

[FOREWORD](#)

[INTRODUCTION](#)

T-BUTYL HYDROPEROXIDE
CAS N°: 75-91-2

Substance

<i>End Point</i>	:	IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES
<i>Chemical Name</i>	:	Hydroperoxide, 1,1-dimethylethyl
<i>Common Name</i>	:	tert-Butyl hydroperoxide
<i>CAS Number</i>	:	75-91-2
<i>RTECS Number</i>	:	EQ4900000

Synonyms

tert-Butylhydroperoxide	Cadox TBH
1,1-Dimethyl hydroperoxide	Perbutyl H
t-Butyl hydroperoxide	TBHP
T Hydro	Trigonox AW70

Properties & Definitions

<i>Molecular Formula</i>	:	C4H10O2
<i>Molecular Weight</i>	:	90.12
<i>State</i>	:	Liquid
<i>Vapour Pressure</i>	:	2.7kPa(20.30mmHg) at 20C
<i>Octanol/Water Partition</i>	:	log Pow = 0.7 at 25C
<i>Coefficient</i>	:	
<i>Water Solubility</i>	:	7.0E+0.5mg/l
<i>Impurities</i>	:	In Arco: tertiarybutylalcohol < 0.45, ketones < 0.15, hydroperoxides < 0.75, other organics < 0.35, dialkyl peroxides < 0.05, water:balance. In Atochem (U.S.A): tertiarybutyl alcohol > 10%, water > 10%.
<i>General Comments</i>	:	Degree of purity:in Arco: 69 +/- 0.05%, Atochem(U.S.A): 90%.

Overall Evaluation

SIDS INITIAL ASSESSMENT

There is need for further work in gathering exposure information.

This chemical warrants special attention because of its genotoxic properties and exposure should be avoided.

SUMMARY OF REASONS SUPPORTING THE RECOMMENDATION

TBHP is manufactured in a closed system and used as an initiator or precursor of other initiators which are used in polymerization reactions in the plastics industry.

Based upon the available information, the initial assessment gave indication for concern for humans as well as for the environment. The assessment is considered to be limited by:

- the available exposure data concern for humans only one site in the U.S.A.
- the scarce exposure data for humans as well as the environment.

FURTHER WORK:

Further information on human exposure as well as environmental exposure are needed.

A test on inherent biodegradability, a semichronic toxicity test as well as an in vivo chromosome aberration test should be carried out.

Production-Trade

Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Geographic Area : **NLD**

Production

<u>Quantity</u>	<u>Year</u>
7200 T - P	1991
6500 T - P	1990
6300 T - P	1989

General Comments : The values given for 1991 are expected quantities produced by ARCO (Botlek, Rotterdam), Netherlands. No information available for other companies.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

Production-Trade

Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Geographic Area : **USA**

Production

<u>Quantity</u>	<u>Year</u>
13000 T - P	1991
12500 T - P	1990
12800 T - P	1989

General Comments : The given values for 1991 are expected quantities produced by ARCO (Bayport, USA). No information available for other companies.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

Uses

Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
<99 %		TBHP is mainly used as an initiator or precursor of other initiators, which are used in polymerization reactions to produce polyethylene, PVC, unsaturated polyesters etc. A small fraction is used as a reagent. No other uses for TBHP have been identified.

References

Secondary References : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

Study

End Point : **Pathway into the Environment and Environmental Fate.**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Method and Conditions

Test method description : Dranc model calculations

Pathway and Transport

Pathway : **AIR** **AQ**
Pathway description : Plant emissions

Quantity Transported

<u>Medium</u>	<u>to Medium</u>	<u>Quantity</u>	<u>Time</u>	<u>Year</u>	<u>to Year</u>
	to AIR	0.0161 %	200 d		

Plant emission to air, % of production based on rated production capacity of 17000T/y of Bayport, Texas, USA. (Estimated)

	to AIR	0.0413 %	200 d		
--	---------------	-----------------	--------------	--	--

