



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

October 17, 2007

**MEMORANDUM**

**SUBJECT:** Product Chemistry Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document

**DP Barcode:** 335401      **Reregistration Case No.:** 2340

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<u>Chemical Name</u>	<u>PC Code</u>	<u>CAS#</u>	<u>Common Name</u>
5-Chloro-2-(2,4-dichlorophenoxy)phenol	54901	3380-34-5	Triclosan

Attached is the Product Chemistry Chapter for the Triclosan RED Document.

**TRICLOSAN**  
**REREGISTRATION ELIGIBILITY DECISION**

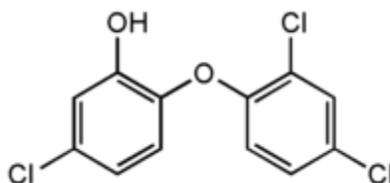
**PRODUCT CHEMISTRY CHAPTER**

**PC Code: 54901; Case No. 2340**

**REGULATORY HISTORY**

5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan) was first registered with the EPA on June 19, 1969. Presently, there are 20 active products, no inert products, and 4 pending products under PC Code 054901, which are listed in Table 1 under Appendix. This chemical is a diphenyl ether derivative primarily used in cosmetics, toilet soaps, and antiseptics. It is also used as a bacteriostat and fungistat in plastics, polymers, textile and implantable medical devices to give these materials "antibacterial properties."

**CHEMICAL IDENTIFICATION**



**Figure 1. Molecular Structure of Triclosan**

<b>Common Name:</b>	Triclosan
<b>Chemical Name:</b>	5-Chloro-2-(2,4-dichlorophenoxy)phenol
<b>Other Name(s):</b>	2,4,4'-Trichloro-2'-hydroxydiphenyl ether Phenol, 5-chloro-2-(2,4-dichlorophenoxy)- 5-Chloro-2-(2,4-dichlorophenoxy)phenol Irgasan DP-300R Irgaguard B1000 VIV-20
<b>CAS Registry Number:</b>	3380-34-5
<b>OPP Chemical Code:</b>	54901
<b>Case Number:</b>	2340
<b>Empirical Formula:</b>	C <sub>12</sub> H <sub>7</sub> Cl <sub>3</sub> O <sub>2</sub>
<b>Molecular Weight:</b>	289.541

**Technical Grade****Manufacturers:**

Ciba Specialty Chemicals Corp  
Harmet International/Vivimed Labs Limited

**End Use****Manufacturers:**

Aeris Technologies Ltd.  
Ciba Specialty Chemicals Corp.  
Huntsman International, LLC  
Microban Products Company  
Rohm and Haas Company  
Sanitized Inc.  
S.C. Johnson & Son Inc.  
Thomson Research Associates  
Troy Chemical Corp.  
Vikon Chemical Co.  
Vivimed Labs Limited

**Percent Active Ingredient**

**In Technical Grade Product:** >99.0% (Ciba) and 99.9% (Harmet/Vivimed)

**Formulation Types****Registered:****Technical Grade Active Ingredient:**

Technical Chemical

**Manufacturing Product:**

Formulation Intermediate

**End Use Products:**

Ready-to-Use  
Pelleted/Tableted  
Emulsifiable Concentrate  
Soluble Concentrate  
Impregnated Materials

**Chemical Properties:**

Triclosan is a white crystalline powder with a faint odor and melting point of 56.5°C (133.7°F). Triclosan is solid and, therefore, has no boiling point. Triclosan has a log  $K_{ow}$  of 4.8 at 25°C and a low vapor pressure of 5.2E-6 mm Hg at 25°C and 2.2E-6 mm Hg at 20°C. Triclosan is soluble in water at 0.012 g/l (12 ppm) at 20°C. Triclosan is readily soluble in alkaline solutions and many organic solvents. It has a bulk density of  $1.55 \times 10^3 \text{ kg/m}^3$  at 22°C.

**PRODUCT CHEMISTRY DATA REQUIREMENTS FOR REREGISTRATION  
OF TRICLOSAN:**

Product chemistry data requirements and results are summarized in Tables 2 and 3 under, “APPENDIX”.

**FINDINGS/CONCLUSIONS:**

All product chemistry data requirements have been fulfilled for the active ingredient triclosan. See Tables 2 and 3 under, “APPENDIX”. RASSB has no objections to the reregistration of triclosan with respect to product chemistry data requirements.

