



UNEP



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**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 (h) 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: 2-naphthylamine**

2-naphthylamine: 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 provided by the Republic of Korea in support of its notification of final regulatory action on 2-naphthylamine.

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

Annex

2-naphthylamine

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.

Ministry of Labor also restricts or bans the hazardous chemicals if they are chronically toxic to workers under the Industrials Safety and Health Act.

The events that led to the regulatory action

No information

Significance of regulatory action

2-Naphthylamine, its hydrochloride, and mixtures containing 0.1% or more of any of these chemicals are banned for manufacture, import and use as an industrial chemical due to risk of carcinogenic effect on humans.

Scope of the regulatory action

2-Naphthylamine, its hydrochloride, and mixtures containing 0.1% or more of any of these chemicals 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

2-Naphthylamine is a carcinogen to humans (IARC group 1) and it can cause hematuria, dysuria, and hemorrhagic cystitis. Other symptoms of exposure include dyspnea, ataxia, and dermatitis. 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.

Reference to national studies, eg toxicological and ecotoxicity studies

Description of toxicological properties of 2-naphthylamine

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

Oral : LD₅₀ rat 727 mg/kg

Mutagenicity: CHO gene mutation : positive

Ames test : positive

Mammalian micronucleous test: positive

Carcinogenicity : carcinogenic to humans (IARC group 1)

- ACHIH, Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices for 1994-1995. Cincinnati, OH: ACGIH, 1994. 27
- DHHS/NTP; Seventh Annual Report on Carcinogens (1994)
- IARC Monographs on Evaluation of the Carcinogenic Risk of Chemicals to Man. WHO, p. V4 106 (1974)

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

2-Naphthylamine's former production and use in the manufacture of rubber and dyes may have resulted in its direct release to the environment. If released to air, a vapor pressure of 2.56×10^{-4} mm Hg at 25 deg C indicates **2-naphthylamine** will exist solely as a vapor in the ambient atmosphere. Vapor-phase **2-naphthylamine** 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 1.9 hours. **2-Naphthylamine** was shown to photolyze in direct sunlight with half-lives ranging from 0.05 to 0.19 hours. If released to soil, **2-naphthylamine** is expected to have low mobility based upon a Koc of 1,000. Results of a batch equilibrium study with various soils indicated that 1-naphthylamine, which is structurally analogous to **2-naphthylamine**, binds to soil in two phases with an initial rapid and reversible equilibrium established between the inorganic and organic components of soil. This equilibrium is followed by a strong association with the humic fraction of soil via covalent binding. Volatilization from moist soil surfaces is not expected to be an important fate process based upon a Henry's Law constant of 8.10×10^{-8} atm-cu m/mole. The pKa of **2-naphthylamine** is 4.16, indicating that this compound will partially exist in cation form in the environment and cations generally adsorb more strongly to organic carbon and clay than their neutral counterparts. **2-Naphthylamine** is not expected to volatilize from dry soil surfaces based upon its vapor pressure. **2-Naphthylamine** did not undergo primary biodegradation after 90 days in chernozem soil. The initial mineralization rate for **2-naphthylamine** in soil/water suspension was 0.12 ug/g-day. These data suggest that biodegradation in soil will be slow. If released into water, **2-naphthylamine** is expected to adsorb to suspended solids and sediment based upon the Koc. Based on primary soil biodegradation and mineralization studies, **2-naphthylamine** is expected to biodegrade slowly in water. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's Henry's Law constant. An estimated BCF of 11 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure and general population exposure should be low or non-existent since **2-naphthylamine** is no longer produced or used. The general population may be exposed to **2-naphthylamine** through the inhalation of cigarette smoke. NIOSH considers 2-naphthylamine 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 to workers and others involved in manufacture, application and use. There is no commercial activity.