

# **Toxicity Associated with Nanomaterials**

## **NRDC perspective**

### **National Capital Area Chapter of the Society of Toxicology (NCAC-SOT) 2013**

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**NATURAL RESOURCES DEFENSE COUNCIL**  
THE EARTH'S BEST DEFENSE

# FIFRA Pesticide Regulation - Nanosilver

Under FIFRA a pesticide cannot be registered unless EPA finds that it can be used without causing any unreasonable adverse effects to human health or the environment.

In deciding whether to register a pesticide, EPA must evaluate the potential risks the pesticide may pose to human health, wildlife, plants, and surface or ground water, based on data and studies submitted by the company seeking the registration (called the “registrant”).

Under Section 3(c)(7) of FIFRA, EPA may grant a conditional registration if all three of the following things are true:

- The registrant has not had sufficient time to generate the data,
- The use of the pesticide during this time will not cause any unreasonable adverse effect on the environment, and
- The use of the pesticide is in the public interest, such as to prevent a disease outbreak. 7 U.S.C. §136a(c)(7)

EPA may also grant conditional registrations when the pesticide and the proposed use are “identical or substantially similar” to a registered pesticide.

EPA can also conditionally amend a new use to a registered pesticide with insufficient data if the amendment would not increase the risk of any unreasonable adverse effect on the environment. These are referred to as 3(c)(7) actions.

In December 2011, EPA conditionally approved the company HeiQ Materials to sell nanosilver used in fabrics.

In early 2012, NRDC filed a lawsuit against EPA seeking to block the approval.

The key part of the November 2013 Ninth Circuit ruling found that the EPA had data showing that nanosilver was right at the level that should have triggered a finding of potential risk, but approved the pesticide anyway.

That led to the Ninth Circuit vacating EPA's approval and sending it back down to the agency for reevaluation.

Before the Court even ruled on AGS-20, EPA had already conditionally registered NanoSilva for textiles and plastics (August, 2013)

# **TSCA Chemical Approval – Carbon Nanotubes**

In June 2013 EPA issued SNURs under Section 5(a)(2) of TSCA for CNTs, MWCNTs, DWCNTs, and SWCNTs.

NRDC joined with labor unions to oppose the approvals.

In its notice of the proposed rule, EPA noted concern for lung toxicity, fibrosis, cancer, mutagenicity, and immunotoxicity

(Docket ID EPA-HQ-OPPT-2010-0279-0130)

Public trust is eroded

Litigation is expanded

We need a transparent, systematic way of collecting data, organizing data, scoring our confidence in data, assessing data, and identifying data gaps

# Can We Use the GreenScreen (GS) to Assess Nanomaterials?



**Goal -** Test the GS as a vehicle to gather and communicate hazard information on nanomaterials

**Approach -** Convene a prominent group of independent scientific experts to: Define scope of nanomaterials and studies to assess; (size distribution, shape, structure charge, coating, surface chemistry, agglomeration/aggregation, etc); Recommend relevant modifications to the GS method.

Apply the GS to selected nanomaterials (use independent contractor, NSF)

Review results with scientific experts and NGOs



# What is the GreenScreen®?

- A method for comparative Chemical Hazard Assessment (CHA) developed by the NGO Clean Production Action
- Allows you to compare chemicals based on hazard in a comprehensive and consistent framework – a level playing field
- Builds on the USEPA DfE approach and other national and international precedents (OECD, GHS)
- Free and publicly accessible, transparent and peer reviewed
- Considers 18 environmental and human health endpoints
- Addresses constituents and breakdown products
- Evaluates hazards for an overall chemical score (Benchmark)

All supporting resources at: <http://www.cleanproduction.org/Greenscreen.v1-2.php>

# GreenScreen Adoption

- Corporate materials selection (HP)
- Corporate policies (Staples)
- State regulations (ME, WA)
- Ecolabels and standards (USGBC LEED v4)
- Alternatives assessments

