Annex XV

Proposal for identification of a substance as a CMR cat 1 or 2, PBT, vPvB or a substance of an equivalent level of concern

Submitted by: Germany

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Version: 2.0 (26.06.2008)

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: 4,4'-Diaminodiphenylmethan
MDA

EC number: 202-974-4

CAS number: [101-77-9]

- *It is proposed to identify the substance as a CMR according to Article 57 (a), (b) and/or (c).*

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria, or is considered to be a substance of an equivalent level of concern

Classification in Annex I of Directive 67/548/EEC, Index No.: 612-051-00-1, 29th ATP (Commission Directive 2004/73/EC):

Carc. Cat.2; R45,

Muta. Cat.3; R68,

T; R39/23/24/25,

Xn; R48/20/21/22

R43

N; R51-53

Registration number(s) of the substance or of substances containing the substance:

JUSTIFICATION

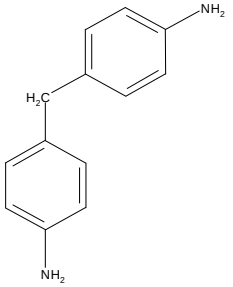
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifier of the substance

Chemical Name: 4,4’-Diaminodiphenylmethane
EC Number: 202-974-4
CAS Number: 101-77-9
IUPAC Name: Bis (4-aminophenyl)methane

1.2 Composition of the substance

Name: Bis (4-aminophenyl)methane
EC Number: 202-974-4
CAS Number: 101-77-9
IUPAC Name: Bis (4-aminophenyl)methane
Molecular Formula: $C_{13}H_{14}N_2$
Structural Formula:



Molecular Weight: 198.3 g/mol
Synonyms: 4,4'-Methylenedianiline, 4,4'-Diaminodiphenylmethane, 4,4’-Diphenylmethane diamine, 4,4’-Methylendibenzolamine, 4,4’-Methylenebisbenzeneamine, 4-(4-Aminobenzyl)aniline, MDA

Technical-grade MDA is used as an intermediate in the form of an isomer mixture with a varying content of tri- and polynuclear amines (so-called „polymers“). A typical standard product with a purity between 59 and 61 %(w/w) is liquid at room temperature and comprises the following:

Impurity	Content []	CAS no.	EC no.	Molecular formula
MDA polymers	ca. 36 % w/w			
2,4’-MDA	ca. 3.5 % w/w	1208-52-2	214-900-8	C13H14N2
2,2’-MDA	< 0.1 % w/w	6582-52-1	229-512-4	C13H14N2
water	< 300 ppm	7732-18-5	231-791-2	H2O
aniline	< 100 ppm	62-53-3	200-539-3	C6H7N

Pure 4,4’-MDA (purity ≥ 98 % w/w) is also used as an intermediate and has the following composition:

Impurity	Content []	CAS no.	EC no.	Molecular formula
2,4'-MDA	(2.2- + 2.4) MDA max. 2 % w/w	1208-52-2	214-900-8	C13H14N2
2,2'-MDA	(2.2- + 2.4) MDA max. 2 % w/w	6582-52-1	229-512-4	C13H14N2
4-amino-4'-methylaminodiphenyl methane	traces			
aniline	traces	62-53-3	200-539-3	C6H7N

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

REACH ref Annex, §	**Property**	**Value**	**[enter comment/ reference or delete column]**
V, 5.1	Physical state at 20 C and 1013 hPa	powder	
V, 5.2	Melting / freezing point	89 °C	
V, 5.3	Boiling point	398-399 °C at 1013 hPa	
V, 5.5	Vapour pressure	$2.87 * 10^{-8}$ hPa at 20 °C	
V, 5.7	Water solubility	1.25 g/l at 20 °C	
V, 5.8	Partition coefficient n-octanol/water (log value)	1.59	
VII, 5.19	Dissociation constant	-	
	[enter other property or delete row]		

2 MANUFACTURE AND USES

Not relevant for this type of dossier.

Information on uses may be useful for prioritisation for inclusion in Annex XIV but this should be summarised under Section 9.2.

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

MDA is listed in Annex I of Directive 67/54/EEC with the following classification:

Carc. Cat.2; R45,

Muta. Cat.3; R68,

T; R39/23/24/25,

Xn; R48/20/21/22

R43

N; R51-53

3.2 Classification according to GHS

3.3 Self classification(s)

This should include the classification, the labelling and the specific concentrations limits. The reason and justification for no classification should be reported here.

