Substance

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

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

**Properties & Definitions**
- **Molecular Formula** : C4H10O2
- **Molecular Weight** : 90.12
- **State** : Liquid
- **Vapour Pressure** : 2.7kPa(20.30mmHg) at 20C
- **Octanol/Water Partition Coefficient** : log Pow = 0.7 at 25C
- **Water Solubility** : 7.0E+0.5mg/l
- **Impurities** : 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%.
- **General Comments** : 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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>7200 T - P</td>
<td>1991</td>
</tr>
<tr>
<td>6500 T - P</td>
<td>1990</td>
</tr>
<tr>
<td>6300 T - P</td>
<td>1989</td>
</tr>
</tbody>
</table>

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

### References

*B* SIDSP  
OECD/SIDS. Screening Information Data Set (SID) 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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>13000 T - P</td>
<td>1991</td>
</tr>
<tr>
<td>12500 T - P</td>
<td>1990</td>
</tr>
<tr>
<td>12800 T - P</td>
<td>1989</td>
</tr>
</tbody>
</table>

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

### References

*B* SIDSP  
OECD/SIDS. Screening Information Data Set (SID) of OECD High Production Volume Chemicals Programme, 4, (1993)
Uses

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

Use

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Year</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>99 %</td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Medium to Medium</th>
<th>Quantity</th>
<th>Time</th>
<th>Year</th>
<th>to Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>to AIR</td>
<td>0.0161 %</td>
<td>200 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to AIR</td>
<td>0.0413 %</td>
<td>200 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to AQ</td>
<td>0.002 %</td>
<td>200 d</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Plant emission to air, % of production based on rated production capacity of 17000T/y of Bayport, Texas, USA. (Estimated)
Plant emission to air, % of production based on rated production capacity of 14000T/y of Botlek, Rotterdam, Netherlands. (Estimated)
Plant emission to water, % of production based on rated production capacity of 14000T/y of Botlek, Rotterdam, Netherlands. (Estimated)

References

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

Study

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

Quantity Transported

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

References

Secondary Reference : ISIDSP* Screening Information Data Set (SDS) 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

<table>
<thead>
<tr>
<th>Medium to Air</th>
<th>Quantity</th>
<th>Time</th>
<th>Year to Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>to AIR</td>
<td>24.6 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to AQ</td>
<td>75.1 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to SOIL</td>
<td>0.3 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to SED</td>
<td>7.4 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to FISH</td>
<td>&lt;0.1 %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>End Point</th>
<th>Chemical Name</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LOSS</td>
<td>75-91-2</td>
</tr>
<tr>
<td></td>
<td>tert-Butyl hydroperoxide</td>
<td></td>
</tr>
</tbody>
</table>

Test Results

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Time</th>
<th>Comments on result</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% LOSS</td>
<td></td>
<td>During industrial use.</td>
</tr>
</tbody>
</table>

General Comments: TBHP degrades completely during use.

References

Secondary Reference: ISIDSP*
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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Medium</th>
<th>Specification</th>
<th>Lifestage</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test Results

<table>
<thead>
<tr>
<th>Matrix</th>
<th>Concentrations</th>
<th>Spec.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.0 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Limited access: peak concentration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.39 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Walkway/access pts.: &quot;worst case&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 0.1 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Walkway/access pts.: mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.44 mg/m3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EHE &quot;worst case&quot; (expected human exposure) (also reported as 0.39ppm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EHE mean (expected human exposure) (also reported as &lt; 0.1ppm)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

References

**Secondary Reference**: ISIDSP*

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 (Drac) 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/SDS. Screening Information Data Set (SDS) 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

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments
RBT SKN ADULT M LD50

References

Secondary Reference : ISIDSP*
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

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

References

Secondary Reference : ISIDSP*
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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Medium</th>
<th>Spec.</th>
<th>Route</th>
<th>Lifestage</th>
<th>Sex</th>
<th>Effect</th>
<th>Effect Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAT</td>
<td></td>
<td>IHL</td>
<td>ADULT</td>
<td>M</td>
<td></td>
<td></td>
<td>F</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LC50</td>
<td></td>
</tr>
</tbody>
</table>

References

Secondary Reference : ISIDSP*: 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**  

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

Study

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

Test Subject

Organism Medium Specification Route Lifespan Sex Number exposed Number controls
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

Exposure - Controls

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected In</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

RBC DESC
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.

KIDNEY 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.

KIDNEY 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 : ISDSP*
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

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Negative results of dominant lethal test.

CHROM MUT
Positive results.

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

References

Secondary Reference : ISIDSP*
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

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMW</td>
<td>CELL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: ISIDSP*
OECD/SIDS. Screening Information Data Set (SID) 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: ISIDSP*
OECD/SIDS. Screening Information Data Set (SID) 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

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

References

Secondary Reference: ISIDSP*
OECD/SIDS. Screening Information Data Set (SID) 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

Organ Effect Rev. OnSet Sex Affected in Exposed - Controls

CHROM MUT

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

References

Secondary Reference: ISIDSP^ 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

Organ Effect Rev. OnSet Sex Affected in Exposed - Controls

MUT

Positive results for mutation.
References

Secondary Reference: 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: HAMST
Medium: 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

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA</td>
<td>CHNG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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: 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**: Species/strain/system: Drosophila melanogaster (fruit fly)

**Test Method and Conditions**: Genetic changes testing methods SLRL and reciprocal translocation.

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

Test Results

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHROM</td>
<td>GENE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLRL positive effects.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reciprocal negative results**


References

**Secondary Reference**: ISO/DIS. 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**: MOUSE
**Specification**: VTR
Test Method and Conditions

Test method description: Mouse lymphoma assay.

