# Potassium citrate

**Botanical Source**

**Synonyms** CITRIC ACID,TRIPOTASSIUM SALT;
TRIPOTASSIUM CITRATE;
C6 H5 K3 O7;
Potassium citrate monohydrate

**IUPAC Name**

**CAS Reference** 866-84-2
6100-05-6

**E Number** E332(ii)

## Food Legislation

| **Council of Europe (CoE)** | |
|---|---|
| Number | Comment |
| - | - |

| **US Food and Drug Administration** | |
|---|---|
| Number | Comment |
| 182.1625 | Approved by the US FDA. FDA 21 CFR 182.1625 |

| **Joint FAO/WHO Expert Committee on Food Additives (JECFA)** | | |
|---|---|---|
| Number | ADI | Comment |
| - | - | On the basis of the available data, the total daily intake arising from use levels necessary to achieve the desired effect does not represent a hazard to health |

| **FEMA** | |
|---|---|
| FEMA No. | Comment |
| | Generally recognised as safe as a flavour ingredient:GRAS List Number 3 |

| **Natural Occurrence and Use in Food** |
|---|
| - |

| **Estimated Intake from Food and Drink** | |
|---|---|
| Daily Intake mg/kg/day | FEMA Possible Average Daily Intake mg |

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|---|---|
| - | - |

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## Tobacco Product Related Chemical and Biological Studies for Ingredients Added in a Mixture

| **Smoke Chemistry** | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| BAT | 0.00100 | At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke. |

| **Ames Activity** | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| BAT | 0.00100 | Within the sensitivity and specificity of the system the Ames activity of the cigarette smoke condensate was not increased by the addition of the ingredient. |

| **Micronucleus** | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| BAT | 0.00100 | Within the sensitivity of the in vitro micronucleus assay the activity of the cigarette smoke condensate was not increased by the addition of the ingredient. |

| **Neutral Red** | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| BAT | 0.00100 | Within the sensitivity of the test system the in vitro cytotoxicity of the cigarette smoke condensate was not increased by the addition of the ingredient. |

| **Inhalation** | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| BAT | 0.00100 | The data indicate that the addition of the ingredient, when added with one of three groups, did not increase the inhalation toxicity of the smoke. |

| Mouse Skin Painting | | |
|---|---|---|
| Published Source | Level Tested % | Comment |
| | | |

| References |
|---|
| Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives. Food Chem Toxicol. 2004; 42 Suppl:S3-37. |
| Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part II: casing ingredients. Food Chem Toxicol. 2004; 42 Suppl:S39-52. |
| Baker RR, Massey ED, Smith G. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. Food Chem Toxicol. 2004; 42 Suppl:S53-83. |

# Potassium citrate

## Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

| References |
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| Baker RR, Bishop LJ. The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions. J. Anal. Appl. Pyrolysis 2005, 74, 145-170. |

# Potassium citrate

## Toxicological Data on the Unburnt Ingredient

[+ve, positive; -ve, negative; ?, equivocal; with, with metabolic activation; without, without metabolic activation]

In vivo

| Species | Test conditions | Endpoint | Results | Reference |
|---|---|---|---|---|
| Rat (numbers unspecified) | Dominant lethal assay. Citric acid doses of up to 3 g/kg bw/day administered for 5 days (route not specified). [Presumably males treated and mated with untreated females, and early foetal deaths monitored.] | Germ cell mutation | -ve | LBI, 1975a |
| Rat (numbers unspecified) | Chromosome aberration assay. Oral doses of up to 3 g citric acid/kg bw/day for 5 days. Bone marrow examined. | Chromosome damage | -ve | LBI, 1975a |

In vitro

| Test system | Test conditions | Endpoint | Activation status | Results | Reference |
|---|---|---|---|---|---|
| Human embryonic lung culture cells (WI-38) | Chromosome aberration assay. Citric acid tested up to 0.6 mg/ml. | Chromosome damage | Not known | -ve | LBI, 1975a |

