

<b>SAFETY DATA SHEET</b>		
<b>TEREPHTHALIC ACID</b>		Edition : 01 Revision: 00 Date: 01/18/2011

In accordance with Regulations (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010 (Annex I)

**SECTION 1.  
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY**

**1.1. Substance identifier**

Substance name:	<b>TEREPHTHALIC ACID</b>
Other names (if available): Synonyms:	1,4-Benzenedicarboxylic acid; p-Benzenedicarboxylic acid; p-Carboxybenzoic acid; p-Phthalic acid; Acide terephthalique;
CAS number	100-21-0
IUPAC name	Terephthalic acid
REACH registration number	01-2119485970-27-0041

**1.2. Relevant identified uses of the substance and uses advised against**

Relevant use(s)	Industrial manufacture of poly(ethyleneterephthalate) and other polyester polymers; laboratory chemical.
Uses advised against	Fireworks applications.

**1.3. Details of the supplier of the safety data sheet**

**Identification of the company (supplier):**

**TPT PETROCHEMICALS PUBLIC COMPANY LIMITED**

3, I-7 Road, Map Ta Phut Industrial Estate, Tambol Map Ta Phut, Amphur Muang, Rayong 21150, Thailand

Tel: +66 (0)38-683-288-98 Fax: +66 (0) 38-683-300

[www.tptpetro.com](http://www.tptpetro.com)

[www.indoramaventures.com](http://www.indoramaventures.com)

E-mail address of competent person: [ghosh@tptpetro.com](mailto:ghosh@tptpetro.com)

**1.4. Emergency telephone number**

Address of Associate Factory at Rotterdam: Markweg 201, 3198 NB Europoort Harbour Number 6347 Rotterdam, The Netherlands

Emergency telephone number (office hours): (+)31-(0)181-285 472

**SECTION 2  
HAZARDS IDENTIFICATION**

**2.1 Classification of the substance**

**- Classification of the substance in accordance with Regulation (CE) n. 1272/2008:**

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Hazard class	Class code and hazard category	Hazard statement	Hazard warning
<b>Not classified</b>	<b>Not classified</b>	<b>Not classified</b>	<b>Not classified</b>

**- Classification in accordance with Directive 67/548/CEE :**

Classification	Hazard symbol	Risk phrases
<b>Not classified</b>	<b>Not classified</b>	<b>Not classified</b>

**Main adverse effects**

*Physico-chemical effects:*

*Health effects*

No adverse physico-chemical effects are expected under normal conditions of use

Ingestion: not known.

Inhalation exposure: slight irritant.

Contact with skin: may cause irritation to skin.

Contact with eyes: may cause irritation to eyes.

Sensitization: the substance might cause allergic skin reactions.

*Environmental effects*

See also sections from 9 to 12

No adverse environmental effects are expected under normal condition of use.

**2.2 Label elements**

**- Labelling in accordance with Regulation n. 1272/2008/EC**

Pictogram(s)	<b>Not foreseen</b>
Warning	<b>Not foreseen</b>
Hazard statements	<b>Not foreseen</b>

**2.3 Other hazards (which do not results in the classification)**

- Physico-chemical hazards

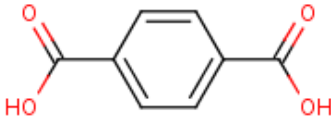
The substance is organic, it may form explosive mixtures with air under certain conditions (e.g. temperature, pressure, particle size of dusts, humidity, concentration of combusive agents).

**SECTION 3  
COMPOSITION/INFORMATION ON INGREDIENTS**

Description

<i>Name of the component</i>	Terephthalic acid
<i>Concentration</i>	Mono-constituent organic substance $\geq 99.9\%$ (w/w)

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Structural formula	
Chemical formula	C <sub>8</sub> H <sub>6</sub> O <sub>4</sub>
Molecular weight	166.1308 [g/mol]
Substance with Community OEL	NO
CAS name	Terephthalic acid
CAS number	100-21-0
IUPAC name	Terephthalic acid
EC number	202-830-0
Impurity/ies (if classified)	There are no impurities. Pure substance.
Additive/ies (if classified)	There are no additives

**SECTION 4  
FIRST AID MEASURES**

**4.1 Description of the first aid measures**

- *Eye contact* Wash immediately with large amounts of water or normal saline. Keep eyelids open with the finger. Get medical advice and show him the label.
- *Skin contact* Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical immediately.
- *Ingestion* If swallowed wash mouth with water provided person is conscious. Get medical immediately and show container or label.
- *Inhalation* Avoid breathing dusts that may be generated by handling of the product. Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms will appear.