It should be stated whether the classification is made according to Directive 67/548/EEC criteria or according to GHS criteria

4 ENVIRONMENTAL FATE ROPERTIES

4.1 Degradation

4.1.1 Stability

Corresponds to IUCLID 4.1

4.1.2 Biodegradation

4.1.2.1 Biodegradation estimation

4.1.2.2 Screening tests

4.1.2.3 Simulation tests

4.1.3 Summary and discussion of persistence

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Corresponds to IUCLID 4.4.1

4.2.2 Volatilisation

Corresponds to IUCLID 4.4.2

4.2.3 Distribution modelling

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

4.3.1.1 Bioaccumulation estimation

e. g. use of Kow, predicted BCF

4.3.1.2 Measured bioaccumulation data

4.3.2 Terrestrial bioaccumulation

4.3.3 Summary and discussion of bioaccumulation

4.4 Secondary poisoning

Assessment of the potential for secondary poisoning

5 HUMAN HEALTH HAZARD ASSESSMENT

MDA is listed in Annex I of Directive 67/548/EEC (see 3.1)

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2 Acute toxicity

5.2.1 Acute toxicity: oral

5.2.2 Acute toxicity: inhalation

5.2.3 Acute toxicity: dermal

5.2.4 Acute toxicity: other routes

C&L including weight-of-evidence considerations.

5.3 Irritation

Not relevant for this type of dossier.

5.4 Corrosivity

Not relevant for this type of dossier.

5.5 Sensitisation

Not relevant for this type of dossier.

5.6 Repeated dose toxicity

5.6.1 Repeated dose toxicity: oral

5.6.2 Repeated dose toxicity: inhalation

5.6.3 Repeated dose toxicity: dermal

5.6.4 Other relevant information

5.6.5 Summary and discussion of repeated dose toxicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.7 Mutagenicity

5.7.1 *In vitro* data

5.7.2 *In vivo* data

5.7.3 Human data

5.7.4 Other relevant information

5.7.5 Summary and discussion of mutagenicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.8 Carcinogenicity

5.8.1 Carcinogenicity: oral

5.8.2 Carcinogenicity: inhalation

5.8.3 Carcinogenicity: dermal

5.8.4 Carcinogenicity: human data

5.8.5 Other relevant information

5.8.6 Summary and discussion of carcinogenicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.2 Developmental toxicity

5.9.3 Human data

5.9.4 Other relevant information

5.9.5 Summary and discussion of reproductive toxicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.10 Other effects

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation)

5.11.3 Application of assessment factors

5.11.4 Selection / identification of the critical DNEL(s) / the leading health effect

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

Not relevant for this type of dossier.

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

Short-term toxicity to fish

Long-term toxicity to fish

7.1.1.2 Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Long-term toxicity to aquatic invertebrates

7.1.1.3 Algae and aquatic plants

7.1.1.4 Sediment organisms

7.1.1.5 Other aquatic organisms

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

7.1.2.2 PNEC sediment

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macroorganisms

7.2.1.2 Toxicity to terrestrial plants

7.2.1.3 Toxicity to soil microorganisms

7.2.1.4 Toxicity to other terrestrial organisms

Toxicity to birds

Toxicity to other above ground organisms

7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

7.3 Atmospheric compartment

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic microorganisms

7.4.2 PNEC for sewage treatment plant

7.5 Calculation of Predicted No Effect Concentration for secondary poisoning (PNEC oral)

7.6 Conclusion on the environmental classification and labelling

8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

8.1 Comparison with criteria from Annex XIII

8.2 Assessment of substances of an equivalent level of concern

8.3 Emission characterisation

8.4 Conclusion of PBT and vPvB or equivalent level of concern assessment

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON EXPOSURE

Risk-related information for 4,4´-MDA is taken from the Risk Assessment Report, published by the ECB in November 2001.

1.1 Occupational exposure

Exposure-related information for 4,4´-MDA is taken from the Risk Assessment Report, published by the ECB in November 2001:

MDA is synthesized by reaction of formaldehyde and aniline in the presence of hydrochloric acid. In Western Europe, the substance is manufactured at 11 sites. In 1993, the production volume of MDA was about 430,000 t. More than 98% of the total production volume are processed to methylenediphenyl diisocyanate (MDI), exclusively at the same site. MDI is further used for polyurethane production. About 4000 t MDA are annually used as hardener for epoxy resins, hardener in adhesives, intermediate in the manufacture of high-performance polymers, and processed to 4,4'-methylenebis(cyclohexaneamine). There is no information about the total EU export and import volumes.

MDA is produced continuously as a liquid isomer mixture (technical grade) which typically contains about 60 % 4,4'-MDA or as pure 4,4'-MDA placed on the market in flake or granulate form or as a prill. The product life cycle covers uses in chemical industry, other industrial areas and skilled trade.

