engineering Controls: Recommend local exhaust ventilation
Procedures: Recommend Standard Operating Procedures
Exposure Potential: To be determined. With basic containment and control measures expect non detectable – below acceptable exposure limits
Estimated Exposure and Dose: Recommend area monitoring. Expect non detectable – below acceptable exposure limits
Unknowns and Uncertainties: Customers containment and control measures for safe handling of materials.

Potential for Direct Human Contact — Summary Table			
Lifecycle Stage* ***Pre-Commercial Development***	***Consumers/Users of dual ovenable frozen food trays***		
Material Form	***Dual ovenable frozen food trays***		
Material	***Crystar® - poly-(ethylene terephthalate) and encapsulated sepiolite Clay, Pangel S-9***		
Step (e.g. process step, transfer step, cleanup/disposal procedures)	**Engineering Controls**	**Personal Protection Equipment (PPE)**	**Exposure Potential**
Distribution	***No action necessary***	***No action necessary***	***No potential for exposure***
Use	***No action necessary***	***No action necessary***	***No potential for exposure***
Recycle/Disposal	• ***Collection*** • ***Landfill*** • ***Incineration***	***Basic recycle/disposal practices.***	***De minimus exposure potential if any***

Elaboration

Lifecycle Stage: Pre-Commercial Development – Consumers/Users of dual ovenable frozen food trays
Step Name: Consumers/Users of dual ovenable frozen food trays
Material Form: Dual ovenable frozen food trays
Number of People Potentially Exposed: The market space is being determined
Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal): No exposure expected during use of dual ovenable frozen food trays.
Personal Protection Equipment: N/A
Engineering Controls: N/A
Procedures: N/A
Exposure Potential: No potential for exposure to nanoscale materials during use. De minimus exposure potential if any from landfill or incineration.
Estimated Exposure and Dose: None to De minimus exposure potential if any from landfill or incineration.
Unknowns and Uncertainties:

Potential for Environmental Release

This Risk Assessment is based on the current Pre-Commercial stage of development for the nanoscale material application. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed will be obtained to facilitate the risk management process.

Potential for Environmental Release — Summary Table			
Lifecycle Stage* ***Pre Commercial Development***	***Raw Material***		
Material	***Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***		
Step (e.g. process step, transfer step)	**Potential Release Medium (e.g., air, water, soil)**	**Engineering Controls**	**Release Potential**
Receiving, storage	***None expected***		***None Expected***

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Potential for Environmental Release — Summary Table			
Lifecycle Stage* ***Pre Commercial Development***	***Polymer matrix via processing***		
Material	***Crystar® - poly-(ethylene terephthalate) (DNM-1 Masterbatch) and Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***		
Step (e.g. process step, transfer step)	**Potential Release Medium (e.g., air, water, soil)**	**Engineering Controls**	**Release Potential**
Processing	***Air***	***Local exhaust ventilation, ventilated enclosure, HEPA vacuum cleaner for contamination control***	***Low***
Housekeeping/cleanup	***Air***	***Local exhaust ventilation, HEPA vacuum cleaner***	***Low***
Spills	***Air***	***Local exhaust ventilation, HEPA vacuum cleaner***	***Low***
Maintenance	***Air***	***Local exhaust***	***Low***

		ventilation where there is exposure potential	
Waste Disposal	Air or Soil	Incinerator or Landfill Containment and Abatement Controls	Low

Potential for Environmental Release — Summary Table			
Lifecycle Stage* ***Pre Commercial Development***	***Customers who produce engineered or molded parts, e.g. dual – ovenable frozen food trays***		
Material	***Crystar® - poly-(ethylene terephthalate) (DNM-1 Masterbatch) and encapsulated Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***		
Step (e.g. process step, transfer step)	**Potential Release Medium (e.g., air, water, soil)**	**Engineering Controls**	**Release Potential**
This Risk Assessment is based on the current Pre-Commercial stage of development for the nanoscale material application. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed from the customers who produce molded parts will be obtained to facilitate the risk management and product stewardship process.			