**4.2 Most important symptoms and effects (acute and delayed)**

- *Acute and delayed effects:* Ingestion: not known.  
Inhalation exposure: slight irritant.  
Contact with skin: redness.  
Contact with eyes: burning sensation, redness of conjunctivae.  
Sensitization: the substance may cause allergic skin reactions.

**4.3 Indication of any immediate medical attention and special treatment needed**

- *Medical monitoring:* Not foreseen
- *Antidotes, if known* Unknown
- *Contraindications* Unknown

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- *Immediate treatment at workplace*                      Not foreseen

**SECTION 5  
FIREFIGHTING MEASURES**

**5.1 Extinguishing media**

- *Suitable extinguishing media*                      Nebulized water, chemical powder, foam , CO2  
Use any means suitable for extinguishing surrounding fire.  
Small fire: carbon dioxide , foam  
Large fire: fog, foam.
- *Unsuitable extinguishing media*                      Unsuitable extinguishing media are not known

**5.2 Special hazards arising from the substance**

- *Hazardous combustion products*                      May produce fumes containing dangerous substances (e.g. COx).
- *Other special hazards*                                      Special hazards related to this substance are not known.

**5.3 Advice for firefighters**

- *Technical actions for protection*                      Do not try to extinguish the fire without an autonomous respiratory device (SCBA) and protective adapted clothes.
- *Special protective equipment for firefighters*                      Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections

**SECTION 6  
ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

- **For non-emergency personnel**
- *Eye*    Wear suitable protected devices. (see section 8)
- *Skin*    Wear suitable clothes with full body protection. (devices see section 8)
- *Inhalation*    In case of fire and/or explosions avoid breathing fumes and vapours. Use a respiratory device autonomous (SCBA) and adapted protective clothes. The vapours can be eliminated through nebulized water.

See also section 8

In case of accidental spilling (non in normal condition of use) the use of Personal Protection Equipment is always recommended. This PPE must be in accordance with EN criteria.

- **For emergency responders**
- *Eye*    see section 8
- *Skin*    see section 8
- *Inhalation*    see section 8

**6.2 Environmental precautions**

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water.

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**6.3 Methods and material for containment and cleaning up**

- *Containment procedures:* Collect all of the material scattered on the ground with appropriate protective equipment and put it in a clean and dry container. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8.
- *Cleaning up procedures:* Recover the substance for suction or with other mechanic means and wash with plenty of water and clean. Store the recovered product waiting for the skilled disposal society.

**6.4 Reference to other sections**

See also section 8 and 13

**SECTION 7  
HANDLING AND STORAGE**

**7.1. Precautions for safe handling**

- *Recommendations for handling:*
  - Handle away from sparkles and flames - sources of ignition
  - Handle in a well ventilated place
  - Avoid contact with incompatible materials
  - Wear suitable Personal Protection Equipment (see section 8)
  - Keep the substance away from drains, surface or ground waters
- *Recommendations for personal hygiene:*
  - Do not eat, drink and smoke in the working areas
  - Wash hands after handling the substance
  - Remove contaminated clothing and protective equipment before entering eating areas

**7.2. Condition for safe storage including any incompatibilities.**

The substance is organic, it may form explosive mixtures with air under certain conditions

Risk Management measures related to :

- *Potential ignition sources:* As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build up of static electricity.
- *Weather conditions:* Do not expose to high temperatures and heat sources.
- *Ambient pressure:* It is not expected any procedure of restriction.
- *Temperature* Store in original container tightly closed in a cool (15 - 25°C), dry place.
- *Sunlight:* Do not expose to the direct light of the sun.
- *Humidity* Do not store in a damp place.
- *Vibration:* It is not expected any procedure of restriction.

