

# NANO RISK FRAMEWORK OUTPUT WORKSHEET

## Nanomaterial Risk Assessment Document — [nanomaterial]

### Section 1: Describe Material and Its Applications

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

#### General Overview:<sup>1</sup>

#### Material Description:

*Material source or producer:*

*Manufacturing process:*

*Appearance:*

*Chemical composition:*

*Physical form/shape:*

*Concentration:*

*Size distribution:*

*Solubility:*

*State of aggregation or agglomeration:*

*Material CAS number (if applicable):*

Material	CAS Number	Composition

#### Main applications (current or expected):

#### Stage of development:

#### General physical and mechanical properties of this material:

#### Past experience with this material or a similar material:

#### Potential benefits/positives of the material:

#### Potential risks/negatives of the material:

*Health:*

*Environmental:*

#### Sources of additional information:

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<sup>1</sup> 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.

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### 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)		
Manufacturing Level I (e.g., processor)		
Manufacturing Level II (e.g., product fabrication)		
Manufacturing Level III (e.g., filling/packaging)		
Distribution (e.g., retailer)		
Use/Reuse/Maintenance (e.g., consumer)		
End of Life (e.g., recycling, disposal)		

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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:*

*Data needs and actions:*

Lifecycles Properties — Summary Table			
<b>Lifecycle Stage*</b>			
<b>Technical or Commercial Name</b>			
<b>Common Form</b>			
	<b>Result</b>	<b>Method</b>	<b>Remarks***</b>
<b>Chemical Composition</b> (including surface coatings)			
Component 1:			
Component 2:			
Component n:			
<b>Crystal Phase/Molecular Structure</b>			
<b>Physical Form/Shape</b>			
<b>Particle Size and Size Distribution</b>			
<b>Surface Area</b>			
<b>Particle Density</b>			
<b>Solubility</b>			
<b>Bulk Density</b>			
<b>Agglomeration/Aggregation State</b>			
<b>Porosity</b>			
<b>Surface Charge</b>			

*User may create rows for data on additional properties, if available.*

*\*Repeat table entries for each lifecycle stage if properties change.*

*\*\*\* E.g., reference, source of data, degree of certainty.*

**Additional Notes:**

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### Section 2B: Develop Lifecycle Hazard Profile

Gather information and characterize the material's potential health, environmental, and safety hazards over the entire lifecycle.

*Summary:*

*Data needs and actions:*

<b>Nanomaterial Lifecycle Hazard Profile — Base Set</b>		
<b>Route</b>	<b>Hazard</b> <small>(characterization [e.g., low, moderate, high] and quantification if available [e.g., LOAEL=x mg/kg])</small>	<b>Source of Information</b> <small>(e.g., report number)</small>
<b>Health Hazard Data</b>		
<b>1. Short-term Toxicity</b>		
<b>a. Pulmonary toxicity</b>		
<b>b. Oral toxicity</b>		
<b>2. Skin sensitization/irritation</b>		
<b>3. Skin penetration*</b>		
<b>4. Genotoxicity</b>		
<b>a. Gene mutation in prokaryotic cells</b>		
<b>b. Chromosomal aberration</b>		
<b>Environmental Hazard Data</b>		
<b>Aquatic Toxicity</b>		
<b>1. Fish (fathead minnow or trout)</b>		
<b>2. Invertebrate (Daphnia)</b>		
<b>3. Aquatic Plant (algae)</b>		
<b>Terrestrial Toxicity (if significant release to terrestrial environments)</b>		
<b>1. Earthworms</b>		
<b>2. Plants</b>		
<b>Environmental Fate Data</b>		
<b>Water Solubility</b>		
<b>Vapor Pressure</b>		
<b>Adsorption/Desorption Coefficients in Release Medium (Soil/Sludge)</b>		
<b>Persistence potential screen</b>		
<b>Bioaccumulation potential screen</b>		

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Base Set of Safety Hazard Data		
Flammability		
Explosivity		
Incompatibility		
Reactivity		
Corrosivity		

*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)
<b>Health Hazard Data — <i>Additional tests as needed</i></b>		
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		
<b>Environmental Hazard Data — <i>Additional tests as needed</i></b>		
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		
<b>Environmental Fate Data — <i>Additional tests as needed</i></b>		
Activated sludge respiration inhibition		
Microorganism toxicity		
Persistence potential in relevant media		
Potential for transformations via oxidation-reduction reactions		

*User may create rows for additional data, if available.*

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### 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:*

*Data needs and actions:*

Potential for Direct Human Contact — Summary Table			
Lifecycle Stage*			
Material Form			
Material			
Step (e.g. process step, transfer step, cleanup/disposal procedures)	Engineering Controls	Personal Protection Equipment (PPE)	Exposure Potential

*\*Repeat table entries for each lifecycle stage.*

### **Elaboration**

Lifecycle Stage:

Step Name:

Material Form:

Number of People Potentially Exposed:

Potential Routes for Exposure (e.g., inhalation, ingestion, eye, dermal):

Personal Protection Equipment:

Engineering Controls:

Procedures:

Exposure Potential:

Estimated Exposure and Dose:

Unknowns and Uncertainties:

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Potential for Environmental Release — Summary Table			
Lifecycle Stage*			
Material			
Step (e.g. process step, transfer step)	Potential Release Medium (e.g., air, water, soil)	Engineering Controls	Release Potential

*\*Repeat table entries for each lifecycle stage.*

### **Elaboration**

Lifecycle Stage:

Step Name:

Potential Release Medium (i.e., routes of entry):

Engineering Controls:

Procedures:

Release Potential:

Map Fates of the Material (e.g., degradation, transformations, or transfers to other media):

Estimated Exposure and Dose:

Unknowns and Uncertainties:

What is the ultimate environmental fate of the material?