Plant emission to air, % of production based on rated production capacity of 14000T/y of Botlek, Rotterdam, Netherlands. (Estimated)

	to AQ	0.002 %	200 d		
--	--------------	----------------	--------------	--	--

Plant emission to water, % of production based on rated production capacity of 14000T/y of Botlek, Rotterdam, Netherlands. (Estimated)

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **Pathway into the Environment and Environmental Fate.**
Chemical Name : **ter-Butyl hydroperoxide**
CAS Number : **75-91-2**

Quantity Transported

General Comments : Exposue occurs due to fugitive emission from equipment leak and emission from shipment (tank truck and drum loading).

References

Secondary Reference : **!SIDSP***
 Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **Pathway into the Environment and Environmental Fate.**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Method and Conditions

Test method description : Fugacity model, Mackay level 1. Calculations were carried out with level 1 fugacity model as supplied by the OECD. All values are calculated.

Quantity Transported

<u>Medium</u>	<u>to Medium</u>	<u>Quantity</u>	<u>Time</u>	<u>Year</u>	<u>to Year</u>
....	to AIR	24.6 %			
	to AQ	75.1 %			
	to SOIL	0.3 %			
	to SED	7.4 %			
	to FISH	<0.1 %			

General Comments : From these calculations it can be concluded that ca. 25% and 75% of TBHP will partition into the atmosphere and water respectively.

References

Primary Reference : **CMSHAF**
Mackay, D. et al. Chemosphere. Chemistry, Biology and Toxicology as related to Environmental Problems, 24(6), 695-717, (1992)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **LOSS**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
100% LOSS		During industrial use.
<i>General Comments</i>	:	TBHP degrades completely during use.

References

Secondary Reference : **!SIDSP***
Screening Information Data Set (SIDS) of OECD High Production
Volume Chemicals Programme, 6, (1993)

Study

End Point : **CONCENTRATION**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Subject

Organism Medium Specification Lifestage Sex

AIR

Test Results

Matrix Concentrations Spec. Date

6.0 ppm

Limited access: peak concentration

0.39 ppm

Walkway/access pts.: "worst case"

< 0.1 ppm

Walkway/access pts.: mean

1.44 mg/m3

EHE "worst case" (expected human exposure) (also reported as 0.39ppm)

0.37 mg/m3

EHE mean (expected human exposure) (also reported as < 0.1ppm)

General Comments : The different "access" may be "access zones" in the plant. Pts was not defined.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **HUMAN INTAKE AND EXPOSURE**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Subject

Organism Medium Specification Route Lifestage Sex

HUMAN

IHL

Test Results

Intake Spec. Date

0.0031 mg/kg

BW/d

A total daily intake, calculated via crops, milk, drinking water and inhalation of air.

Total daily intake values, based on Dutch risk assessment for new chemicals (Dranc) using an estimated emission of 0.0413% to air and 0.002% to water: 0.803ug/m³ (100m from the plant).

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Dose / Concentration : **628- mg/kg**

Test Method and Conditions

Test method description : Acute dermal toxicity was tested in male and female rabbits. Limit test method.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RBT			SKN	ADULT	M F	LD50	

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Method and Conditions

Test method description : Acute toxicity test. Limit test method.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			ORL	ADULT	M F	LD50	Oral LD50 for rats was estimated at 560mg/kg.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Species/strain/system : Not specified
Dose / Concentration : **1850 mg/m3**

Test Method and Conditions

Test method description : Acute toxicity testing in inhalation of 100% TBHP. Limit test method.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			IHL	ADULT	M F	LC50	

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6, (1993)

Study

End Point : **MAMMALIAN TOXICITY**
Chemical Name : **Tert-butylhydroperoxide**
CAS Number : **75-91-2**

Evaluations

Evaluation text : This compound is classified as: toxic by inhalation to rat; harmful by oral route to rat; harmful by dermal route to rat .