The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

Material to keep the integrity of the substance

- *Stabilisers:* Use of stabilisers is not expected
- *Antioxidants:* Use of antioxidants is not expected

Other advice

- *Ventilation requirements* Requested on the base of the storage of the substance
- *Specific design of storage rooms* Not requested on the based of the classification

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- *Quantity limits for storage*                      Not requested on the based of the classification
- *Packaging compatibilities*                      See also 10.5

**7.3. Specific end use(s)**

- Recommendation for specific final use(s)

	YES	NO
- Exposure scenario attached	<input type="checkbox"/>	X
- Industry or sector specific guidance available and attached	<input type="checkbox"/>	X

**SECTION 8  
EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1. Control parameters**

- National/European Occupational Exposure Limits      Not established
- Other National/European Occupational Exposure Limits      Not established
- National/European Biological Limits (BEI):      Not established
- Other National/European Biological Limits (BEI):      Not established
- Recommended monitoring procedures      The measurements of the substance/s in the workplace must be carried out in accordance with standardized methods described by EN guidance.
- DNEL values      **DNELs for workers**  
Dermal: 67 mg/kg bw/d. (Exposure pattern: long-term, systemic effects)<sup>[1]</sup>  
Inhalation: 23 mg/m<sup>3</sup> (Exposure pattern: long-term, systemic effects)<sup>[1]</sup>  
**DNELs for general population**  
Dermal: 33 mg/kg bw/d. (Exposure pattern: long-term, systemic effects)<sup>[1]</sup>  
Inhalation: 5.8 mg/m<sup>3</sup> (Exposure pattern: long-term, systemic effects)<sup>[1]</sup>  
Oral: 3.3 mg/kg bw/d (Exposure pattern: long-term, systemic effects)<sup>[1]</sup>
- PNEC values      **PNEC water**  
PNEC fresh water (mg/l): 0.38 mg/L<sup>[1]</sup>  
PNEC marine water (mg/l): 0.038 mg/L<sup>[1]</sup>  
PNEC aqua, intermittent releases (mg/l): 1.9 mg/L<sup>[1]</sup>  
**PNEC sediment**  
PNEC fresh water: 0.52 mg/kg sediment dw<sup>[1]</sup>  
PNEC marine water: 0.052 mg/kg sediment dw<sup>[1]</sup>  
**PNEC soil**  
PNEC: 0.71 mg/kg soil dw<sup>[1]</sup>  
**PNEC for sewage treatment plant**  
PNEC STP: 50 mg/L<sup>[1]</sup>

**8.2. Exposure controls**

	YES	NO
- Exposure scenario attached	<input type="checkbox"/>	X

**8.2.1. Appropriate engineering controls**

The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

**8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)**

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If the results of the risk evaluation done in accordance with Directive 98/24/EEC showed that the collective and general risk management measures are not sufficient to reduce the risks and, if the exposure to the substance cannot be reduced by other containment means, appropriate PPE must be adopted in compliance with technical EN guidance indication.

- |   |   |
|---|---|
| a) Eye and Face protection                      | Safety goggles as for EN 166; facial shield   |
| b) Skin protection<br>- <i>hands protection</i> | <p>Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/CEE.</p> <p>The gloves material must be waterproof and stable against the substance content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, and thickness.</p> <p>Material : nitrile (nitrilic rubber), ipoallergenic<br/>Thickness : not inferior to 0.12 mm</p>   |
| - <i>other, body protection</i>                 | Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of sketches or EN 13982 in case of powders   |
| c) Respiratory protection                       | <p>When the risk evaluation foresees the need to use respirator devices with assisted ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU)</p> <p>For your information powders are divide in three categories:<br/> <b>2a (inert powder with TLV= 10 mg/m3),</b><br/> <b>2b (hazards powders with TLV = 0,1-10 mg/m3 (excluding asbestos),</b><br/> <b>2c (toxic powders with TLV &lt; 0,1 mg/m3 (asbestos, carcinogens, bacteria, viruses, enzymes, spores, etc).</b><br/> <b>Cat. 2a: P1 filter, Cat. 2b: P2 filter, Cat.2c: P3 filter.</b></p> |
| d) Thermal hazards                              | <p>Not foreseen in the standard use.</p> <p>Assess possible Personal Protection Equipment on the basis of specific uses of the substance.</p>   |

