

# EDSP Status and Review Plan for Inerts

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# EDSP Tier 1 Screening Battery

## Assays

### *In vitro*

- Estrogen receptor (ER) binding – rat uterine cytosol
- Estrogen receptor - (hER $\alpha$ ) transcriptional activation - Human cell line (HeLa-9903)
- Androgen receptor (AR) binding – rat prostate cytosol
- Steroidogenesis – Human cell line (H295R)
- Aromatase – Human recombinant microsomes



# EDSP Tier 1 Screening Battery Assays (continued)

## In vivo Assays

- Uterotrophic (rat)
- Hershberger (rat)
- Pubertal female (rat)
- Pubertal male (rat)
- Amphibian metamorphosis (frog)
- Fish short-term reproduction



# HPV/Inverts selected for EDSP TIER-1



Name of the Chemical	CAS Number	Expected Test Order Date	No. of Identified manufacturers
Acetone	67-41-1	2/26/10 ?	60
Butyl Benzyl phthalate	85-68-7	1/21/10	14
Dibutyl phthalate	84-74-2	1/21/10	30
Diethyl phthalate	84-66-2	1/21/10	13
Dimethyl phthalate	131-11-3	1/21/10	19
Di-sec-octyl phthalate	117-81-7	1/21/10	38
Isophorone	78-59-1	1/14/10	4
Menthyl Ethyl Ketone	78-93-3	1/28/10	42
Toluene	108-88-3	2/26/10 ?	310
Total			530

<b>1.5. Chemical Info:</b>	A. Chemical #:	B. Chemical Name:	C. Company #(s):
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<b>PART 2</b>	<b>Recipient's Initial Response:</b> (Please refer to the Order/DCI for more information about response options, as well as detailed instructions on how to comply with the Order/DCI.)
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**2.1. I will generate new data or am citing/submitting existing data.**

For each assay, check the appropriate box in the following table and follow the Order/DCI instructions to attach the data and/or required documentation.

A. I will generate new data.

B. I am citing existing data and/or other scientifically relevant information.

C. I am submitting existing data and/or other scientifically relevant information.

D. I am entering (or offering to enter) into an agreement to form a Consortium/Task Force to respond to the Order/DCI. The Consortium/Task Force must provide a separate initial response within 150 calendar days from issuance of the Order/DCI (see Initial Response Form for Consortium/Task Force at <http://www.epa.gov/endo/>.)

<b>Assays:</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>Required documentation is attached.</b>
2.1.1. Amphibian Metamorphosis (Frog)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.2. Androgen Receptor Binding (Rat Prostate)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.3. Aromatase (Human Recombinant)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.4. Estrogen Receptor Binding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.5. Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903))	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.6. Fish Short-term Reproduction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.7. Hershberger (Rat)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.8. Female Pubertal (Rat)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.9. Male Pubertal (Rat)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.10. Steroidogenesis (Human Cell Line – H295R)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>
2.1.11. Uterotrophic (Rat)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>

**2.2. I am citing and/or submitting other scientifically relevant information that I believe can be used to satisfy all of the Order/DCI.**

Required documentation is attached.

**2.3. I am not subject to the Order/DCI.**  Required documentation is attached.

**These Response Options Apply Only to Registered Pesticides:**

**2.4. I intend to voluntarily cancel the pesticide registration(s).**  Required documentation is attached.

**2.5. I intend to reformulate the product(s) to exclude this chemical from the formulation.**  Required documentation is attached.

**2.6. I am claiming a *Formulators' Exemption*.**  Required documentation is attached.

**These Response Options Apply Only to Chemicals that are Other Ingredients (aka inerts):**

**2.7. I have/am in the process of discontinuing the manufacture/import of this chemical.**  Required documentation is attached.

**2.8. I do not and will not sell my chemical for use as an inert ingredient to the pesticide market.**

Required documentation is attached.

# Initial Response Form

- Option 1 Generate data
- Option 2 Submit or Cite Existing data
- Option 3 Form a task force or offer to join a task force
- Option 4 Claim not subject to the order
- Option 5 Discontinue the manufacture or import of the chemical
- Option 6 Stop sales into the pesticide market



# Initial Response Form Cont.

- Option 7 Other response options
  - Demonstrate –Chemical is an endocrine disruptor
  - Demonstrate-Substance is not anticipated to produce any effect in humans.
  - Chemical was used by EPA as a positive control

