

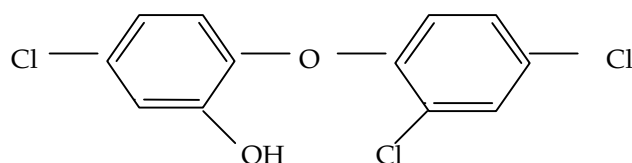
Classification proposal for triclosan (CAS-no 3380-34-5; EINECS-no 222-182-2)

In Norway and in many other countries there is high concern about the increasing use of antibacterial substances, due to their ability to lead to antibiotic resistance in microorganisms. However, according to documentation received from producers and from other data sources, these substances may also have other harmful effects on the environment.

Triclosan has been used as effective antiseptic in soap since the 1960's, and has the recent years been incorporated into a wide range of products, including cosmetics, soap, toothpaste, and plastics for kitchen and table utensils. It has been widely used in textile industry, where it is added to the fibre during manufacture and used among other things in socks, shoe insoles, bicycle shorts and gym wear.

The regulations concerning biocidal products (Biocidal Products Directive, 98/8/EC) will within the next ten years regulate antimicrobial substances like triclosan. Triclosan is recently sent to the EU Scientific Committees on Cosmetic Products (SCCNFP) and Toxicology, Ecotoxicology and Environment (CSTEE) for evaluation of its ability to induce antibiotic resistance in bacteria and for its bioaccumulation properties. Based on the high concern for the aquatic toxicity and long term environmental effects of triclosan, we think it is important to make an evaluation of this substance for classification and labelling of environmental effects previous to the regulations according to the Biocidal Products Directive.

Structure of triclosan



Identification of the substance

Chemical name: 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether
5-Chloro-2-(2,4-dichlorophenoxy)phenol
Cas no: 3380-34-5
EINECS-no: 222-182-2
Molecular formula: $C_{12}H_7Cl_3O_2$
Molecular weight: 289.5

Physiochemical properties:

Water solubility (mg/l):	17	(MITI 1992)
Melting point (°C):	55-57	(MITI 1992)
Log octanol/water coefficient, log P_{ow} :	4.76	(MITI 1992)

Aquatic toxicity data

Toxicological and ecotoxicological properties of the products IRGASAN DP 300, IRGACARE MP and IRGACIDE LP 10, which are all trade names for triclosan, are presented in Ciba Speciality Chemicals brochure no. 2521, published by Ciba Speciality Chemicals. The reported data demonstrate $L(E)C_{50}$ for both fish, daphnia and algae $\ll 1$ mg/l. Additionally, test results from studies with fresh water algae are reported to the US EPA for the notification of triclosan (US EPA report NTIS/OTS0573798). The data demonstrate $L(E)C_{50}$ values of 0.966 µg/l and 4.46 µg/l.

A summary of reported data demonstrating $L(E)C_{50}$ values in the range 0.7 - 390 µg/l is presented in the table below:

Organism		L(E)C ₅₀	Data-source
Fish	Trout (96 h)	0.260 mg/l	Ciba
Crustacea	<i>C. dubia</i> (48 h)	0.130 mg/l	Ciba
	<i>Daphnia magna</i> (48 h)	0.390 mg/l	Ciba
Algae	<i>Scenedesmus sub.</i> (72 h)	0.0007 mg/l	Ciba
	<i>Scenedesmus sub.</i> (72h, 96 h)	0.0014 mg/l	Ciba
	<i>Anabena flos-acuae</i>	0.000966 mg/l	US EPA
	<i>Selenastrum capricornutum</i>	0.00446 mg/l	US EPA

Biodegradation

There are no available data to document ready degradability. A classification of "not readily biodegradable" by default is therefore proposed.

Bioaccumulation

Organism/test	Data	Data - source
	log K _{ow} = 4.76	MITI
Zebra fish (OECD 305C)	BCF= 4160 (3 ppb) BCF= 2530 (30 ppb)	CIBA
OECD 305	BCF= 3730-8400	Schettgen 2000

Health effects

	Data	Data - source
acute toxicity	Oral LD50 rat > 5000 mg/kg Dermal LD50 rabbit > mg/kg	CIBA
Skin and eye irritating Skin sensitization	Moderate skin and eye irritant in rabbit: (PII = 3.0/8.0 and PII = 2.5/8.8) No skin sensitizer	CIBA
Subchronic toxicity, oral	NOEL 25- 100 mg/kg/day	CIBA
Chronic toxicity/carcinogenicity	No carcinogenic effects observed	CIBA
Mutagenicity	No mutagenic effects observed	CIBA
Reproduction and teratology	Not toxic to reproduction and not teratogenic	CIBA

Classification proposal - environment

Based on the presented data on environmental effects, we propose a classification of triclosan for environmental effects with

Symbol N

R-phrases R50, R53

Classification proposal - health

The reported data indicate no classification of triclosan with respect to health effects.

Miscellaneous concerning future concentration limits

The aquatic toxicity data demonstrates that triclosan is very toxic to algae. According to the proposal on specific concentration limits for very toxic substances (ECBI/65/99 Add.10 and Add.13), the reported L(E)C₅₀ range of 0.1-1.0 µg will give rise to the following concentration limits of preparations containing triclosan:

Concentration limits of substance	Classification of preparation
C ≥ 0.025%	N; R50-53
C ≥ 0.0025%	N; R51-53
C ≥ 0.00025%	R52-53