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o-ANISIDINE

CAS No: 90-04-0

EINECS No: 201-963-1

Summary Risk Assessment Report

2002 **Special Publication I.01.69**

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SUMMARY RISK ASSESSMENT REPORT

2002

Austria

Rapporteur for the risk evaluation of o-anisidine was the Federal Ministry of the Environment, Youth and Family and the Federal Chancellery, in consultation with the Federal Environment Agency. Responsible for the risk evaluation and subsequently for the contents of this report is the Rapporteur.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance o-anisidine (1-amino-2-methoxy-benzene) that has been prepared by Austria in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the original risk assessment report that can be obtained from the European Chemicals Bureau[1]. The present summary report should preferably not be used for citation purposes.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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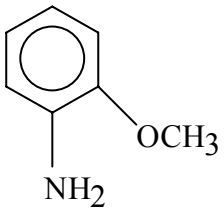
TABLES

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS No:	90-04-0
EINECS No:	201-963-1
IUPAC Name:	1-amino-2-methoxy-benzene
Synonyms:	o-anisidine, 2-methoxyaniline, 2-aminoanisole
Molecular formula::	C_7H_9NO
Structural formula:	



Molecular weight:	123.16 g/mol

1.2 PHYSICO-CHEMICAL PROPERTIES

Physical state:	liquid
Melting point:	5 - > 7°C
Boiling point:	224-225°C at 1,013 hPa
Density:	1.0923-1.1 g/cm^3 (20°C)
Vapour pressure:	0.02/0.05 hPa at 20°C
Water solubility:	15 g/l at 20°C
Partition coefficient n-octanol/water (log value):	1.18
Granulometry:	not applicable
Flammability:	none, based on flashpoint (96°C), autoflammability temperature (415°C) and structural formula and thermodynamic properties
Explosive properties:	none, based on structural formula and thermodynamic properties
Oxidizing properties:	none, based on structural formula and thermodynamic properties

1.3 CLASSIFICATION

Revision of classification was finalised in the Commission Working Groups on the Classification and Labelling of Dangerous Substances in October 1998 (human health) and in January 1999 (environment) and was published in the 26th adaptation to technical progress of Directive 67/548/EEC[2]:

Classification:	Carc.Cat. 2; R45	May cause cancer
	Muta.Cat. 3; R68[3]	Possible risk for irreversible effects
	T; R23/24/25	Also toxic by inhalation, in contact with skin and if swallowed
	Note E	
Labelling:	T R: 45-23/24/25	S: 53-45

[2] The classification of the substance is established by Commission Directive 2001/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 136, 8.6.2000, p.1).

[3] The entries were amended by replacing 'Muta.Cat. 3; R40' to 'Muta. Cat. R68' according to the Commission Directive 2001/59/EC of 6 August 2001 adapting to the technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p.1).

2 GENERAL INFORMATION ON EXPOSURE

In the European Union, 1-amino-2-methoxy-benzene (hereafter referred to as o-anisidine) is used as an intermediate for a number of azo and naphthol pigments and dyes which are used mainly for printing (e.g. packages from cardboard, polymer and aluminium foils, textiles; ca. 90 % in a total) and to a minor extent also for paper and textile dyeing (ca. 3 and 7 %, respectively). The substance is produced from o-nitroanisol by catalytic reduction with hydrogen. In 1993, the production occurred at one site in the EU in amounts > 1,000 t/y. At present the produced quantity is < 1,000 t/y. About 99 % of the produced amount are handled captively by this largest EU producing and processing company. Small quantities are sold to other processing companies. Data on import/export volumes of individual EU countries were not available.

Industrial category IC 3	Chemical industry - chemicals used in synthesis
Use category UC 33	Intermediates
Main category MC 1a	Use in closed systems, non-isolated intermediates
Main category MC 1c	Use in closed systems, isolated intermediate with controlled transport

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

o-Anisidine may be released into the environment during its production and processing. Minor amounts are assumed to be emitted during the use of printed and dyed consumer products due to residual free substance as well as hydrolytic and metabolic degradation processes of o-anisidine based pigments and dyes. The hydrosphere is expected to be the main target compartment.

