

201-15787A

# Propylene Carbonate

CAS Number 108-32-7

USEPA HPV Challenge Program Submission  
Final Submission

## Overview of Robust Summaries

December 17, 2004

Submitted by:

Propylene Carbonate / t-Butyl Alcohol HPV Committee

Members:

Lyondell Chemical Company  
Huntsman Corporation

Prepared by:

ToxWorks

1153 Roadstown Road  
Bridgeton, New Jersey 08302-6640  
Phone: 856-453-3478

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**I. INTRODUCTION**

The Propylene Carbonate / t-Butyl Alcohol HPV Committee and its member companies have committed voluntarily to develop screening level human health effects, environmental fate and effects, and physicochemical test data for propylene carbonate under the Environmental Protection Agency's High Production Volume Challenge Program. Robust Summaries and a Test Plan were submitted to EPA April 10, 2002. The Committee has now completed the proposed testing and submits this final report. All SIDS level I endpoints have reliable and adequate data.

**Manufacture and Use**

Propylene Carbonate (PC) is produced in a continuous process by the reaction of propylene oxide (PO) with CO<sub>2</sub> and sold as different purity and color grades dependent on the supplier. PC may be used as a solvent for chemical reactions or as a carrier of cosmetically active agents, medicinal agents, biocides, and fungicides. PC may also be used as a reactive intermediate in alkoxylation, transesterifications, polymerizations, reaction with amines, or carboxylic acids. PC is a popular solvent for lithium ion batteries. It is used in the production of electrochromic or "auto-dimming" mirrors for automobiles.

**II. DATA SUMMARY**

Endpoint	Previous Data Adequate	Testing Recommended	Endpoint Value
Melting Point	Yes	No	-48°C
Boiling Point	Yes	No	242°C
Vapor Pressure	Yes	No	0.045 mm Hg @ 25°C
Partition Coefficient	Yes	No	-0.41
Water Solubility	Yes	No	175,000 mg/l @ 25°C
Stability in Water	No	Complete	Stable at pH 4; degradation increases with pH and temperature
Transport	Yes	No	1%, to air; 46% to water; 53% to soil
Photodegradation	Yes	No	Does not absorb UV
Biodegradation	No	Complete	Readily biodegradable
Acute Toxicity to Fish	Yes	No	LC <sub>50</sub> = 480 mg/l (butylcarbonate)
Acute Toxicity to Invertebrates	Yes	No	EC <sub>50</sub> > 1000 mg/l
Acute Toxicity to Aquatic Plants	No	Complete	EC <sub>50</sub> ≥ 929 mg/l
Acute Tox – Oral	Yes	No	LD <sub>50</sub> > 5000 mg/kg
Acute Tox – Dermal	Yes	No	LD <sub>50</sub> ≥ 3000 mg/kg
Gene Tox <i>in vivo</i> – MN	Yes	No	Negative
Gene Tox <i>in vitro</i> – Ames	Yes	No	Negative
Repeat Dose – Oral (90 day)	Yes	No	Rat, Male: NOEL >5000 mg/kg Rat, Female: NOEL >5000 mg/kg
Repeat Dose- Inhalation (90 day)	Yes	No	Rat: NOAEL = 100 mg/m <sup>3</sup> (male and female)

Endpoint	Previous Data Adequate	Testing Recommended	Endpoint Value
Reproductive Toxicity	Yes	No	Rat: No effects on reproduction organs in 90 day study; NOAEL 5000 mg/kg/day
Developmental Tox	Yes	No	Not a teratogen Maternal Tox: NOAEL = 1000 mg/kg/day Dev. Tox: NOEL = 5000 ppm

### **III. TEST PLAN, RATIONALE AND RESULTS**

#### **A. Physical Chemical Data**

The physical/chemical data for propylene carbonate are found in standard reference works. The underlying data were not found, but additional testing is not justified. Data on the stability of propylene carbonate in water and transport between environmental compartments was not adequate.