| | | | | | |
|---|---|---|---|---|---|
| Chinese hamster lung fibroblast cells | Chromosome aberration/polyploidy assay. Citric acid and sodium citrate (said to be CAS 18996-35-5) tested at up to 1 mg/ml and 3 mg/ml, respectively. 48-hr incubation. | Chromosome damage and changes in chromosome number | Without | -ve<br><br>(May be same study as below) | Ishidate et al. 1984 |
| Chinese hamster lung fibroblast cells | Chromosome aberration/polyploidy assay. Citric acid and "sodium citrate" (CAS given as 68-04-2, which actually corresponds to trisodium citrate) tested up to 1 mg/ml and 3 mg/ml, respectively. 48-hr incubation. | Chromosome damage and changes in chromosome number | Without | -ve<br><br>(May be same study as above) | Ishidate, 1987 |
| *Drosophila melanogaster*<br><br>[Some investigators consider this to be an *in vivo* assay.] | Citric acid [solution] tested for ability to induce sex-linked recessive lethal mutations. No further details provided. | Germ cell mutation | Not applicable | -ve (Presumably)<br><br>[A mutation rate of between 0.2 and 0.5% (not further specified) was reported.] | von Brandt & Hoehne, 1951 |
| *Salmonella typhimurium*, strains TA92, TA94, TA98, TA100, TA1535, TA1537 | Ames assay. Citric acid and sodium citrate (CAS 18996-35-5) tested up to 5 mg/plate. | Mutation | With S9 | -ve<br><br>[Testing without S9 is also generally recommended] | Ishidate et al. 1984 |
| *Salmonella* | Ames assay. | Mutation | With and | -ve | Fujita et |

| | | | | | |
|---|---|---|---|---|---|
| *typhimurium*, strains TA97, TA102 | Potassium dihydrogen citrate, tripotassium citrate and trisodium citrate tested up to 10 mg/plate. Paper in Japanese, abstract and data tables only in English. | | without S9 | [Limited assay, as only two strains used. Guidelines suggest that at least four are tested.] | al. 1992 |
| *Salmonella typhimurium*, strains TA97, TA98, TA100, TA104 | Ames assay. Citric acid tested up to 2 mg/plate. | Mutation | With and without S9 | -ve | Al-Ani & Al-Lami, 1988 |
| *Salmonella typhimurium*, strains TA1535, TA1537, TA1538 and *Saccharomyces cerevisiae*, strain D4 | Sodium and potassium citrates tested. No further details provided in citing source. | Mutation | With and without S9 | -ve | LBI, 1975b,c |
| (Unspecified) laboratory species and *Salmonella typhimurium*, strains TA1530, G46 or *Saccharomyces cerevisiae*, strain D3 | Host-mediated mutagenicity assay. For *S. cerevisiae* tested up to 3.5 g/kg bw (route unspecified). No further details provided in citing source. | Mutation/mitotic recombination | Host-mediated | -ve for mutation ("no clear indication of mutagenicity")<br><br>? for mitotic recombination (+ve at low dose only)<br><br>Some experts consider this to be an *in vitro* assay. | LBI, 1975a |
| *Escherichia coli*, strain not specified in citing sources | Citric acid [and/or possibly one or more of its simple salts] tested. No further | Mutation | With and without S9 | -ve | Hayes et al. 1984 |

| | | | | | |
|---|---|---|---|---|---|
| | details provided in citing sources. | | | | |
| *Saccharomyces cerevisiae*, strain D3 | Citric acid tested. No further details provided in citing source. | Mitotic recombination | Not known | +ve | LBI, 1975a |

References


Al-Ani F.Y. & Al-Lami S.K. (1988). Absence of mutagenic activity of acidity regulators in the Ames Salmonella/microsome test. Mutation Research 206, 467-470 (cited in CCRIS, 1991).

BIBRA (1993). Toxicity Profile for citric acid and its common salts. P.099. BIBRA International Limited, Carshalton, Surrey.

CCRIS (1991). Chemical Carcinogenesis Response Information System. Record for citric acid, last revision date "19911001". Record accessed 14 April 2004.

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LBI (1975b). Litton Bionetics Inc. Mutagenic evaluation of compound FDA 75-4 (006100-05-6) potassium citrate, NF, FCC granular. Contract No. 223-74-2104 (cited in BIBRA, 1993; FASEB, 1977).

LBI (1975c). Litton Bionetics Inc. Mutagenic evaluation of compound FDA 75-12 (006132-04-3) sodium citrate, USP, FCC hydrous, granular. Contract No. 223-74-2104 (cited in BIBRA, 1993; FASEB, 1977).

von Brandt H & Hoehne G. (1951). Mutagenic action of some chemicals. Drosophila Information Service 25, 132-133.