References

Primary Reference : **OJEC****
Official Journal of the European Communities, L25G, (1979)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, (1993)

Study

End Point : **MAMMALIAN TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
RAT			ORL	ADULT	M F		

Test Method and Conditions

Test method description : Repeated dose toxicity test.

Exposure

Exposure Type : **Short**
Exposure Period : **45 d**
Dose / Concentration : **10-30 mg/kg BW**
Exposure comments : Dose of 0,3,10 and 30mg/kg body weight/day of TBHP.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	NEF				

Oral NOAL (no adverse effect level) was established at 3mg/kg/day.

RBC DECR

Reticulocyte count was decreased in male rats at dose level of 30mg/kg/day.

BLOOD BIOCH

The bilirubin level was increased in male rats of dose groups 10 and 30 mg/kg/day; it was decreased in female rats of 10 and 30mg/kg/day.

KIDNY TUBUL

Treatment related changes in the form of tubular nephrosis were observed in male rats of dose groups 10 and 30mg/kg body weight/day.

KIDNY TUBUL

Multifocal, increased accumulation of tubular proteinaceous material was observed at the dose levels of 10 and 30mg/kg/day. EDLC was calculated as = 0.02mg/kg/body weight using uncertainty factor.

General Comments : The accumulation of intratubular protein in male rats is considered as male rat characteristic and of low significance for human health. The UF was used as 500 because a fully significant period for this study was considered as 90 days. Recommendation was made for subchronic oral toxicity study (OECD 409).

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 7, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Method and Conditions

Test method description : Dominant lethal test.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

NEF

Negative results of dominant lethal test.

CHROM MUT

Positive results.

General Comments : Insufficiently reported study. Author: Epstein et al. (1972)

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Method and Conditions

Test method description : Bone marrow cytogenetic assay in vivo.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

BMW CELL

Positive results.

BMW NEF

Negative results.

General Comments : Positive results were reported by Katsova (1977), the negative by Ben-Dyke and Hogan (1981).

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Evaluations

Evaluation text : Conclusion: TBHP is a genotoxic compound in vitro. The available in vivo studies do not provide fully conclusive evidence as to a possible effect on the endpoints examined but TBHP should be considered as a human genotoxic agent.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Method and Conditions

Test method description : Dominant lethal test, limited study.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
CHROM	MUT				
Positive results.					
<i>General Comments</i> : Reference: Katsova et al. (1977)					

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT

VTR

Test Method and Conditions

Test method description : Ames test with and without metabolic activation.

Exposure

Exposure Type : **SHORT**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
CHROM	MUT				

The results were positive for mutation effect in cultures without metabolic activation. They were equivocal with metabolic activation.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

FUNG

VTR

Species/strain/system : Neurospora crassa fungus

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	MUT				

Positive results for mutation.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

HAMST

VTR

Species/strain/system : Chinese hamster ovary cells: line 9CHO K-1

Test Method and Conditions

Test method description : EPA Guideline 1990/SIDS testing.

Exposure

Exposure comments : Sister chromatid exchange, cell transformation assay, chromosomal aberration assay under exposure of CHO cells to TBHP, plus chromosomal aberration assay tested on CHO cell line 9CHO K-1. All tests were done with and without metabolic activation.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----

DNA

CHNG

Sister chromatid exchange test gave positive results with and without metabolic activation.

NEF

Cell transformation assay was negative without metabolic activation.

CHROM

CHNG

Chromosomal aberration assay was positive with and without metabolic activation (CHO cells and 9CHO K-1 line).

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

INSEC

VTR

Species/strain/system : Drosophila melanogaster (fruit fly)

Test Method and Conditions

Test method description : Genetic changes testing methods SLRL and reciprocal translocation.