### 8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Appearance:	Solid, white, free-flowing, crystalline powder (Physical state at 20°C and 101.3 kPa).
pH:	3.88 at 25°C. <sup>[1]</sup>
Melting point:	427 °C under sealed tube conditions. <sup>[1]</sup>
Initial boiling point and boiling range:	Not applicable.
Flammability:	Non flammable. <sup>[1]</sup>
Vapour pressure:	0.00158 Pa at 25 °C (estimated using the QSAR model MPBPVP v.1.43 of the US EPA). <sup>[1]</sup>
Density:	Crystal density: 1.58 g/cm <sup>3</sup> at 25 °C. <sup>[1]</sup> Specific gravity: 1.522 at 25 °C. <sup>[1]</sup>
Water solubility:	ca17 - 19 mg/L at 25 °C. <sup>[1]</sup>
Solubility in organic solvents:	At 25 °C in glacial acetic acid: 0.013 % w/w; in methanol: 0.1 % w/w; in dimethylformamide: 6.7 % w/w and in dimethylsulfoxide:

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Partition coefficient octanol/water (Log Kow):	19 % w/w. <sup>[1]</sup> 2 at 25 °C (estimated using the KOWWIN v1.67 QSAR model available from the US EPA). <sup>[1]</sup>
Explosive properties:	Non explosive; based on the chemical structure. <sup>[1]</sup>
Oxidising properties:	No oxidising properties; based on the chemical structure. <sup>[1]</sup>

**9.2. Other information**

Henry's Law	$3.93 \times 10^{-8}$ Pa m <sup>3</sup> /mole at 25 °C estimated using the HENRYWIN v3.20 QSAR model available from the US EPA. <sup>[1]</sup>
Dissociation constant	pK1: 3.54. pK2: 4.46 at 25°C. <sup>[1]</sup>

**SECTION 10  
STABILITY AND REACTIVITY**

**10.1. Reactivity**

This substance is considered not reactive under the normal conditions of the storage.

**10.2. Chemical stability**

The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X	-	
- Change in physical appearance	X	-	
- Other hazards(temperature, pressure)	X		

**10.3. Possibility of hazardous reactions**

	NO	SI
- Possibility of an exothermic reaction:	X	-
- Possibility of a reaction releasing excessive pressure	X	-
- Possible degradation with instable product formation	X	-

**10.4. Conditions to avoid**

Potential ignition sources, moisture.

**10.5. Incompatible materials**

Strong oxidising agents and bases.

**10.6. Hazardous decomposition products**

If heated at high temperatures, it decomposes releasing fumes and toxic gases of CO<sub>x</sub> and organic compounds (e.g. HCOOH).

**SECTION 11  
INFORMATION ON TOXICOLOGICAL EFFECTS**

	YES	NO
- <b>Exposure routes:</b>		
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	

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- Eye contact:

X	
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**- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):**

- Ingestion: Ingestion: not known.
- Inhalation: Inhalation exposure: slight irritant.
- Skin contact: Contact with skin: redness.
- Eye contact: Contact with eyes: burning sensation, redness of conjunctivae.

**- Toxicokinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):**

*Absorption*

The toxicokinetics of terephthalic acid (TPA) have been investigated in a number of investigative studies and a guideline-compliant mouse study. Following oral administration, Terephthalic acid is rapidly absorbed and is excreted rapidly and predominantly in the urine as the sulphate conjugate. The weight of evidence indicates that there is little potential for bioaccumulation. Moffit *et al* (1975) report no significant dermal absorption of radiolabelled TPA in the rat following a single or repeated dermal application of 80 mg. In contrast, dermal absorption of 11% of a single dose and 13% of a repeated dose of the related compound dimethylterephthalate is reported.<sup>[1]</sup>

*Distribution*

(Hoshi & Kuretani, 1968) investigated the distribution of TPA in the tissues of rats. Female Wistar King-A rats were fed a diet containing 0.5% radiolabelled TPA for 1 day, 3 days, or 3 days followed by a 1 day recovery period. Rats were sacrificed at the end of the respective feeding periods and the tissues assayed for radioactivity to determine the TPA content. Another group of female rats was administered a single oral dose by gavage of 85 mg/kg bw radiolabelled TPA, and sacrificed at various intervals post-administration for determination of TPA content in the tissues. In the rats fed TPA-diets, radioactivity was highest in the kidney (40-50 µg/g), liver (16-23 µg/g) and plasma (8 -10 µg/ml). Content in the other tissues was low. A single administered dose was distributed rapidly in the tissues within 2 hours of administration, and the distribution pattern in the tissues was similar to that seen in the feeding study. The maximum radioactivity level in the tissues was seen within 2 hours of administration, whereas in the brain the maximum content was seen 8 hours after administration. Only small amounts of TPA remained in the tissues at 24 hours after single administration, and 24 hours after completion of a 3 day feeding period.<sup>[1]</sup>

*Metabolism*

Following administration by gavage, a longer terminal half-life was obtained, indicating that dissolution of TPA or absorption from the gut may be partially rate-limiting. No evidence of metabolism of TPA was obtained by HPLC analysis of urine. TPA was transported to the foetus after administration of the compound to pregnant rats; however, the concentrations in foetal tissues were low relative to the corresponding maternal tissues.<sup>[1]</sup>

*Elimination*

Terephthalic acid is excreted rapidly and predominantly in the urine as the sulphate conjugate.<sup>[1]</sup>

**- Acute Toxicity**

- Oral: Rat LD50: > 15380 mg/kg bw (male/female), 20% mortality (1M, 1F).<sup>[1]</sup>
- Dermal: Rabbit LD50: > 2000 mg/kg bw (male/female).<sup>[1]</sup>
- Inhalation: Rat (Sprague-Dawley), LC50 (2 h): > 2.02 mg/L air (analytical) (male/female).<sup>[1]</sup>  
Rat (Fischer 344), LC50 (30 min): > 235 mg/m<sup>3</sup> air (analytical) (male).<sup>[1]</sup>  
Rat LC50 (4 h): > 1000 mg/m<sup>3</sup> air (nominal) (male).<sup>[1]</sup>

- **Corrosion/Irritation effects:** Rabbit (New Zealand White). coverage: semi occlusive (shaved): not irritating. Primary dermal irritation index (PDII): 0.2 (mean) (Time point: 24, 48 and 72 hours) (fully reversible within: 72 hours).  
Rabbit: coverage: occlusive (abraded and intact): not irritating. Erythema score: 0.17 of max. 1 (mean) (Time point: 24 hours) (fully reversible within: 72 hours) (Intact skin) 0.33 of max. 1 (mean) (Time point: 24h) (not fully reversible within: 72h) (abraded skin).

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The results of a guideline-comparable study (with 24 -hour application) show minimal irritant effects on intact skin (Baker, 1975). No evidence of corrosivity was seen in a screening study (DuPont, 1981). The results of an irritation study reported in summary form only (Hatoum & Goun, 1990) are also consistent in indicating very low potential for dermal irritation.<sup>[1]</sup>

**- Severe ocular lesion :** Rabbit: not irritating. Cornea score: 0.06 of max. 1 (mean) (Time point: 24-72h) (fully reversible within: 48 hours) (effect seen in 1/6 animals).  
Iris score: 0 of max. 0 (mean) (Time point: 24-72 hours) (no effects seen).  
Mild irritation was seen in a guideline-comparable study (Baker, 1975).<sup>[1]</sup>  
Conjunctivae score: 0.17 of max. 1 (mean) (Time point: 24-72h) (fully reversible within: 48h) (effects seen in 6/6 animals).<sup>[1]</sup>