The degradation and distribution behaviour of o-anisidine which is relevant for the exposure assessment is characterised as follows: no hydrolysis, an estimated atmospheric half-life through reaction with OH-radicals of about 4 hours, biodegradable and at certain favouring conditions which are most probably depending on the inoculum also readily biodegradable, a Henry's Law constant of 0.03 Pa x m^{-3} x mol^{-1} at 20°C indicating that volatilisation of o-anisidine from surface waters and moist soil is expected to be moderate to low and a relatively low log K_{ow} of 1.18. From this log K_{ow} a K_{oc} value for soil of 38 l/kg is derived indicating that o-anisidine has a low potential for adsorption onto soil or sediment.

There are no experimental bioconcentration factors available. From the log K_{ow} a BCF-value of 2 is derived, indicating a low bioaccumulation potential in the environment.

As a worst-case estimation, the derivation of the PEC values was based on the data of the only European manufacturer assuming the maximum possible production capacity. The exposure assessment is based on the EU Technical Guidance Document (TGD) applying the European Union System for the Evaluation of Substances, EUSES. In addition, the substance releases from the printing of textiles were estimated from the TGD emission scenario document for the textile finishing industry. These are based on a residual o-anisidine content in the respective pigments between 10 and 50 mg/kg. The calculated PEC values are compiled in **Table 3.1**:

Table 3.1 Calculated local PEC values for the various exposure scenarios

Exposure scenario	PEC_{STP} a)	PEC_{water}	$PEC_{sediment}$	PEC_{air}	PEC_{soil}
Production	1.82 mg/l	0.26 µg/l	0.86 µg/kg	7.1 ng/m^3	negligible
Processing (2 sites)	0.4 mg/l and 0.05 mg/l	0.12 µg/l and 0.03 µg/l	0.4 µg/kg and 0.1 µg/kg	1.7 ng/m^3	negligible
Printing of textiles	1.4 – 64 µg/l	0.05 – 2 µg/l	0.02 – 0.66 µg/kg	negligible	negligible

a) PEC_{STP} = local concentration in the untreated waste water as the best estimation for intermittent releases

It was not possible to carry out generic emission scenarios for other potential processing sites in the European Union as data on the processed amounts are lacking for these manufacturers. Therefore a calculation of regional and continental PEC values would give no additional information. Also the contribution of further emissions into surface water on a regional scale from the use of consumer products printed or dyed with o-anisidine based pigments and dyes cannot be quantified with the available data. Bioaccumulation of o-anisidine via the food chain is not expected because of the low n-octanol/water-partition coefficient and the degradation characteristics of the substance.

Monitoring data for German and Dutch rivers in the vast majority of cases yielded o-anisidine levels below or slightly above the detection limit of 0.5 µg/l. Only peak concentrations in a highly polluted German river, however, were equal or above 5 µg/l. Information on possible emission sources is not available.

3.2 EFFECTS ASSESSMENT

For each trophic level required in the TGD at least one short-term toxicity test on o-anisidine is available conducted in compliance with internationally harmonized guidelines, although some tests have not been described in sufficient detail. The PNEC for the aquatic compartment is extrapolated from a NOEC of 54.9 µg/l for a chronic test with *Daphnia magna*. As this species was also the most sensitive one in the short term tests and the potential of bioaccumulation is low an assessment factor of 10 can be applied which leads to a PNEC for the aquatic environment of 5.5 µg/l. Measured data for deriving a PNEC for sediment-dwelling organisms are not available. The equilibrium partitioning method on the basis of the $PNEC_{water}$ gave a $PNEC_{sediment}$ of 8.0 µg/kg.

The PNEC for microorganisms is extrapolated from the EC_{50} for activated sludge (800 mg/l in a respiration inhibition test) using an extrapolation factor of 100. This leads to a PNEC of 8 mg/l.

Since there are no measured data available for directly deriving a PNEC for the terrestrial compartment the $PNEC_{terrestrial}$ was also estimated using the equilibrium partitioning approach. This results in a $PNEC_{terrestrial}$ of 3.7 µg/kg.