Exposure

Exposure Type : **SHORT**
Exposure comments : Testing for genetic aberration in drosophila under the exposure to TBMP.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
CHROM	GENE				
SLRL positive effects.					
	NEF				
Reciprocal negative results					
<i>General Comments</i>	: Reference given in SDIS dossier: Summary of genetic toxicology studies. A review of published as well as unpublished (CHO cells chromosome aberration / SCE's) results, d. d. June 28, 1990.				

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

MOUSE

VTR

Test Method and Conditions

Test method description : Mouse lymphoma assay.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
CHROM	CHNG				

Positive results with and without metabolic activation.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

<i>Organism</i>	<i>Medium</i>	<i>Specification</i>	<i>Route</i>	<i>Lifestage</i>	<i>Sex</i>	<i>Number exposed</i>	<i>Number controls</i>
PLANT			VTR				

Species/strain/system : Vicia faba (horse bean)

Test Method and Conditions

Test method description : Mutagenicity testing in plants.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	MUT				

Positive results were recorded.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **REPRODUCTION**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
RAT			ORL	ADULT	M F		

Species/strain/system : Unspecified strain

Exposure

Dose / Concentration : **3-30 mg/kg BW**
Exposure comments : In a combined repeated dose and reproduction/teratogenic study male and female rats were given 0,3,10 and 30mg/kg/body weight in oral administration.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
	NEF				

No effects on male and female reproduction were observed.

NOAEL

Oral NOAEL for rat reproduction was established as > 30mg/kg /body weight (the highest dose tested).

OFSPR NOAEL

NOAEL for F1 generation was established as > 30mg/kg/body weight (the highest dose tested).

EDLC

Oral EDLC (effective dose of low concern) for rat reproduction was calculated as equal or higher than 0.06mg/kg/body weight using UF = 500.

Inhalation EDLC for rat reproduction was calculated from oral EDLC as equal or higher than 0.29mg/m³ using conversion formula of Van de Meent and Toet.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 8, (1993)

Study

End Point : **TERATOGENICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT **ORL** **F**

Species/strain/system : Mated female rats

Test Method and Conditions

Test method description : OECD - Teratogenicity/developmental toxicity study.

Exposure

Dose / Concentration : **5-50 mg/kg**
Exposure comments : Oral dosage level of 0,5,15 and 50mg/kg/body weight administered to mated female rats. Study was evaluated for exposure in utero from 6-15 day of gestation.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
FETUS	NEF				

No embryotoxic, nor teratogenic effects have been found up to the dose of 50mg/kg/body weight.

General Comments : Recommendation: although the EHE is higher than EDLC repro, there is no need for a further follow up test since no embryotoxic and teratogenic effects have been found up to a dose of 50 mg/kg body weight.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 8, (1993)

Study

End Point : **AQUATIC ACUTE TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Exposure Period : **96 h**

Test Method and Conditions

Test method description : Dranc model calculations

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
FISH						LC50	LC50 = 42.3mg/l for 96hours.

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

ALGAE

Species/strain/system : Algae

Test Method and Conditions

Test method description : Dranc model calculations.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	EC50				
	Reported as ErC50 = 2.1mg/l				
	EC50				
	Reported as EbC50 = 1.2mg/l				
	NOEC (growth rate and biomass) = 0.32mg/l				

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **tert-Butyl hydroperoxide**
CAS Number : **75-91-2**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

CRUS

Species/strain/system : Water flea (Daphnia magna)

Test Method and Conditions

Test method description : Dranc model calculations

Exposure

Exposure Period : 48 h

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	EC50				

EC50 = 20mg/l for 48hours (calculated)

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 10, (1993)

Substance

Chemical Name : **HYDROPEROXYDE DE BUTYLE TERTIAIRE (FR)**
HYDROPEROXYDE DETERT-BUTYLE (FR)
Reported Name : **TERT-BUTYL HYDROPEROXIDE**
CAS Number : **75-91-2**
Area Type Subject Spec. Description Level / Summary Information :