**APPENDIX:**

**Table 1. Registered Active Products of Triclosan**

<b>EPA Reg. No.</b>	<b>Percent Active Ingredient</b>	<b>Registrant</b>
2829-139	99%	Rohm & Hass Company
2829-145	10%	Rohm & Hass Company
3090-165	10%	Sanitized Inc.
3090-215	99%	Sanitized Inc
3090-219	7.5%	Sanitized Inc.
4822-429	0.06%	S.C. Johnson & Son Inc.
5383-127	99%	Troy Chemical Corp.
6390-25	2%	Vikon Chemical Company, Inc.
10466-24	1.6%	Thomson Research Associates
10466-27	3%	Thomson Research Associates
10466-38	99%	Thomson Research Associates
10466-42	1%	Thomson Research Associates
42182-1	99%	Microban Products Company
70404-2	99%	Ciba Specialty Chemicals Corporation
70404-5	99%	Ciba Specialty Chemicals Corporation
73951-1	99.9%	Vivimed Labs Limited
82523-1	0.69%	Aeris Technologies LTD
83884-7	10%	Huntsman International, LLC
83884-9	99%	Huntsman International, LLC
83884-10	99%	Huntsman International, LLC

**Table 2: Manufacturing and Impurity Data for Triclosan**  
**Product Identity, Composition, and Analysis**

Old Guideline No.	New Guideline No.	Requirement	Use Pattern <sup>2</sup>	MRID	Status <sup>1</sup>	Details or Deficiency
61-1	830.1550	Product identity and composition	3,4,7	42027901 45358501	A	Refer to Chemical Identification on page 2
61-2a	830.1600	Description of materials used to produce the product	3,4,7	42027901 45358502	A	CBI
61-2a	830.1620	Description of production process	3,4,7	42027901 45358502 45487201	A	CBI
61-2a	830.1650	Description of formulation process	3,4,7	42027901 45358502 45487201	A	CBI
61-2b	830.1670	Discussion of formation of impurities	3,4,7	42027901 42027902 43277802 45358503 45358504	A	CBI
62-1	830.1700	Preliminary analysis	3,4,7	42027902 45358504	A	CBI
62-2	830.1750	Certified limits	3,4,7	42027901 43277802 43533901 45358503 45358505	A	CBI
62-3	830.1800	Enforcement analytical method	3,4,7	42027902 45358506	A	Reverse Phase HPLC Method Gas Chromatography
64-1	830.1900	Submittal of samples	3,4,7		N/A	

<sup>1</sup>A = Acceptable; N/A = Not Applicable.

<sup>2</sup>Use Pattern:

- (3) Commercial, institutional and industrial premises and equipment
- (4) Residential and public access premises
- (7) Materials preservatives

**Table 3: Physical and Chemical Properties for Triclosan**

Old Guideline No.	New Guideline No.	Requirement	Use Pattern <sup>2</sup>	MRID	Status <sup>1</sup>	Results or Deficiency
63-2	830.6302	Color	3,4,7	42027902 45358502	A	White Crystals
63-3	830.6303	Physical state	3,4,7	42027902 45358502	A	Crystalline Powder
63-4	830.6304	Odor	3,4,7	42027902	A	Faint Odor
63-5	830.7200	Melting Point	3,4,7	42027904	A	56.5°C
63-6	830.7220	Boiling Point	3,4,7		N/A	
63-7	830.7300	Density, Bulk Density, or Specific Gravity	3,4,7	42027904	A	1.55 x 10 <sup>3</sup> kg/m <sup>3</sup> at 22°C
63-8	830.7840	Water solubility: column elusion method; <b>shake flask method.</b>  Fat Solubility:	3,4,7	42027904	A	0.012 g/l at 20°C
					A	> 65g/100g fat at 37°C
63-8	830-xxxx	Solubility in organic solvents	3,4,7		N/A	Readily soluble (Source: TOXNET)
63-9	830.7950	Vapor Pressure	3,4,7	42027904	A	5.2E-6 mm Hg at 25°C 2.2E-6 mm Hg at 20°C
63-10	830.7370	Dissociation constants in water	3,4,7	42027904	A	pK <sub>a</sub> =8.14 at 20°C
63-11	830.7550	Partition coefficient (n-octanol / water), shake flask method.	3,4,7	42027902 42027904	A	Log P <sub>o/w</sub> = 4.8 at 25°C
63-12	830.7000	pH	3,4,7		N/A	
63-13	830.6313	Stability to normal and elevated temperatures. Stability to metals  Stability to metal ions	3,4,7	42027902	A	No thermal effect.
				43022601	A	Stable when exposed to Metals.
				43277801	A	Triclosan exposed to zinc and zinc ions showed the same decrease in % a.i. as control.  Triclosan exposed to iron ions showed a greater decrease in % a.i. than the control.
63-17	830.6317	Storage stability	3,4,7	45358502		No deterioration after 12 months storage

<sup>1</sup> A = Acceptable; N/A = Not applicable.

<sup>2</sup>Use Pattern:

- (3) Commercial, institutional and industrial premises and equipment
- (4) Residential and public access premises
- (7) Materials preservatives

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<u>MRID</u>	<u>Citation</u>
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Sign-off Date : 10/17/07

DP Barcode No. : D335401