3.3 RISK CHARACTERISATION

The PEC/PNEC ratios for the STP, surface water and the sediment based on the local releases of o-anisidine at the production and processing facilities of the largest European producer are all well below 1 **(conclusion ii)**. The same holds for the emission scenario "Printing of textiles". Also the monitoring data for German and Dutch rivers in general gave no reason of concern. In isolated cases, however, the measured peak levels were close to or above the PNEC for aquatic organisms.

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

The following workplace concentrations (TWA values) were measured during production and processing of o-anisidine:

- production 0.06 – 0.07 mg/m^3
- processing 0.05 – 0.15 mg/m^3 (long term) 0.05 – 0.09 mg/m^3 (short term).

For the formulation of pigments (especially printing inks) exposure concentrations between 0.07 and 28 ng/m^3 were estimated.

The dermal exposure concentrations at the workplace were calculated using the EASE model. Significant exposure concentrations were derived only for the installation of gas compensation pipes resulting in a maximum effective dermal dose of 0.6 mg/kg bw/d. The effective dermal doses for the formulation and use of o-anisidine based printing inks are in the range of $6 \cdot 10^{-5}$ to $1.5 \cdot 10^{-3}$ mg/kg bw/d.

4.1.1.2 Consumer exposure

The consumer may be exposed to o-anisidine from dermal contact during the use of packings or textiles containing o-anisidine based printing inks or dye products. Exposure may occur either form residual free substance, from the hydrolytic degradation of the dyes or the reductive cleavage of the azo bond of dyes and pigments.

For printed polymer or aluminium foils effective dermal doses between $1 \cdot 10^{-8}$ to $1.1 \cdot 10^{-7}$ mg/kg bw/d were derived from model calculations. For the skin contact with dyed textiles effective dermal doses in the range of $6 \cdot 10^{-6}$ to $2 \cdot 10^{-2}$ mg/kg bw/d were derived, the lower value applying for adults, the higher for babies.

Depending on the degree of cleavage of the azo bond oral doses between about $3 \cdot 10^{-4}$ and 0.13 mg/kg bw/d were derived for young children sucking at dyed clothes.

4.1.1.3 Humans exposed via the environment

As a biomagnification of o-anisidine is not expected, the indirect exposure of man via the environment results almost exclusively from the releases of o-anisidine into the hydrosphere and the atmosphere during the production and processing. EUSES calculations gave oral doses between $1.4 \cdot 10^{-6}$ and $2.2 \cdot 10^{-5}$ mg/kg bw/d for food and drinking water and inhalative doses between $2 \cdot 10^{-8}$ and $1.5 \cdot 10^{-6}$ mg/kg bw/d.

4.1.2 Effects assessment

Studies dealing specifically with o-anisidine absorption or providing detailed information on the distribution and metabolism in the body are not available. From studies with experimental animals it can be assumed that o-anisidine is absorbed through the skin, in the gastrointestinal and the respiratory tract. For risk characterisation 100 % absorption is assumed for all routes of exposure. There is no evidence for accumulation in the body.

In rodents, o-anisidine is classified as toxic after acute oral uptake. The substance produces signs of toxicity after inhalation as well as after dermal application, but no classification is necessary. The formation of methaemoglobin was seen in rodents and in cats.

In valid rabbit skin and eye irritation studies only a weak irritation potential was found, clearly below the classification threshold.

o-anisidine is not adequately tested for sensitising properties. There are indications of sensitising properties in a study with guinea pigs with intra- and epicutaneous application (study insufficiently documented). The information from available data on structural analogues has to be regarded as inconclusive. Data on sensitising effects in humans are not available.

In rats and mice, the repeated oral administration resulted in haemolytic anaemia and changes in enzyme parameters or organ weights (liver, kidney, and spleen). From a valid oral 28 d study with rats, a NO(A)EL of 16 mg/kg bw/d was derived. Inhalation and dermal studies with repeated application are not available. Therefore, for these routes of exposure a route-to-route extrapolation based on the results from the oral study was performed.

o-Anisidine (tested as hydrochloride) was carcinogenic in rats and mice after oral exposure. It can be assumed that the carcinogenic effect is due to o-anisidine itself. Tumours of the urinary system, especially of the bladder, occurred at high incidences. In addition, an increased incidence of tumours in the thyroid was observed in male rats. There is sufficient evidence that o-anisidine is mutagenic *in vitro*, while the *in vivo* assays gave contradictory results.