CAN	REG	USE STORE LABEL	OCC	RQR	
					INGREDIENT DISCLOSURE LIST CONCENTRATION 1% WEIGHT/WEIGHT. THE WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM (WHMIS) IS A NATIONAL SYSTEM TO PROVIDE INFORMATION ON HAZARDOUS MATERIALS USED IN THE WORKPLACE. WHMIS IS IMPLEMENTED BY THE HAZARDOUS PRODUCTS ACT AND THE CONTROLLED PRODUCTS REGULATIONS (ADMINISTERED BY THE DEPARTMENT OF CONSUMER AND CORPORATE AFFAIRS). THE REGULATIONS IMPOSE STANDARDS ON EMPLOYERS FOR THE USE, STORAGE AND HANDLING OF CONTROLLED PRODUCTS AND ADDRESS LABELLING AND IDENTIFICATION, EMPLOYEE INSTRUCTION AND TRAINING, AS WELL AS THE UPKEEP OF A MATERIALS SAFETY DATA SHEET (MSDS). THE PRESENCE IN A CONTROLLED PRODUCT OF AN INGREDIENT IN A CONCENTRATION EQUAL TO OR GREATER THAN SPECIFIED IN THE INGREDIENT DISCLOSURE LIST MUST BE DISCLOSED IN THE SAFETY DATA SHEET.

Title :**Reference :****Effective Date :** 31DEC1987
Last Amendment : CAGAAK, 122, 2, 551, 1988
 CANADA GAZETTE PART II
Entry / Update : APR1991

Substance

Chemical Name : **TERT-BUTYLHYDROPEROXIDE**
HYDROPEROXYDE DE TERT-BUTYLE (FR)
Reported Name : **TERT-BUTYL HYDROPEROXIDE**
CAS Number : **75-91-2**
Area Type Subject Spec. Description Level / Summary Information :

CAN	REG	TRNSP LABEL PACK	-	CLASS RQR	
					MORE THAN 72% BUT NOT MORE THAN 90%, WITH WATER. PIN (PRODUCT IDENTIFICATION NO.): UN2094. CLASS (5.2): ORGANIC PEROXIDE; CLASS (I): DAMAGING TO THE EYES. SPECIAL PROVISIONS: 46, 48, 56, 63, 74, 83, 99. PACKING GROUP I, (I=GREAT DANGER, III=MINOR DANGER). MAXIMUM AMOUNT PER PACKAGE THAT MAY BE TRANSPORTED ON A CARGO AIRCRAFT OR VEHICLE: 1 L. MAXIMUM AMOUNT PER PACKAGE THAT MAY BE TRANSPORTED ON A CARGO AIRCRAFT: 5 L. PRESCRIBED BY THE TRANSPORTATION OF DANGEROUS GOODS REGULATIONS, UNDER THE TRANSPORTATION OF DANGEROUS GOODS ACT (ADMINISTERED BY THE DEPARTMENT OF TRANSPORT). THE ACT AND REGULATIONS ARE INTENDED TO PROMOTE SAFETY IN THE TRANSPORTATION OF DANGEROUS GOODS IN CANADA, AS WELL AS PROVIDE ONE COMPREHENSIVE SET OF RULES APPLICABLE TO ALL MODES OF TRANSPORT ACCROSS CANADA. THESE ARE BASED ON UNITED NATIONS RECOMMENDATIONS. THE ACT AND REGULATIONS SHOULD BE CONSULTED FOR DETAILS. RECORDS ARE ENTERED UNDER THE PROPER SHIPPING NAME FOUND IN THE REGULATIONS; THIS MAY INCLUDE VERY GENERAL GROUPS OF CHEMICAL SUBSTANCES.