**- Sensitisation:**

**- Dermal and respiratory::** No data are available for TPA; however a negative Buehler study is reported for the read-across substance isophthalic acid (IPA). The OECD QSAR Toolbox does not report any structural alerts for protein binding activity (relevant for skin sensitisation) for TPA.<sup>[1]</sup>

**- Repeated dose toxicity (experimental.):**

Rat male/female sub-chronic (oral: feed). 0, 1, 3.2, 10 % (nominal in diet). Exposure: 90 days (Daily) 90 day repeat dose toxicity test in rats. NOEL: 1 % (male/female).

Rat (Wistar) male/female sub-chronic (oral: feed) 5% reduced to 3% (nominal in diet). Exposure: 13 weeks (Continuous, in the diet). The study was a 90 day dietary toxicity study, with one dose level. No NOAEL identified (male/female). LOAEL: 3 % in the diet (male/female). (Reduced weight gain and food consumption, urinalysis increased kidney weights, renal and urinary bladder calculi and associated pathology. Dose level calculated to be equivalent to 2070 mg/kg bw/d and 2490 mg/kg bw/d for males and females respectively during the final study week.)

Rat (Wistar and CD) male/female combined repeated dose and reproduction / developmental screening (oral: feed). NOAEL: 1250 ppm (male/female) (Reduced terminal body weights / weight gains at higher dose levels). LOEL: 300 ppm (male) (Decreased urinary pH in CD males fed diet containing 0.03% TPA).<sup>[1]</sup>

**- CMR effects:**

**- Germinal cell mutagenicity**

***In vitro data.***

*In vitro* genotoxicity studies. Bacterial reverse mutation assay (e.g. Ames test) (gene mutation) *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with and without). The test concentration: 500-10000 µg/plate. Negative for *S. typhimurium*.

Mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells, (met. act.: with and without) Doses: concentrations : 7.5, 25, 75, 250, 750 and 2500 µg/ml. Results: negative.

*In vitro* mammalian chromosome aberration test lymphocytes: primary culture (human) (met. act.: with and without): positive without metabolic activation. Concentrations tested: 500, 250 and 50 µg/mL.

Positive without metabolic activation.<sup>[1]</sup>

***In vivo data.***

*In vivo* genotoxicity studies. Micronucleus assay (chromosome aberration) mouse (ICR) male/female intraperitoneal: negative.

Unscheduled DNA synthesis (DNA damage and/or repair) rat (Alpk:APfSD) male oral: gavage 2000 mg/kg (nominal conc.): negative.

No evidence of mutagenicity was seen in a guideline-comparable Ames test (DuPont, 1979). The clastogenicity of terephthalic acid was investigated in human lymphocytes (Fox, 2006); this study reports a positive result in the absence of metabolic activation. However, negative results were seen in studies with sodium terephthalate (Fox, 2006; 2007), indicating that the terephthalate anion itself is not clastogenic.<sup>[1]</sup>

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### - Carcinogenicity:

#### **Carcinogenicity oral.**

Rat (Fischer 344) male/female oral: feed 0, 20, 142 and 1000 mg/kg/bodyweight/day (nominal in diet). Exposure: 24 months (with interim sacrifices at 6 and 12 months). No NOAEL identified: neoplastic effects seen.

Evidence of carcinogenicity was seen in a chronic rat study (Preache, 1983; Ackerman, 1983) in which female rats had an increased incidence of transitional cell adenomas and carcinomas at the highest dose level equivalent to approximately 1000 mg/kg bw/d. Findings were secondary to urolithiasis and associated with inflammation and irritation. Several other effects were noted in this study (retinal degeneration and uterine adenocarcinomas), but could not be attributed to treatment as they were seen with similar incidence across all treated and control groups and were associated with a defective lighting system which resulted in 24h/day exposure to artificial light for an undetermined period of time.

Data indicate that the chronic administration of terephthalic acid at high concentrations results in the formation of urinary bladder tumours as a consequence of chronic inflammation secondary to calculus formation.