Specific data regarding effects on fertility in humans and animals are not available. However, as the histopathological examinations of the reproductive organs in the long term studies did not yield any changes, effects on fertility are not considered as very probable.

Developmental effects cannot be evaluated due to lack of data on o-anisidine. There is a concern for embryotoxicity and teratogenicity from evidence on related substances.

4.1.3 Risk characterisation

4.1.3.1 Workers

Acute toxicity, skin and eye irritation

Given the effects observed in acute toxicity studies, skin and eye irritation studies, and the anticipated occupational exposure levels, there is no concern for workers with regard to acute effects (oral, inhalation, or dermal exposure), and skin or eye irritation (**conclusion ii**). [4]

Sensitisation

Risk characterization with respect to sensitising effects cannot be performed due to lack of data. Risk reduction measures are required in view of the carcinogenic properties of o-anisidine. The need for a test will be revisited in the light of the risk reduction strategy.

Repeated dose toxicity

Oral exposure is considered highly unlikely to occur under conditions of normal handling and use. Therefore, a risk by this route is not anticipated (**conclusion ii**).[4]

Studies with experimental animals concerning repeated inhalation or dermal exposure are not available. A valid NOAEL of 16 mg/kg bw/d (rat, subacute, oral) was used for route to route extrapolation (oral $\rightarrow$ inhalation or oral $\rightarrow$ dermal, respectively).

For **exposure by inhalation** a NAEL of 42 mg/m^3 was obtained assuming a respiratory volume of the rat of 0.8 l/min/kg, 8 h exposure and 100 % resorption.

The calculated Margins of Safety (MOS) are in the range of 280 to 840 for production and processing workplaces and $1.5 \cdot 10^6$ to $6 \cdot 10^8$ for the formulation and use of printing inks. Therefore, health risks due to repeated exposure by inhalation exposure are not anticipated (**conclusion ii**).[4]

For **dermal exposure** a NAEL of 4 mg/kg bw was derived assuming 100 % dermal absorption and applying a factor of 4 for metabolic rate scaling from rats to humans. The calculated MOS are between infinitely high (for production and processing workplaces), ≥ 7 (installation of gas compensation pipes), and $2.7 \cdot 10^3$ - $6.7 \cdot 10^4$ (formulation and use of o-anisidine based printing inks), respectively. It is concluded that adverse effects due to repeated dermal exposure for all workplaces except instillation of gas compensation pipes are not expected (**conclusion ii**).[4] Taking into account a tentative factor of 10 for species to species extrapolation concerning higher human sensitivity to methemoglobin forming agents, in the case of installation of gas compensation pipes a MOS of < 1 is obtained. This appears insufficient for human health protection (**conclusion iii**).[5]

[4] **Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.

[5] **Conclusion (iii)** There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account.

Mutagenicity

There is sufficient evidence that o-anisidine is mutagenic *in vitro*, while *in vivo* assays gave contradictory results. The substance (tested as hydrochloride) was carcinogenic in rats and mice, so that o-anisidine is considered a genotoxic carcinogen (**conclusion iii**).[5]

Carcinogenicity

There are no data available concerning carcinogenic effects in humans. o-Anisidine (tested as hydrochloride) was carcinogenic in rats and mice after oral administration. It can be assumed that the carcinogenic effect of o-anisidine hydrochloride after oral administration is due to o-anisidine itself.

For workers, **repeated oral exposure** is considered highly unlikely to occur under conditions of normal handling and use. Therefore, a risk by this route is not anticipated (**conclusion ii**).[4]

Data concerning carcinogenic effects after **repeated inhalation or dermal exposure** are not available. Therefore, a calculated T25 value of 39.7 mg/kg bw from the oral study was the starting-point for the risk assessment with regard to carcinogenic effects. This value was used for route-to-route extrapolation (oral → inhalation or oral → dermal, respectively).