Title :**Reference :****Effective Date :** 06DEC1990
Last Amendment : CAGAAK, 124, 26, 5523, 1990
 CANADA GAZETTE PART II
Entry / Update : OCT1991

Substance

Chemical Name : **TERT-BUTYLHYDROPEROXIDE**
HYDROPEROXYDE DE TERT-BUTYLE (FR)
Reported Name : **TERT-BUTYL HYDROPEROXIDE**
CAS Number : **75-91-2**

<u>Area</u>	<u>Type</u>	<u>Subject</u>	<u>Spec.</u>	<u>Description</u>	<u>Level / Summary Information :</u>
CAN	REG	TRNSP LABEL PACK	-	CLASS RQR	NOT MORE THAN 72%, WITH WATER. PIN (PRODUCT IDENTIFICATION NO.): UN2093. CLASS (5.2): ORGANIC PEROXIDE. SPECIAL PROVISIONS: 46, 56, 63, 89, 99. PACKING GROUP II, (I=GREAT DANGER, III=MINOR DANGER). MAXIMUM AMOUNT PER PACKAGE THAT MAY BE TRANSPORTED ON A CARGO AIRCRAFT OR VEHICLE: 1 L. MAXIMUM AMOUNT PER PACKAGE THAT MAY BE TRANSPORTED ON A CARGO AIRCRAFT: 5 L. PRESCRIBED BY THE TRANSPORTATION OF DANGEROUS GOODS REGULATIONS, UNDER THE TRANSPORTATION OF DANGEROUS GOODS ACT (ADMINISTERED BY THE DEPARTMENT OF TRANSPORT). THE ACT AND REGULATIONS ARE INTENDED TO PROMOTE SAFETY IN THE TRANSPORTATION OF DANGEROUS GOODS IN CANADA, AS WELL AS PROVIDE ONE COMPREHENSIVE SET OF RULES APPLICABLE TO ALL MODES OF TRANSPORT ACCROSS CANADA. THESE ARE BASED ON UNITED NATIONS RECOMMENDATIONS. THE ACT AND REGULATIONS SHOULD BE CONSULTED FOR DETAILS. RECORDS ARE ENTERED UNDER THE PROPER SHIPPING NAME FOUND IN THE REGULATIONS; THIS MAY INCLUDE VERY GENERAL GROUPS OF CHEMICAL SUBSTANCES. <u>Title :</u> <u>Reference _____ :</u> <u>Last Amendment :</u>
					<u>Effective Date :</u> 06DEC1990 <u>Entry / Update :</u> OCT1991
				CAGAAK, 124, 26, 5523, CANADA GAZETTE PART II	

Substance

Chemical Name :
Reported Name : **TERT-BUTYL HYDROPEROXIDE**
CAS Number : **75-91-2**

<u>Area</u>	<u>Type</u>	<u>Subject</u>	<u>Spec.</u>	<u>Description</u>	<u>Level / Summary Information :</u>
DEU	REC	AIR	OCC	MAK	ORGANIC PEROXIDE. MODERATE INFLAMMATORY AND CAUSTIC EFFECTS ON SKIN. NO MAK VALUE ESTABLISHED. <u>Title :</u> MAXIMUM CONCENTRATIONS AT THE WORKPLACE AND BIOLOGICAL TOLERANCE VALUES FOR WORKING MATERIALS (MAXIMALE ARBEITSPLATZKONZENTRATIONEN UND BIOLOGISCHE ARBEITSTOFFTOLERANZWERTE) <u>Reference _____ :</u> MPGDFD, XXVII, 17, 1991 <u>Last Amendment :</u>
					<u>Effective Date :</u> MITTEILUNG DER SENATSKOMMISSION ZUR PRUEFUNG GESUNDHEITSSCHAEDLICHER ARBEITSTOFFE (DEUTSCHE FORSCHUNGSGEMEINSCHAFT) <u>Entry / Update :</u> JAN1992

Substance

Chemical Name :
Reported Name : **T-BUTYLHYDROPEROXIDE**
CAS Number : **75-91-2**