LOAEL: 1000 mg/kg bw/d (route:oral).

Humans are generally considered to be less sensitive than rats to urolithiasis for anatomical reasons; it is possible that urolithiasis could occur in exposed humans; however it is extremely unlikely that humans could be exposed to the levels of TPA of the magnitude used in the rat toxicity studies, or for similarly long periods.<sup>[1]</sup>

### - Reproductive toxicity:

#### **Experimental study on fertility:**

Rat (Wistar) male/female two-generation study oral: feed: NOAEL (reproductive) (all): 20000 ppm (nominal in diet) (male/female). No effects seen on reproduction and development.

In a one-generation screening study (Ledoux *et al*, 1982), administration of TPA in the diet up to 5% did not affect reproduction or fertility parameters in CD and Wistar rats. Dose-dependent treatment-related effects were observed in the F1 generation; TPA exposure decreased Day 1 bodyweight of newborns and 21 day survival, whilst increasing the incidence of renal and bladder calculi at day 51 in pups fed the same test diets as their mothers. The NOAEL for offspring toxicity was 0.5% TPA in the diet.

NOAEL: 2010.9 mg/kg bw/d (route: oral).<sup>[1]</sup>

#### **Developmental toxicity:**

Rat (Sprague-Dawley) inhalation: aerosol (whole body) 0.0, 1.0, 5.0 and 10.0 mg/m<sup>3</sup> (nominal conc.): NOAEL (maternal toxicity): 10 mg/m<sup>3</sup> air (nominal).

No evidence of developmental toxicity was seen in an inhalation study in rats exposed to TPA at levels of up to 10 mg/m<sup>3</sup> (Ryan *et al*, 1990). It is also relevant that toxicokinetics studies (Tyl *et al*, 1982) indicate only limited placental transport of TPA following intravenous injection due to the rapid maternal urinary excretion of the substance.

NOAEC: 10 mg/m<sup>3</sup> (route: inhalation).<sup>[1]</sup>

### - Specific Target Organ Toxicity (STOT)-single exposure:

No data are available for TPA.

### - Specific Target Organ Toxicity (STOT)- repeated exposure :

Target organs: urogenital: urinary bladder. (Carcinogenicity).<sup>[1]</sup>

### - Epidemiological information:

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No data are available for TPA.

**- Other Information:**

There is no indication of neurotoxicity and immunotoxicity from the standard toxicity studies; additional specific investigations are not required.<sup>[1]</sup>

**- Reasons for no classification:** : data conclusive but not sufficient for classification.

**SECTION 12  
ECOLOGICAL INFORMATION**

**12.1. Toxicity**

**Short-term toxicity to fish**

*Leuciscus idus melanotus* freshwater static: LC<sub>50</sub> (96 h): > 961 mg/L.<sup>[1]</sup>

*Pimephales promelas* freshwater static: LC<sub>50</sub> (96 h): > 100 mg/L.<sup>[1]</sup>

*Oryzias latipes* freshwater semi-static: LC<sub>50</sub> (96 h): > 18.6 mg/L.<sup>[1]</sup>

**Short-term toxicity to aquatic invertebrates**

*Daphnia magna* freshwater static: EC<sub>50</sub> (48 h) : > 967 mg/L.<sup>[1]</sup>

*Daphnia magna* (aquatic crustacean), *Dugesia tigrina* (flatworm), *Helisoma trivolvis* (snail) freshwater static: LC<sub>50</sub> (96 h) : > 100 mg/L.<sup>[1]</sup>

*Daphnia magna* freshwater semi-static: EC<sub>50</sub> (48 h) : > 20.1 mg/L test.<sup>[1]</sup>

**Long-term toxicity to aquatic invertebrates**

*Daphnia magna* freshwater semi-static: NOEC (21 d): 19.5 mg/L.<sup>[1]</sup>

**Algae and aquatic plants**

*Scenedesmus subspicatus* (new name: *Desmodesmus subspicatus*) (algae) freshwater static: NOEC (96 h): 1000 mg/L (nominal). NOEC (96 h): 668 mg/L; meas. (arithm. mean)<sup>[1]</sup>