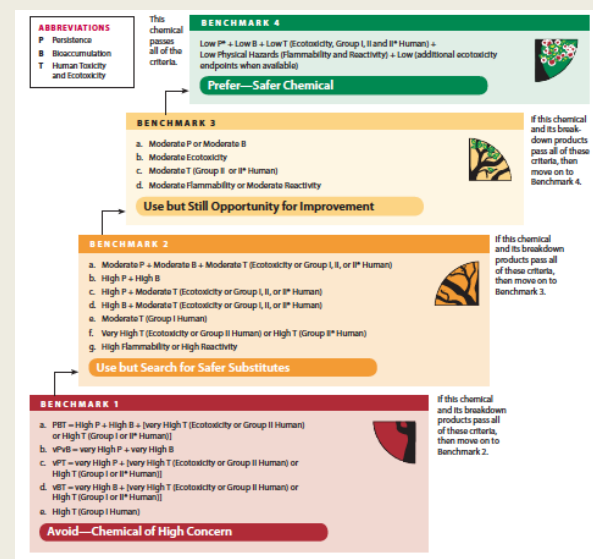
# 18 Hazard Endpoints

Human Health Group I	Human Health Group II and II*	Environmental Toxicity & Fate	Physical Hazards
Carcinogenicity	Acute Toxicity	Acute Aquatic Toxicity	Reactivity
Mutagenicity & Genotoxicity	Systemic Toxicity & Organ Effects	Chronic Aquatic Toxicity	Flammability
Reproductive Toxicity	Neurotoxicity	Other Ecotoxicity studies when available	
Developmental Toxicity	Skin Sensitization	Persistence	
	Respiratory Sensitization		
Endocrine Activity	Skin Irritation	Bioaccumulation	
	Eye Irritation		

Assign a level of concern for each hazard endpoint e.g. carcinogenicity (H, M or L)

# Make Informed Decisions

- Know what you know, and what you don't know
- Benchmarks provide a simple 1-4 score that supports taking action
  - BM1 – avoid/phase out
  - BM2 – manage, to use safely
  - BM3 – getting there
  - BM4 – inherently low hazard
- Can be used by non experts in toxicology to support product design, policies and regulations



The specific materials evaluated for this case study were nanoscale metallic silver, a nano silica-silver nanocomposite (AGS-2-0), and conventional silver (dispersed low-solubility dispersed silver and silver salts).

The extent of nanoscale test material characterization was considered in assessing the adequacy of the studies used.

# GreenScreen Results - nanosilver

Route	GreenScreen™ Hazard Ratings: Dispersed (low-solubility, non-nanoscale) silver - <b>Benchmark Score of 1</b> based on combined very High Persistence coupled with very High Ecotoxicity, as determined in standardized tests.																				
	Group I Human					Group II and II Human										Ecotox		Fate		Physical	
	C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F	
							Single	Repeat ed	Single	Repeat ed											
Oral	DG	L	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	L	L	
Dermal	DG	L	DG	DG		L	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	L	L	
Inhalation	DG	L	DG	DG		DG	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	L	L	

Route	GreenScreen™ Hazard Ratings: Nanosilver, metallic - <b>Benchmark Score of 1</b> based on very High Persistence coupled with High systemic toxicity and very High Ecotoxicity.																				
	Group I Human					Group II and II Human										Ecotox		Fate		Physical	
	C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F	
							Single	Repeat ed	Single	Repeat ed											
Oral	DG	L	DG	DG	DG	L	DG	M	DG	DG	L	DG	L	L	vH	vH	vH	L	DG	DG	
Dermal	DG	L	DG	DG		L	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	DG	DG	
Inhalation	DG	L	DG	DG		vH	DG	H	DG	DG	L	DG	L	L	vH	vH	vH	L	DG	DG	

Route	GreenScreen™ Hazard Ratings: AGS-20 (silver-silica nanocomposite containing 19.3% silver nanoparticles imbedded in a matrix of amorphous silicon dioxide) - <b>Benchmark Score of U (unspecified)</b> based on numerous datagaps.																				
	Group I Human					Group II and II Human										Ecotox		Fate		Physical	
	C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F	
							Single	Repeat ed	Single	Repeat ed											
Oral	DG	DG	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	M	DG	DG	vH	DG	L	L	
Dermal	DG		DG	DG		L	DG	DG	DG	DG	L	DG	L	M	DG	DG	vH	DG	L	L	
Inhalation	DG		DG	DG		M	DG	DG	DG	DG	L	DG	L	M	DG	DG	vH	DG	L	L	

# Summary of GS Results

- Both silver (dispersed) and nanoscale (metallic) silver were classified BM1 (highest concern benchmark score)
  - aquatic toxicity, persistence and acute inhalation toxicity
- Silica-nanosilver composite (AGS-20) unassigned (U) due to data gaps
- Acute inhalation hazard – form matters
  - Nanosilver >>Silica-nanosilver composite
- Eye irritation hazard – form matters
  - Silica-nanosilver composite > nanosilver = silver
- Aquatic toxicity – size matters
  - Particle aggregation reduced acute aquatic toxicity

# Conclusions

- It is possible to use comparative hazard assessments such as GreenScreen and existing toxicology today – to see what we know and what we do not know (i.e., data gaps)
- Ensure nanomaterials are screened before they are introduced in food & other products:
  - require assessment and public disclosure of results by businesses, NGOs and public sector
  - regulate and require transparency about nanomaterial use in specific products



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