Potential for Environmental Release — Summary Table	
Lifecycle Stage* ***Pre Commercial Development***	***Consumers/Users of dual ovenable frozen food trays***
Material	***Dual ovenable frozen food trays***

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Step (e.g. process step, transfer step)	Potential Release Medium (e.g., air, water, soil)	Engineering Controls	Release Potential
Disposal - Landfill	***Soil***	***Landfill containment and controls***	***None to de minimus release potential***
Disposal - Inicneration	***Air***	***Incineration containment and abatement controls***	***None to de minimus release potential***

Elaboration

Lifecycle Stage: Pre Commercial Development - Consumers/Users of dual ovenable frozen food trays
Step Name: Recycle/Disposal - Landfill
Potential Release Medium (i.e., routes of entry): Soil
Engineering Controls: Landfill containment and controls
Procedures: Landfill procedures
Release Potential: None to de minimus release potential
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): Degradation
Estimated Exposure and Dose: None to de minimus release potential
Unknowns and Uncertainties: Testing of leaching capability with a Toxicity Characteristic Leaching Procedure study.

Elaboration

Lifecycle Stage: Pre Commercial Development - Consumers/Users of dual ovenable frozen food trays
Step Name: Recycle/Disposal - Inicneration
Potential Release Medium (i.e., routes of entry): Air
Engineering Controls: Incineration containment and abatement controls
Procedures: Inicneration procedures
Release Potential: None to de minimus release potential
Map Fates of the Material (e.g., degradation, transformations, or transfers to other media): Decomposition
Estimated Exposure and Dose: None to de minimus release potential
Unknowns and Uncertainties:

What is the ultimate environmental fate of the material? ***To be determined.***

Does it accumulate in a particular environmental sink? ***To be determined.***

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What are the populations that may be exposed? ***Commercial customers who use dual ovenable frozen food trays.***

What is the bioaccumulation potential? ***To be determined.***

Exposure Data – Summary Table
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Exposure Data — Summary Table				
Nanomaterial Manufacture				
	Information			
Stage of Development	Pre Commercial Development			
Number and Location of Manufacturing Sites				
Annual Production Volumes (current and expected)				
Manufacturing Site's NAICS Code				
Manufacturing Method				
Number of Workers Handling Nanomaterials at the Manufacturing Site				
Industrial Functions (e.g., adhesive, coloring agent)	**Percent of Production**	**Physical Form & Concentration**		
Function 1:				
Function 2:				
Function 3:				
Function n:				
Material Processing				
Type of Downstream Industrial Processing or Use	***Polymer matrix processing - Crystar® - poly-(ethylene terephthalate) (DNM-1 Masterbatch) and Hydrated Magnesium Silicate (Sepiolite Clay, Pangel S-9 from Tolsa SA – CAS# 63800-37-3)***			
Number of Processing or Commercial Use Sites	***One***			
NAICS Code of Processors				
Industrial Functions	**Percent of Production**	**Number of Sites**	**Numbers of**	**Number of**

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			Workers at Site	Workers Exposed
Function 1:***Masterbatch***	***<1%***	***one***	***500***	***three***
Function 2:				
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:***Consumer***		***Food trays***	***Confidential Business Information***	***Non detectable***	***Consumers of food trays***
Product Type 2:					
Product Type 3:					
Product Type n:					

Distribution/Storage	
Methods of Delivery and Storage	
Manufacturer	
Processors	
Distributors	
Retailers	

Post-Use Management		
	Expected disposal methods	Expected Recovery/ Reuse/Recycle Methods
Manufacturer		
Processors		
End-Users		

This Risk Assessment is based on the current Pre-Commercial stage of development for the nanoscale material application. The market space is being determined and economics evaluated versus the value-in-use, as determined by down-stream manufacturing and applications. If the product advances to Commercialization, additional safety, health and environmental data as needed from the customers who produce molded parts will be obtained to facilitate the risk management and product stewardship process.

- 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).

- Elaborate on the use of the material in commercial and 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 for use by children or other sensitive populations?

- Elaborate on the post-use management of the material across the lifecycle:

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Section 3: Evaluate Risks
Using a synthesis of information collected in Step 2, produce a ***Risk Evaluation*** — estimates of the nature, likelihood, and magnitude of adverse effects on human health and the environment.

Summary:
The risk assessment based on current knowledge of hazard and exposure potential, DuPont operations with containment and control measures and other risk management practices showed that human health risk and environmental risk is low when handling Sepiolite S-9 particle raw material during internal processing. Potential for exposure to um or nm size particulates is during the processing stage for the polymer matrix, Crystar® 6920 poly-(ethylene terephthalate) resin with Sepiolite. The same risk is expected of customers who process mold dual ovenable food trays. Consumer risk from use – exposure to finished dual ovenable frozen food trays is believed to be negligible if any.
Data needs and actions:
This Risk Assessment is based on the current Pre-Commercial stage of development for the nanoscale material application. If the product advances to Commercialization, additional safety, health and environmental data as needed from the customers who produce molded parts will be obtained to facilitate the risk management and product stewardship process.