<u>Area</u>	<u>Type</u>	<u>Subject</u>	<u>Spec.</u>	<u>Description</u>	<u>Level / Summary Information :</u>
RUS	REG	AIR	OCC	MAC CLASS	CLV: 5.0MG/M3 (VAPOUR) HAZARD CLASS: III <u>Title :</u> <u>Reference _____ :</u> <u>Last Amendment :</u>
					<u>Effective Date :</u> 01JAN1989 <u>Entry / Update :</u> MAY1990
				GOSTS*, 12.1.005, 1988 GOSUDARSTVENNYI STANDART SSSR (STATE STANDARD OF USSR)	

Substance

Chemical Name :
 Reported Name : **TERT-BUTYL HYDROPEROXIDE**
 CAS Number : **75-91-2**

Area Type Subject Spec. Description Level / Summary Information :

USA	REG	FOOD TRANS STORE PACK	ADDIT	RSTR RSTR RSTR RSTR	<p>; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF SUBSTANCES USED TO PREPARE ADHESIVES WHICH MAY BE SAFELY USED AS COMPONENTS OF ARTICLES INTENDED FOR USE IN PACKAGING, TRANSPORTATION, OR HOLDING FOOD IN ACCORDANCE WITH THE FOLLOWING PRESCRIBED CONDITIONS: SUBSTANCE MUST BE SEPARATED FROM THE FOOD BY A FUNCTIONAL BARRIER, MUST NOT EXCEED LIMITS OF GOOD MANUFACTURING PRACTICE USED WITH DRY FOODS, OR NOT EXCEED TRACE AMOUNTS AT SEAMS AND EDGE EXPOSURES WHEN USED WITH FATTY AND AQUEOUS FOODS. ALSO REGULATED BY SEA M INTEGRITY, LABELING STANDARDS, AND ANY PROVISION UNDER 21 CFR 175</p> <p><u>Title :</u> SUBSTANCES FOR USE ONLY AS COMPONENTS OF ADHESIVES</p> <p><u>Reference :</u> FEREAC, 42, 14534, 1977 <u>Effective Date :</u> 1977 Federal Register</p> <p><u>Last Amendment :</u> CFRUS*, 21, 175, 105, 1988 <u>Entry / Update :</u> NOV1991 Code of Federal Regulations</p>
-----	-----	--------------------------------	-------	------------------------------	--

Substance

Chemical Name :
 Reported Name : **TERT-BUTYL HYDROPEROXIDE**
 CAS Number : **75-91-2**

Area Type Subject Spec. Description Level / Summary Information :