For **exposure by inhalation** a T25 of 294 mg/m^3 was derived assuming a respiratory volume of the rat of 0.8 l/min/kg, 8h exposure and 100 % resorption. The calculated Margins of Exposure (MOE) are in the range of 1,960 to 5,880 for production and processing workplaces and $1.1 \cdot 10^7$ to $4.2 \cdot 10^9$ during formulation of printing inks (**conclusion iiia**).[6]

For **dermal exposure** a T25 of 28.2 mg/kg bw was obtained, assuming 100 % absorption and applying a factor of 4 for metabolic rate scaling from rats to humans. The calculated MOE are $1.9 \cdot 10^4$ to $4.7 \cdot 10^5$ for the formulation and use of printing inks (**conclusion iiia**)[6] and about 47 for the installation of gas compensation pipes (**conclusion iiib**).[7]

Reproductive toxicity

Specific data concerning fertility impairment or developmental toxicity/teratogenicity in humans or experimental animals are not available. The lack of observed effects in histopathological examinations of the reproductive organs in a two-year carcinogenicity study (o-anisidine given as hydrochloride) as well as the results from a subacute study indicate that o-anisidine does not impair reproduction (**conclusion ii**).[4]

o-Anisidine has not been tested for developmental toxicity/teratogenicity. The need for a test to evaluate developmental toxicity will be revisited in the light of the risk reduction strategy due to its carcinogenic properties.

[6] **Conclusion (iiia)** Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

[7] **Conclusion (iiib)** There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account.

4.1.3.2 Consumers

Acute toxicity, skin and eye irritation:

Given the effects observed in acute toxicity studies, skin and eye irritation studies, and the anticipated exposure levels, there is no concern for consumers with regard to acute effects (oral or dermal exposure), and skin or eye irritation (**conclusion ii**).[4]

Sensitisation

Risk characterization with respect to sensitising effects cannot be performed due to lack of data. Risk reduction measures are required in view of the carcinogenic properties of o-anisidine. The need for a test will be revisited in the light of the risk reduction strategy.

Repeated dose toxicity

For **young children**, who may come in contact with o-anisidine while **sucking at dyed clothes**, a MOS in the range of 31 – 13,333 was calculated. The lower MOS is insufficient for the protection of the health of children (**conclusion iii**)[5], if one considers possible higher sensitivity of young children, frequent exposure and species differences.

In the case of **dermal contact with dyed textiles,** a MOS of 200 – $6.7 \cdot 10^5$ from a worst-case approach is obtained, which may be insufficient for human health protection (**conclusion iii**)[5] if one considers long-term exposure and possible higher sensitivity of humans compared to rats. The calculated MOS values for dermal exposure via skin contact with printed paper or foils are $\geq 7 \cdot 10^4$ (**conclusion ii**).[4]

Mutagenicity

o-Anisidine is considered to be a genotoxic carcinogen and consumers may come into contact via the oral or dermal route. **Dermal exposure** arising from textiles coloured with dyes based on the substance gives rise to concern for an unquantifiable risk for consumers (**conclusion iii**).[5]

Carcinogenicity

There are no data available concerning carcinogenic effects in humans. The substance (tested as hydrochloride) was carcinogenic in rats and mice after oral administration.

For **oral exposure** (young children sucking textiles coloured on the basis of o-anisidine dyes) or **dermal exposure in the case of skin contact with dyed textiles**, the calculated MOE are ≥ 76 or ≥ 495, respectively. This appears to be insufficient for the protection of human health (**conclusion iiib**).[7]

The calculated MOE values for **dermal exposure via skin contact with printed paper or foils** are $\geq 1 \cdot 10^7$ (**conclusion iiia**).[6]

Reproductive toxicity

As given in Section 4.3.1, there are not data available concerning fertility impairment or developmental toxicity/teratogenicity. Founded on the lack of changes observed in the reproductive organs in long-term studies, effects on fertility are unlikely (**conclusion ii**).[4]

o-Anisidine has not been tested for developmental toxicity/teratogenicity. The need for a test to evaluate developmental toxicity will be revisited in the light of the risk reduction strategy due to its carcinogenic properties.