Does it accumulate in a particular environmental sink?

What are the populations that may be exposed?

What is the bioaccumulation potential?

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Exposure Data — Summary Table					
<b>Nanomaterial Manufacture</b>					
	<b>Information</b>				
Stage of 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)	<b>Percent of Production</b>	<b>Physical Form &amp; Concentration</b>			
Function 1:					
Function 2:					
Function 3:					
Function n:					
<b>Material Processing</b>					
Type of Downstream Industrial Processing or Use					
Number of Processing or Commercial Use Sites					
NAICS Code of Processors					
Industrial Functions	<b>Percent of Production</b>	<b>Number of Sites</b>	<b>Numbers of Workers at Site</b>	<b>Number of Workers Exposed</b>	
Function 1:					
Function 2:					
Function 3:					
Function n:					
<b>Material Use</b>					
Commercial or Consumer Product Types	<b>Percent of Production</b>	<b>Setting for Use (homes, outdoors)</b>	<b>Concentration in Product</b>	<b>Released During Use?</b>	<b>Est. Number of Exposed Users</b>
Product Type 1:					
Product Type 2:					
Product Type 3:					
Product Type n:					

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<b>Distribution/Storage</b>		
Methods of Delivery and Storage		
Manufacturer		
Processors		
Distributors		
Retailers		
Consumers		
<b>Post-Use Management</b>		
	Expected disposal methods	Expected Recovery/ Reuse/Recycle Methods
Manufacturer		
Processors		
End-Users		

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:*

*Data needs and actions:*

<b>Risk Evaluation — Summary Table*</b>		
<b>Risk Type</b>	<b>Nature, Magnitude, and Probability</b>	<b>Source(s) of Risk Assessment</b>
<b>Human</b>		
<b>Respiratory</b>	Nature: Magnitude: Probability:	
<b>Dermal</b>	Nature: Magnitude: Probability:	
<b>Ingestion</b>	Nature: Magnitude: Probability:	
<b>Other health</b> (e.g., reproductive, developmental, neural)		
<b>Environmental</b>		
<b>Aquatic</b>		
<b>Avian</b>		
<b>Mammalian</b>		
<b>Terrestrial</b>		
<b>Other</b> (e.g., sludge)		

*\*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:*

*Data needs and actions:*

*Review cycle and conditions:*

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

<b>Material Safety and Handling (manufacturer of nanomaterial)</b>		
<b>Material Hazard Event</b>	<b>Recommended Precaution/Action</b>	<b>Expected Effectiveness of Recommended Action</b> (e.g., what level of exposure will be achieved)
<b>Receipt</b>		
<b>Processing</b>		
<b>Storage</b>		
<b>Handling</b>		
<b>Spills</b>		
<b>Transport</b>		
<b>Packaging</b>		
<b>Use</b>		
<b>Recycling</b>		
<b>Disposal</b> (including packaging materials)		
<b>Other:</b>		

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<b>Material Safety and Handling (nanomaterial user)</b>		
<b>Material Hazard Event</b>	<b>Recommended Precaution/Action</b>	<b>Expected effectiveness of recommended action (e.g., what level of exposure will be achieved)</b>
<b>Receipt</b>		
<b>Processing</b>		
<b>Storage</b>		
<b>Handling</b>		
<b>Spills</b>		
<b>Transport</b>		
<b>Packaging</b>		
<b>Use</b>		
<b>Recycling</b>		
<b>Disposal</b> (including packaging materials)		
<b>Other:</b>		

<b>Material Safety and Handling (end-product user)</b>		
<b>Material Hazard Event</b>	<b>Recommended Precaution/Action</b>	<b>Expected effectiveness of recommended action (e.g., what level of exposure will be achieved)</b>
<b>Receipt</b>		
<b>Storage</b>		
<b>Handling</b>		
<b>Spills</b>		
<b>Transport</b>		
<b>Packaging</b>		
<b>Use</b>		
<b>Recycling</b>		
<b>Disposal</b> (including packaging materials)		
<b>Other:</b>		

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<b>Material Safety and Handling (end of life)</b>		
<b>Material Hazard Event</b>	<b>Recommended Precaution/Action</b>	<b>Expected effectiveness of recommended action (e.g., what level of exposure will be achieved)</b>
<b>Receipt</b>		
<b>Processing</b>		
<b>Storage</b>		
<b>Handling</b>		
<b>Spills</b>		
<b>Transport</b>		
<b>Packaging</b>		
<b>Use</b>		
<b>Recycling</b>		
<b>Disposal</b> (including packaging materials)		
<b>Other:</b>		

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

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### 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:

Additional data needs:

Additional data-collection assignments:

Product steward:

Review team:

Product review cycle:

Needed actions and responsible persons:

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### 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):

Conditions that triggered review(s):

Changes made in report and rationale (e.g., changes to lifecycle profiles):

Actions taken and rationale (e.g., revised risk management practices):

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### Additional References:

*User may add additional references as appropriate*