*Pseudokirchnerella subcapitata* (reported as *Selenastrum capricornutum*) (algae) freshwater static: EC<sub>50</sub> (72 h): > 19 mg/L.<sup>[1]</sup>

**Toxicity to aquatic micro-organisms**

Activated sludge of a predominantly domestic sewage freshwater static EC<sub>50</sub> (3 h): 1393 mg/L (nominal).<sup>[1]</sup>

**12.2. Persistence and degradability**

The log Kow of Terephthalic acid is < 3.0 and TPA is readily biodegradable.<sup>[1]</sup>

**12.3. Bioaccumulative potential**

QSAR-predicted and measured log<sub>10</sub> Kow values for Terephthalic acid are less than 3.0. The potential for Terephthalic acid to bioaccumulate in the tissues of organisms that inhabit aquatic or terrestrial matrices contaminated with TPA is therefore negligible. The risk that Terephthalic acid may biomagnify through successive trophic levels of aquatic or terrestrial food chains is consequently also negligible.<sup>[1]</sup>

The calculated BCF of Terephthalic acid is 3.16 L/kg wet weight and below the threshold of 2000.<sup>[1]</sup>

**12.4. Mobility in soil**

Terephthalic acid is a dicarboxylic acid. The first step that may be predicted in its environmental fate, prior to biodegradation, is its conversion to terephthalate salts. Three reliable, GLP-compliant short-term studies are available in which TPA was treated with NaOH solution to convert the free acid to its highly soluble sodium terephthalate salt(s) prior to exposure to fish, daphnia and algae.

No adverse effects occurred in these studies, up to and including the highest nominal TPA equivalent concentrations of 1000 mg/L.

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**12.5. Results of PBT e vPvB assessment**

1. Terephthalic acid cannot be considered to be persistent in the environment as it readily biodegradable.
2. The calculated BCF of Terephthalic acid is 3.16 L/kg wet weight and below the threshold of 2000.
3. The long-term NOECs for freshwater algae and invertebrates are 19.0 and 19.5 mg/L, respectively, for the free acid form of TPA. Both values exceed the trigger value of 0.01 mg/L.

Terephthalic acid is not a CMR and not classified T, R48, or Xn, R48 according to Directive 67/548/EEC. Terephthalic acid does not satisfy the criteria for classification as PBT nor a vPvB substance.

**12.6. Other adverse effects**

Not found after bibliographic research.

**SECTION 13  
DISPOSAL CONSIDERATION**

**13.1. Waste treatment methods**

	Incineration	Recycling	Landfilling
- Substance wastes:	X		
- Contaminated packaging:	X		

**Sewage disposal is not allowed.**  
**Refers to Community/National/Local requirements concerning the waste disposal.**

**SECTION 14  
TRANSPORT INFORMATION**

Not classified for transport in agreement with regulation RID/ADR, IMO/IMDG, ICAO/IATA.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: not applicable.

**SECTION 15  
REGULATORY INFORMATION**

All other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

**15.1 Safety, Health and Environmental regulation/legislation specific for the substance**

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183, 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131, 05/05/1998 P. 0011 - 0023

**15.2. Chemical Safety Assessment**

- Exposure scenario attached
- Chemical Safety Assessment (CSA) attached

YES	NO
	X
	X

**SECTION 16  
OTHER INFORMATION**

**Revisions:**

- **Edition n. 01 dated 01/18/2011**
- **Revision n. 00**

**Bibliographic sources:**

- [1] Terephthalic acid Chemical Safety Report  
ChemIdplus Lite  
stneasy.fiz-karlsruhe.de  
pubchem.ncbi.nlm.

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**Acronyms**

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI: Biological Exposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for reproduction substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: Not Applicable
- N.A.: Not Available
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE: Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

**Information on workers training**

Follow criteria of Directive 98/24/CE, its amendments and National reinforcements



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**Restriction of use:** None

**Substance under authorisation:** No

**DISCLAIMER**

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