Test Results

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHROM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHENG</td>
</tr>
</tbody>
</table>

Positive results with and without metabolic activation.

References

Secondary Reference: ISIDSP* 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: PLANT
Medium: VTR
Specification: 
Route: 
Lifestage: 
Sex: 
Number exposed: 
Number controls: 
Species/strain/system: Vicia faba (horse bean)

Test Method and Conditions

Test method description: Mutagenicity testing in plants.

Test Results

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MUT</td>
</tr>
</tbody>
</table>

Positive results were recorded.

References

Secondary Reference: ISIDSP* 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**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Medium</th>
<th>Specification</th>
<th>Route</th>
<th>Life stage</th>
<th>Sex</th>
<th>Number exposed</th>
<th>Number controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAT</td>
<td>ORL</td>
<td>ADULT</td>
<td>M</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
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</thead>
<tbody>
<tr>
<td>NEF</td>
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</tbody>
</table>

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).

**OFSPF**  **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**: ISIDSP
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

<table>
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<tr>
<th>Organism</th>
<th>Medium</th>
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<th>Lifestage</th>
<th>Sex</th>
<th>Number exposed</th>
<th>Number controls</th>
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</thead>
<tbody>
<tr>
<td>RAT</td>
<td>ORL</td>
<td></td>
<td>F</td>
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<td></td>
<td></td>
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</tbody>
</table>

**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 50 mg/kg/body weight administered to mated female rats. Study was evaluated for exposure in utero from 6-15 day of gestation.

Test Results

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>FETUS</td>
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</tbody>
</table>

No embryos toxic, nor teratogenic effects have been found up to the dose of 50 mg/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**: ISIDSP
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

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<tr>
<th>Organism</th>
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<th>Spec.</th>
<th>Route</th>
<th>Lifestage</th>
<th>Sex</th>
<th>Effect</th>
<th>Effect Comments</th>
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</thead>
<tbody>
<tr>
<td>FISH</td>
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<td>LC50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LC50 = 42.3mg/l for 96 hours.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Organ</th>
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<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in Exposed - Controls</th>
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</thead>
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<tr>
<td></td>
<td>Reported as ErC50 = 2.1mg/l</td>
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<td></td>
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<tr>
<td>EC50</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reported as EbC50 = 1.2mg/l</td>
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</tr>
</tbody>
</table>

NOEC (growth rate and biomass) = 0.32mg/l

References

Secondary Reference : ISIDSP+ 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

IRPTC Data Profile
Exposure

Exposure Period : 48 h

Test Results

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effect</th>
<th>Rev.</th>
<th>OnSet</th>
<th>Sex</th>
<th>Affected in</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Exposed - Controls</td>
</tr>
</tbody>
</table>

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

References

Secondary Reference : ISIDSP*
OECID/SIDS. Screening Information Data Set (SID) of OECD High Production Volume Chemicals Programme, 10, (1993)
INGREDIENT DISCLOSURE LIST CONCENTRATION % WEIGHT/WIGHT. 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 UPTAKE OF A MATERIALS SAFETY DATA SHEET (MSD). THE PRESENCE OF 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: CAGAAK, 122, 2, 551, 1986
Entry / Update: APR1991

Reference: CAGAAK, 124, 25, 5523, 1990
Entry / Update: OCT1991

Reference: CANADA GAZETTE PART II

Reference: CANADA GAZETTE PART II
### Substance

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

---

**Title:**  
**Reference:** CAGAAK, 124, 26, 5523,  
**Entry / Update:** OCT1991  
**Effective Date:** 06DEC1990

---

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

---

**Title:**  
**Reference:** GOSUDARSTVENNYI STANDART SSSR (STATE STANDARD OF USSR)  
**Entry / Update:** MAY1990  
**Effective Date:** 01JAN1989

---

**Chemical Name:** CLV: 5.0MG/M3 (VAPOUR) HAZARD CLASS: III

---

**Title:**  
**Reference:**  
**Entry / Update:**  
**Effective Date:**
Substance

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

Area Type Subject Spec Description Level/Summary Information:
USA REG FOOD ADDIT RSTR : 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
Title : SUBSTANCES FOR USE ONLY AS COMPONENTS OF ADHESIVES
Reference : FEREAC, 42, 14534, 1977 Effective Date : 1977
Code of Federal Regulations

Substance

Chemical Name : TERT-BUTYL HYDROPEROXIDE
Reported Name : 75-91-2
CAS Number : 75-91-2
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/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% 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 80% 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. 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: 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 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: 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% 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.

Title: HAZARDOUS MATERIALS REGULATIONS. PART 172- HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS REGULATIONS

Effective Date: OCT 1991

Last Amendment: CFRUS*, 49, 172, 101, 1999
Entry/Update: NOV 1991

Code of Federal Regulations

Chemical Name: TERT-BUTYL HYDROPEROXIDE
CAS Number: 75-91-2
<table>
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<tr>
<th>Area</th>
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<th>Subject</th>
<th>Spec.</th>
<th>Description</th>
<th>Level / Summary Information</th>
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<tr>
<td>USA</td>
<td>REG</td>
<td>FOOD</td>
<td>ADDIT</td>
<td>RSTR</td>
<td>FOR USE ONLY AS POLYMERIZATION CATALYST. Summary: 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(i).</td>
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iRPTC Data Profile