Risk Evaluation — Summary Table*		
Risk Type	**Nature, Magnitude, and Probability**	**Source(s) of Risk Assessment**
Human	***For Raw Material Handling– Melt Processing***	
Respiratory	Nature: ***Inhalation of airborne material in a manufacturing setting.*** Magnitude: ***Low*** Probability: ***Low***	***DuPont internal Exposure and Risk Assessment***
Dermal	Nature: ***Worker contact with material in a manufacturing setting.*** Magnitude: ***Low*** Probability: ***Low***	***DuPont internal Exposure and Risk Assessment***
Ingestion	Nature: ***Worker contact with material in a manufacturing setting.*** Magnitude: ***Low*** Probability: ***Low***	***DuPont internal Exposure and Risk Assessment***
Other health (e.g., reproductive,	• ***Sepiolte is classified by IARC as Class 3.*** • ***None Known for Teratogenic***	***MSDS*** ***MSDS***

developmental, neural)	***or Mutagenic Effects, and Developmental Toxicity*** • ***DuPont Haskell pulmonary bioassay screening study with Sepiolite – Hydrated Magnesium Silicate CAS # 63800-37-3 and Sepiolite Nanoclay – Organically Modified Hydrated Magnesium Silicate was conducted in rats. The histopathology results indicated that lung exposures to sepiolite particles produced evidence of multinucleate giant cells in airspaces and patchy evidence of minimal septal lung tissue thickening, suggesting the development of early phase lung fibrosis. Biological significance to be determined w/follow-up study.***	***DuPont Haskell Pulmonary Bioassay screening study, TSCA 8(e) submittal***
Environmental		
Aquatic		
Avian		
Mammalian		
Terrestrial		
Other (e,g., sludge)	***Ecotoxicity: No specific adverse effects are known.***	***MSDS***

**Information contained in this table is based on existing studies. Where no information is available, a reasonable worst-case assumption may be made.*

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Section 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***, ***Monitoring, Compliance, and Reporting***, based on the gathered exposure information.

Summary: The Dupont Risk Assessment determined that with prudent workplace practices in place the risk is low for worker exposure. With the nanoscale material incorporated into a polymer matrix in the form of pellets, the review also believes there are no substantive risk issues for end-product users.

Data needs and actions:

As the product development advances beyond the Pre-Commercial development stage additional safety, health and environmental data as needed will be identified and addressed.

Review cycle and conditions:

If the product is commercialized the following Risk Management review criteria apply:

- ***Product Stewardship Review will be conducted after two years of commercial sales.***
- ***The subsequent product stewardship review cycle is four 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 process are performed on a five year frequency.***

Plan and timeline for risk management, monitoring, compliance, and reporting:

Material Safety and Handling (*Sepiolite*)		
Material Hazard Event	**Recommended Precaution/Action**	**Expected Effectiveness of Recommended Action** (e.g., what level of exposure will be achieved)
Receipt	***No action necessary***	
Processing	• ***Perform industrial hygiene exposure and area assessment. If above acceptable exposure limit, address additional containment and control needs, e.g.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to***

	local exhaust, personal protective equipment, administrative controls. • ***Establish non-routine equipment maintenance and decon procedures and include in standard operating procedures.*** • ***Provide hazards review and training for operators.***	***conduct the task/operation safely.***
Storage	***No action necessary.***	
Handling	• ***Perform industrial hygiene exposure and area assessment. If above acceptable exposure limit, address additional containment and control needs, e.g. local exhaust, personal protective equipment, administrative controls.*** • ***Establish non-routine equipment maintenance and decon procedures and include in standard operating procedures.*** • ***Provide hazards review and training for operators.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Spills	• ***Establish spill clean up procedures and record in the standard***	• ***Containment and controls should eliminate or reduce***

	operating procedure. • ***Provide worker safe handling training.***	***exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Transport	***No action necessary***	
Packaging	***No action necessary***	
Use	***Follow safe use, storage and handling information.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Disposal (including packaging materials)	***Dispose in accordance with local and Federal regulations.***	***If information is followed the material should be handled safely to mitigate exposures.***
Other:		