##### Testing Conducted:

##### 1. Stability in Water: OECD Test Guideline 111

Propylene carbonate is stable in water at pH = 4. At pH = 7 or 9, propylene carbonate hydrolyzed to some extent. Hydrolysis increased with increasing pH and with increasing temperature. Half-life at pH 7 and 17 C was 61 days; at pH 9 and 17 C was 1.03 days.

##### 2. Transport and Distribution between Environmental Compartments: Level 3 EQC Model

Data on the transport of propylene carbonate between environmental compartments has been estimated using EPIWIN; propylene carbonate will partition mostly to water and soil.

#### **B. Ecotoxicity**

Acute toxicity studies on fish and daphnia on a propylene carbonate analog, butylene carbonate, were conducted according to OECD Guidelines, following GLP guidelines. Butylene carbonate (CAS # 4437-85-8) is considered an acceptable surrogate for propylene carbonate because of similar physical-chemical properties.

In rainbow trout the LC50 for butylene carbonate was 480 mg/l and in Daphnia the EC50 was >1000 mg/l. Based on similarity to butylene carbonate, propylene carbonate is not expected to be significantly more toxic to aquatic organisms. The low toxicity of butylene carbonate provides adequate information to conclude that propylene carbonate is not likely to be more than slightly toxic to aquatic organisms. A test of propylene carbonate toxicity to algae was conducted.

A biodegradation study of propylene carbonate was published in German in Git. Fachz. Lab. Based on the English abstract, propylene carbonate is readily biodegradable; more than 80% biodegraded during 10 days. An additional biodegradation study was conducted.

Ecotoxicity Testing Conducted:

1. Toxicity to Aquatic plants (e.g., Algae): OECD Test Guideline 201

Propylene carbonate did not affect cell density, area under the growth curve, or growth rate of unicellular green alga, *Selenastrum capricornutum*, after 72 and 96 hours of exposure at levels up to 929 mg/l, measured concentration (Hughes, 2003).

2. Biodegradation: OECD Test Guideline 301B (Modified Sturm Test)

Propylene carbonate was readily biodegradable by activated domestic sludge under aerobic conditions. More than 85% degraded after 29 days.

**C. Mammalian Toxicity**

Numerous adequate and reliable acute toxicity tests are available on propylene carbonate. Oral and dermal tests meet OECD and EPA test guidelines. Propylene carbonate is practically nontoxic following acute exposures; the oral LD50 is >5000 mg/kg and the dermal LD50 is >3000 mg/kg. No further testing is recommended.

Subchronic studies (13-14 weeks) of propylene carbonate by inhalation (aerosol) and oral (gavage) routes were conducted in rats according to current guidelines. The oral study indicated low systemic toxicity from propylene carbonate (NOAEL = 5000 mg/kg/day). In the inhalation study, no systemic toxicity was seen at concentrations up to 1000 mg/m<sup>3</sup>; however, there was periocular irritation and swelling in a few males at 500 and 1000 mg/m<sup>3</sup>. A dermal carcinogenicity study in mice did not indicate tumorigenic potential or systemic toxicity from 2 years of exposure to propylene carbonate. No further testing is recommended.

There is a negative Ames *in vitro* mutagenicity assay of propylene carbonate. A single intraperitoneal injection of 1666 mg/kg propylene carbonate did not induce an increase in micronuclei when examined after 30, 48 and 72 hours. The mutagenicity battery is satisfactorily filled; no further mutagenicity testing is recommended.

Gavage administration of propylene carbonate to pregnant rats days 6-15 of gestation resulted in systemic toxicity at doses of 3000 and 5000 mg/kg/day, including mortality (not seen in 13 week study of non-pregnant rats). The NOAEL for maternal toxicity was 1000 mg/kg/day. This indicates that pregnant rats are more susceptible to propylene carbonate than are non-pregnant rats. There were no significant differences in live litter size, average fetal weight, percentage of males, or malformed fetuses. No further developmental toxicity testing is recommended.

No studies of the effect of propylene carbonate on reproduction are available. However, no adverse effects on testis, ovaries, or accessory sex organs were noted in rats following oral or inhalation of propylene carbonate for 13 weeks. Therefore, reproductive effects from propylene carbonate are unlikely and further testing is not recommended.