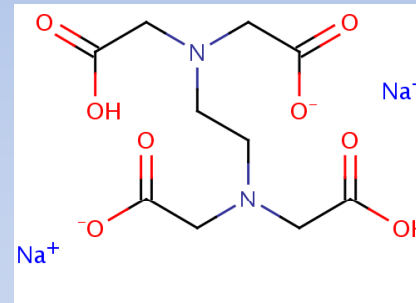


DISODIUM EDTA

- **General Information**

- Substance identification**

- **INCI NAME:** DISODIUM EDTA
 - **EC Number**
 - **CAS Number:** 139-33-3
 - **Molecular weight:** 336,21 g/mol
 - **IUPAC Name:** Disodium dihydrogen ethylenediaminetetraacetate
 - **Color:** white
 - **Odour:** odourless



DISODIUM EDTA

Dati chimico fisici

- Physical form : solid
- Melting point 248°C (DECOMPOSES)
- Boiling point: not applicable
- Vapour pressure: not applicable
- Water solubility: highly soluble to miscible in water (generally > 10,000 mg/L)
- Solubility: insoluble in organic solvents, therefore also possessing negative partition coefficients (log K_{ow}s).
- Incompatible with strong oxidizing agents.
- Bioaccumulative: Not Bioaccumulative
- Persistent : Not Persistent

DISODIUM EDTA

| End point | Test | Dose | Result |
|---|---------------------------------|---|--|
| <i>Toxicokinetics, Metabolism and Distribution</i> | Dermal absorption | n.s. | Poorly adsorbed, 95% eliminated via the kidneys, not found in the blood, found at 0,001% in the urine. |
| | Oral absorption | | Poorly adsorbed, Expected due to electrolyte structure |
| <i>Oral Acute Toxicity</i> | Comparable to OECD 401 del 1973 | 2500/3200/4000/5000/6400 mg/Kg bW on 5 rats (5 male and 5 female) | Letal dose 2800 mg/kg |

| End point | Test | Dose | Result |
|---|---------------------------------|---|---|
| <i>Inhalation Acute Toxicity</i> | OECD 412 GLP | 30/300/1000 mg/m ³ for 5 days on 10 male rats | 1103 mg/m ³ for 6 h/day LOAEC = 30 mg/m ³ |
| <i>Skin Irritation</i> | Comparable to OECD 404 del 1973 | 2 ml sol. Water 50% on dorsal skin of 2 rabbits for 1/5/15 min. duration 20 h; on ear duration 20 h | 1/5/15 min: not irritant 20 h: light erythema reversible NOT IRRITANT |
| <i>Ocular Irritation</i> | Comparable to OECD 405 del 1973 | 50 mg on eye of 2 rabbits for 8 days | Reversible redness NOT IRRITANT |
| <i>Sensitisation</i> | OECD 406 del 2000 | Studies on 10 Guinea pigs : intradermal 0,5% in corn oil Topical in 30% corn oil | NOT SKIN SENSITIZER |

| Endpoint | Test | Dose | Result |
|---|---------------------------------------|---|--|
| <i>Repeated-dose Toxicity Oral</i> | Test 1970 no GLP and 1977 Read across | On male rats at 1/5/10 % of diet for 13 weeks | NOAEL > 500 mg /Kg bw/day Some adverse effects are evident at 5%. |
| <i>Repeated-dose Toxicity Inhalation</i> | OECD 412 del 2010 GLP | On male rats at 30/300/1000 mg/m ³ | LOAEC = 30 mg/m ³ |
| <i>Genetic Toxicity</i> | OECD 476 Mammalian cell gene mutation | 250/500/1000/1500/2000 µg/ml in water | NOT GENOTOXIC |
| <i>Carcinogenicity</i> | Read across study 1977 | 248/495 mg /kg/day for 103 weeks on rats oral | NOT EXPECTED BE CARCINOGENS |

DISODIUM EDTA

| Endpoint | Test | Dose | Result |
|--|------------------|---|----------------------------|
| <i>Toxicity to reproduction</i> | Read across 1963 | On 23 male and 23 female rats for 2 years at 0,50/125/250 mg/kg | NO EFFECTS ON REPRODUCTION |
| | | | |
| | | | |

DISODIUM EDTA

Scenari espositivi: dentifricio per adulti allo 0,2%

| | Assorbimento | Appl./die | mgxKgxdie |
|-----------|--------------|-----------|-----------|
| Rinse off | 5 % | 3 | 43,29 |

$$\text{SED} = \frac{5 \times 43,29 \times 0,002}{100} = 0,004$$

$$\text{MOS} = \frac{500}{0,004} = 125000$$

DISODIUM EDTA

Conclusioni:

**Scarso assorbimento sia dermico che orale,
Non irritante sulla cute e sugli occhi, non
sensibilizzante, NOAEL 500 mg/kg , inoltre non
si dimostra essere mutageno, cancerogeno e
tossico per la riproduzione**

GRAZIE PER L'ATTENZIONE
Gruppo IV