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Material Safety and Handling (*Polymer matrix with Sepiolite as nanoscale material*)		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Receipt	***No action necessary***	
Processing	• ***Perform industrial hygiene exposure and area assessment. If above acceptable exposure limit, address additional containment and control needs, e.g. local exhaust, personal protective equipment, administrative controls.*** • ***Establish non-routine equipment maintenance and decon procedures and include in standard operating procedures.*** • ***Provide hazards review and training for operators.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Storage	***No action necessary***	
Handling	***Follow safe use, storage and handling information.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***

Spills	• ***Establish spill clean up procedures and record in the standard operating procedure.*** • ***Provide worker safe handling training.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Transport	***No action necessary***	
Packaging	***No action necessary***	
Use	***Follow safe use, storage and handling information.***	• ***Containment and controls should eliminate or reduce exposure potential to an acceptable level.*** • ***Standard Operating Procedures provide workers a means to conduct the task/operation safely.***
Disposal (including packaging materials)	***Dispose in accordance with local and Federal regulations.***	***If information is followed the material should be handled safely to mitigate exposures.***
Other:		

Material Safety and Handling (*end-product user*)		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Receipt	***No action necessary***	
Storage	***Follow safe use, storage and handling information as included on the package.***	
Handling	***Follow safe use, storage and handling information as included on the package.***	
Spills	***Follow safe use, storage and handling information.***	

Transport	***Follow safe use, storage, handling and transportation information.***	
Packaging	***Follow safe use, storage and handling information.***	
Use	***Follow safe use, storage and handling information.***	
Disposal (including packaging materials)	***Dispose in accordance with local and Federal regulations.***	
Other:		

Material Safety and Handling (*end of life*)		
Material Hazard Event	**Recommended Precaution/Action**	**Expected effectiveness of recommended action** (e.g., what level of exposure will be achieved)
Receipt	***No action necessary***	
Processing	***No action necessary***	
Storage	***No action necessary***	
Handling	***No action necessary***	
Spills	***No action necessary***	
Transport	***No action necessary***	
Packaging	***No action necessary***	
Use	***No action necessary***	
Disposal (including packaging materials)	***Dispose in accordance with local and Federal regulations.***	
Other:		

User may add tables for additional steps in the value chain as appropriate

Section 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.

Go/no-go/redirect decision and rationale:
Continue with Pre-Commercial product development. This decision is based on the current knowledge from Pre-Commercial stage of development process for the nanoscale material application. If the product advances to Commercialization, additional safety, health and environmental data as needed from the customers who produce molded parts will be obtained to facilitate the risk management and product stewardship process.

Additional data needs:

- ***DuPont Haskell pulmonary bioassay screening study with Sepiolite – Hydrated Magnesium Silicate CAS # 63800-37-3 and Sepiolite Nanoclay – Organically Modified Hydrated Magnesium Silicate was conducted in rats. The histopathology results indicated that lung exposures to sepiolite particles produced evidence of multinucleate giant cells in airspaces and patchy evidence of minimal septal lung tissue thickening, suggesting the development of early phase lung fibrosis. Biological significance to be determined w/follow-up study.***
- ***Test of leaching capability with a Toxicity Characteristic Leaching Procedure study***

Additional data-collection assignments:

Product steward: ***Greg Sevenich – Product Stewardship Leader for Product***

Review team: ***DuPont Applied BioSciences Product Stewardship Team – Product Steward Manager, Product Steward, Workforce Representative, SHE Resource, Legal, other subject matter experts as needed.***

Product review cycle: ***If the product is commercialized the following Risk Management review criteria apply:***

- ***Product Stewardship Review will be conducted after two years of commercial sales.***
- ***The subsequent product stewardship review cycle is four 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 process are performed on a five year frequency.***

Needed actions and responsible persons: ***Questions recorded during the meeting and requests for clarification to be 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.

List of reviews held (dates): ***Pre-Commercial product development risk assessment reviews – June and July, 2008.***

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***

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Additional References:

1) Material Safety Data Sheet

- ***Sepiolite Pangel S-9, Tolsa, April 2006. FDS-900-02***
- ***"CRYSTAR" Polyester Terephthalate 6920 Series Resin, Sept. 9,2005. OHP028***
- ***"CRYSTAR" Polyester Terephthalate DNM-1 Masterbatch, May 30,2008. OHP033.***