USA	REG	TRNSP PACK LABEL	-	PRMT CNTRL RQR	<p>MORE THAN 72% BUT NOT MORE THAN 90% WITH WATER: LIQUID AS FLAMMABLE LIQUID: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO VESSELS ON DECK. FORBIDDEN IN PASSENGER VESSELS. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED FLAMMABLE LIQUID AND ORGANIC PEROXIDE. MORE THAN 72% BUT NOT MORE THAN 90% WITH WATER: LIQUID AS ORGANIC PEROXIDE: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO AND PASSENGER VESSELS ON AND BELOW DECK. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED ORGANIC PEROXIDE. NOT MORE THAN 72% WITH WATER: LIQUID AS FLAMMABLE LIQUID: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PAC KAGE. MAY BE TRANSPORTED IN CARGO VESSELS ON DECK. FORBIDDEN IN PASSENGER VESSELS. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED FLAMMABLE LIQUID AND ORGANIC PEROXIDE. NOT MORE THAN 72% WITH WATER: LIQUID AS FLAMMABLE LIQUID: LIQUID AS ORGANIC PEROXIDE: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO AND PASSENGER VESSELS ON AND BELOW DECK. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED ORGANIC PEROXIDE. NOT MORE THAN 80% IN DI-TERT-BUTYL PEROXIDE AND SOLVENT: LIQUID AS FLAMMABLE LIQUID: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO VESSELS ON DECK. FORBIDDEN IN PASSENGER VESSELS. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED ORGANIC PEROXIDE. NOT MORE THAN 80% IN DI-TERT-BUTYL PEROXIDE AND SOLVENT: LIQUID AS ORGANIC PEROXIDE: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO AND PASSENGER VESSELS ON AND BELOW DECK. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED ORGANIC PEROXIDE. NOT MORE THAN 80% IN DI-TERT-BUTYL PEROXIDE: LIQUID AS FLAMMABLE LIQUID: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO VESSELS ON DECK. FORBIDDEN IN PASSENGER VESSELS. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED FLAMMABLE LIQUID AND ORGANIC PEROXIDE. NOT MORE THAN 80% IN DI-TERT-BUTYL PEROXIDE: LIQUID AS FLAMMABLE LIQUID: FORBIDDEN IN PASSENGER AIRCRAFT AND PASSENGER RAILCAR. MAY BE TRANSPORTED IN CARGO AIRCRAFT NOT TO EXCEED 1 QUART/PACKAGE. MAY BE TRANSPORTED IN CARGO AND PASSENGER VESSELS ON AND BELOW DECK. VESSEL SHIPMENTS MUST BE STOWED SEPARATE FROM COMBUSTIBLE MATERIALS, EXPLOSIVES, OR ACIDS. ALL SHIPMENTS MUST BE LABELED ORGANIC PEROXIDE. MORE THAN 90% WITH WATER: FORBIDDEN IN TRANSPORT.; Summary - THIS REGULATION LISTS AND CLASSIFIES THOSE MATERIALS WHICH THE DEPARTMENT OF TRANSPORTATION HAS DESIGNATED AS HAZARDOUS MATERIALS FOR SHIPPING PAPERS, PACKAGE MARKING, LABELING, AND TRANSPORT VEHICLE PLACARDING APPLICABLE TO THE SHIPMENT AND TRANSPORT OF THOSE HAZARDOUS MATERIALS.</p> <p>Title : HAZARDOUS MATERIALS REGULATIONS, PART 172-- HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS REGULATIONS</p> <p>Reference : CFRUS*, 49, 172, 101, 1984 Code of Federal Regulations</p> <p>Effective Date : OCT1991</p> <p>Last Amendment : CFRUS*, 49, 172, 101, 1990 Code of Federal Regulations</p> <p>Entry / Update : NOV1991</p>
-----	-----	------------------------	---	----------------------	--

Substance

Chemical Name :
 Reported Name : **TERT-BUTYL HYDROPEROXIDE**
 CAS Number : **75-91-2**

<u>Area</u>	<u>Type</u>	<u>Subject</u>	<u>Spec.</u>	<u>Description</u>	<u>Level / Summary Information :</u>
USA	REG	FOOD MANUF STORE PACK	ADDIT	RSTR RSTR RSTR RSTR	<p>FOR USE ONLY AS POLYMERIZATION CATALYST.; <u>Summary</u> - THIS SUBSTANCE IS INCLUDED ON A LIST OF SUBSTANCES WHICH HAVE BEEN CONDITIONALLY APPROVED TO BE USED AS COMPONENTS OF THE UNCOATED OR COATED FOOD-CONTACT SURFACE OF PAPER AND PAPERBOARD FOR USE WITH MANUFACTURING, PACKING, PROCESSING, PREPARING, TREATING , TRANSPORTING OR HOLDING AQUEOUS AND FATTY FOODS. THESE ARE EXEMPTED FROM EXTRACTION ANALYSIS IN 21 CFR 176.170(C).</p> <p><u>Title</u> : INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS- COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS</p> <p><u>Reference</u> _____ : FEREAC, 42, 14554, 1977 <u>Effective Date</u> : 1977 Federal Register</p> <p><u>Last Amendment</u> : CFRUS*, 21, 176, 170, 1988 <u>Entry / Update</u> : NOV1991 Code of Federal Regulations</p>