



UNEP



**United Nations
Environment Programme**

**Food and Agriculture Organization
of the United Nations**

Distr.: General
11 January 2005

English only

**Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous
Chemicals and Pesticides in International Trade
Chemical Review Committee**

First meeting

Geneva, 11–18 February 2005

Item 7 (j) of the provisional agenda*

**Inclusion of chemicals in Annex III of the Rotterdam Convention:
review of notifications of final regulatory actions to ban
or severely restrict a chemical: benzidine**

Benzidine: supporting documentation from the Republic of Korea

Note by the secretariat

The secretariat has the honour to provide, in the annex to the present note, the supporting documentation received from the Republic of Korea in support of its notification of final regulatory action on benzidine.

* UNEP/FAO/RC/CRC.1/1.

Annex

benzidine

Focussed Summary of the Notification of a Final Regulatory Action by Republic of Korea

I. INTRODUCTION

Overview of the regulatory system

Under the Toxic Chemicals Control Act (TCCA), Ministry of Environment (MOE) is responsible for the restriction or prohibition of the severely Toxic Chemicals after consultation with relevant ministries. The National Institute of Environmental Research (NIER), an affiliated organization of MOE, conducts the hazard assessment of new chemicals or existing chemicals of concerns and then designates them as Toxic Chemicals if toxic to human health or the aquatic organisms, based on the designation criteria of TCCA.

The events that led to the regulatory action

No information

Significance of regulatory action

. As for Benzidine and mixtures containing 0.1% or more of Benzidine, they are banned due to risk of carcinogenic effect on humans. Benzidine might cause risk to human health by ingestion or short term direct exposure and might cause damage to or adverse effects on human organs through exposure when assessed for carcinogenicity and genetic toxicity.

Scope of the regulatory action

Benzidine and mixtures containing 0.1% or more of Benzidine are banned for manufacture, import and use as an industrial chemical. No remaining uses are allowed except the use for research or laboratory purposes.

II. RISK EVALUATION

Key findings of the national risk evaluation

Key data reviews consulted and a brief description

Benzidine is a carcinogen to humans(IARC group 1) and it causes irritation of eyes, skin, and respiratory tract. Laboratory studies shows it is genotoxic in bacterial and mammalian assays, including a transplacental micronucleus test.

Reference to national studies, eg toxicological and ecotoxicity studies

The information on the substance in HSDB, RTECS, ECOTOX at present is quoted below

Toxicity:

Acute oral: LD₅₀ mouse 214mg/kg, rat 309mg/kg

Carcinogenic to humans (IARC group 1, NTP group a)

Ecotoxicity:

Fish toxicity: LC₅₀(fathead minnow, 96hr) > 20mg/l

LC₅₀(rainbow trout, 96hr) 7.4mg/l

Earthworm toxicity : NOEC (eisenia fetida, 28days) 100mg/kg

-U.S. EPA IRIS on Benzidine from the National Library of Medicine's TOXNET System, November 1, 1994

-ACGIH. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and

Biological Exposure Indices (BEIs) for 1995-1996. Cincinnati, OH: ACGIH, 1995.

-IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: WHO, International Agency for Research on Cancer, p. S7 58 (1987)

- DHHS/NTP; Seventh Annual Report on Carcinogens (1994)

Summary of actual (or potential) human exposure and/or environmental fate (referred from HSDB)

Benzidine's former production and use in the manufacture of azo dyes, a reagent for the detection of blood, and rubber compounding agent may have resulted in its release to the environment through various waste streams. Today, **benzidine** may only be produced for captive use in the United States and its direct release to the environment is unlikely. When released to air, an estimated vapor pressure of 7×10^{-7} mm Hg at 25 deg C indicates **benzidine** will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase **benzidine** will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 2 hours. **Benzidine** absorbs light in the environmental UV spectrum and may also undergo direct photolysis in the atmosphere. Particulate-phase **benzidine** will be removed from the atmosphere by wet and dry deposition. If released to soil, **benzidine** is expected to be essentially immobile based upon Koc values in the range of 227,000 to 882,000, measured in 4 soils. **Benzidine** is a weak base with 2 amine functional groups having pKa values of 4.3 and 3.3. These values indicate that **benzidine** can partially exist in the protonated form under acidic conditions. Volatilization from moist soil surfaces is not expected to be an important fate process because cations do not volatilize, and the estimated Henry's Law constant of the neutral species (free base) is 5.2×10^{-11} atm-cu m/mole. **Benzidine** is not expected to volatilize from dry soil surfaces based on its estimated vapor pressure. **Benzidine** is resistant to biodegradation at high concentrations due to its microbial toxicity, however it has been shown to undergo biodegradation at concentrations in the ppb range. **Benzidine** is oxidized rapidly by Fe(III) and other cations which are frequently found in soil and water. If released into water, **benzidine** is expected to adsorb to suspended solids and sediment based upon the Koc values. Volatilization from water surfaces is not expected to be an important fate process for either the free base or its conjugate acid based upon this compound's estimated Henry's Law constant and the fact that cations are non-volatile. **Benzidine** has been shown to undergo degradation in aerated water samples upon illumination with UV light, suggesting that photolysis in sunlit surface waters may occur. **Benzidine** is not expected to undergo hydrolysis due to a lack of hydrolyzable functional groups. BCF values of 40 and 55, measured in fish, suggest bioconcentration in aquatic organisms is moderate. Since **benzidine** may only be produced for captive use in the United States, the general population will not be exposed to this compound. Workers employed at laboratories where **benzidine** is made for research purposes, may be exposed to small quantities of **benzidine** via inhalation or dermal contact during its production or use. NIOSH considers **benzidine** to be a potential occupational carcinogen.

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

It is expected that the regulatory action will significantly reduce the potential risk of carcinogenic effect to workers and others involved in dye manufacturing industry.

a) Estimates of the quantity of chemicals used, or imported/exported at the time of the regulatory action and, if possible information on ongoing trade

- exported quantity : 10.80 MT (1998)

- used quantity : 317.600 MT (1998) , 199.881 MT (1996)

b) Relevance to other States i.e. those with similar conditions of use

No information