4.1.3.3 Humans exposed via the environment

There are no experimental data available concerning indirect exposure of humans via the environment. Therefore, calculations with the program EUSES have been performed concerning **repeated oral or inhalative** uptake. The calculated MOS of $1.7 \cdot 10^5$ for the production site and $> 2{,}9 \cdot 10^6$ for the two processing sites do not give rise to concern of an increased risk (**conclusion ii**).[4]

Concerning carcinogenic effects, the calculated MOE for the production site are $4.2 \cdot 10^4$ and $< 7.3 \cdot 10^6$ for the two processing sites. Although the MOE seems sufficiently high, a residual risk cannot be ruled out (**conclusion iiia**).[6]

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.

5 RESULTS

5.1 ENVIRONMENT

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

o-Anisidine has not been tested adequately for sensitising properties and no test is available on developmental toxicity. Risk reduction measures are required in view of the carcinogenic properties of this substance. The need for tests to evaluate these endpoints will be revisited in the light of the risk reduction strategy.

5.2.1.1 Workers

Workers may come into contact with o-anisidine during production, processing and during the formulation and use of o-anisidine based pigments. The main possible exposure routes appear to be via inhalational and dermal contact.

Concerning production and processing, measured workplace concentrations are available for the exposure to o-anisidine via inhalation at the German reporting manufacturer. Although o-anisidine is a non-threshold carcinogen, the risk for the different workplace operations at this plant concerning the uptake of the substance via inhalation can be regarded as negligible as the exposure levels are low and appropriate personal protective equipment is applied.

The dermal exposure to o-anisidine is unquantifiably low for the most workplace operations at the manufacturer. Relevant exposure concentrations estimated from EASE calculations were only determined for the possible dermal contact with the substance during the installation of gas compensation pipes. Therefore, the following conclusions can be drawn:

Conclusion (iiib) There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account.

This conclusion applies to

- concerns for general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of exposure arising from the installation of gas compensation pipes at production of the substance.

Conclusion (iiia) Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing

controls and the feasibility and practicability of further specific risk reduction measures.

5.2.1.2 Consumers

The general population may come into contact with the substance during the use of consumer products coloured with pigments or dyes based on o-anisidine. From the use pattern of the substance the contact with printed packings and foils and with dyed textiles can be identified as most important. These materials may contain free o-anisidine as residues or from degradation during the printing/dyeing process or during their use. Especially in the case of dyes an unintentional release due to reductive cleavage after resorption may occur in addition. The main exposure routes appear to be dermal (skin contact with printed packings and foils and dyed textiles) and oral (young children sucking at dyed textiles). A non-negligible risk was derived from exposure estimations concerning the dermal contact with dyed textiles and the oral uptake by young children sucking at dyed textiles.

A migration of o-anisidine residues from packings into food need not be considered as the packings are superficially printed so that the substance cannot be in direct contact with the food.

From the estimation of the possible risks the following conclusions can be drawn:

Conclusion (iiib) There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account.

This conclusion applies to

- concerns for general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of dermal exposure arising from textiles coloured with dyes based on the substance,
- concerns for young children for general systemic toxicity, mutagenicity and carcinogenicity, as a consequence of oral exposure by sucking textiles coloured with dyes based on the substance.

Conclusion (iiia) Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

5.2.1.3 Humans exposed via the environment

Indirect exposure via the environment could occur by the intake of drinking water, as the main target compartment of o-anisidine is the hydrosphere. Concentrations of o-anisidine in drinking water are not reported. Relevant intake via drinking water is not to be expected considering the use pattern of o-anisidine. Relevant intake of the substance through food consumption is also not to be expected since there is no significant potential for biomagnification along the food chain. From calculations with EUSES very low exposure concentrations were derived for uptake by inhalation or ingestion of ambient air and water, respectively, in the vicinity of the production and processing sites.

Conclusion (iiia) Risks can not be excluded, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

5.2.2 Human health (risks from physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.