Occupational exposure scenarios in the chemical industry, in the industrial area and in skilled trade have to be considered. The exposure assessment is based on measured data (limited), expert judgement and estimations according to the EASE model. With regard to inhalation exposure, exposure to MDA in dust form is of primary concern here. Inhalation exposure to MDA vapour is not relevant (vapour pressure << 1 Pa). Concerning dermal exposure investigations have shown that glove material is used which does not provide complete protection and materials for which information about the suitability is not available. Therefore dermal exposures are estimated for all exposure situations.

Summary of exposure data

Exposure scenario	Form of exposure	Duration and frequency[2]	Inhalative exposure shift average [mg/m³]	Dermal exposure shift average [mg/p/d][1]
Chemical industry				
manufacturing and further processing as a chemical intermediate	flakes, granules (dust)	shift length, daily	0.52 (workplace measurements)	42 - 420
	liquid (vapour) (approx. 60 %)	shift length, daily	very low (exp. judg.)	25 - 252
production of preparations				
imid preparations max. 10 % MDA	powder (dust)	batch processing 2 hours/daily	0.05 - 0.125 (EASE)	4 - 42
curing formulations max. 60 % MDA	flakes; granules (dust)	batch processing 2 hours/daily	lower than above (exp. judg.)	25 - 252
max. 5 % MDA		batch processing 2 hours/daily	lower than above (exp. judg.)	2 - 21
Industrial area				
manufacturing of formulations using powdery MDA	powder (dust)	batch processing 2 hours/daily	0.6 (workplace measurements)	42 - 420
formulating putties using liquid MDA (approx. 60 %)	liquid MDA	batch processing 2 hours/daily	very low (exp. judg.)	25 - 252
production of preparations				
imid preparations max. 10 % MDA	powder (dust)	batch processing 2 hours/daily	0.1 - 1.25 (EASE)	4 - 42
curing formulations max. 60 % MDA	flakes; granules (dust)	batch processing 2 hours/daily	0 - 0.75 (EASE)	25 - 252
max. 5 % MDA			0 - 0.08 (EASE)	2 - 21
mixing curing formulations (max. 60 % MDA) with resin for epoxies	flakes, granules (dust)	short-term (0.5 h), daily	0 - 0.2 (EASE, without LEV)	50 - 504
handling of formulations containing MDA and epoxide resins (4.5 - 30 %)	liquids	short-term (0.5 h), daily	very low (exp. judg.)	50 - 504
		shift length, daily	very low (exp. judg.)	25 - 252
mixing curing formulations (max. 5 % MDA) with resin for polyurethanes	flakes, granules (dust)	short-term (0.5 h), daily	0 - 0.02 (EASE, without LEV)	4.2 - 42
handling of formulations containing MDA and polyurethane (2 - 3 %)	liquid, pastes	shift length, daily	very low (exp. judg.)	2.5 - 25
handling formulations containing MDA (0.1 - 10 %) and imid resins	powder	short-term (0.5 h), daily	0.03 - 0.3 (EASE)	8.4 - 84
	paste	shift length, daily	very low (exp. judg.)	8.4 - 84

Exposure scenario	Form of exposure	Duration and frequency[2]	Inhalative exposure shift average [mg/m^3]	Dermal exposure shift average [mg/p/d][1]
Skilled trade				
mixing of formulations containing MDA (9 - 60 %) with epoxide resins	flakes, granules (dust)	short-term (0.5 h), not daily	0 - 0.2 (EASE, without LEV)	504 - 2 520
handling of formulations containing MDA and epoxide resins (4 - 30 %)		duration and frequency not known assumed: not daily	very low (exp. judg.)	252 - 1 260

1 Estimation according to the EASE model (without PPE)
2 Information about frequency and duration of exposure not available

2 INFORMATION ON ALTERNATIVES

The two sub-sections on alternatives should be used as appropriate

2.1 Alternative substances

Risk Assessment Report, published by the ECB in November 2001 identified the greatest risks for the open use of preparations containing MDA in the skilled trade area. Comprehensive data on specific uses, types of use or use categories as well as the quantities of MDA utilised were not available, though, information from the Danish, Swedish and Norwegian product registers indicated a considerable extent of use.

Under Directive 793/93 detailed data on specific uses, types of use or use categories could not be compiled, accordingly there is no information on alternative substances.

Therefore, the Risk Reduction Strategy submitted in February 2000 proposed a generic restriction on the marketing and use of MDA and preparations containing MDA (more than 0.1%) intended to be used in open systems in the skilled trade area.

The proposal included the assumption that more detailed information would become available and would be considered in the regulatory process. However, the regulatory process never started. Informal consultations with industry representatives gave some insight into the uses and fields of application of MDA that might be categorised as “open use in the skilled trade area” but information could not be released to the public.

Industry in principle supported the idea of substitution of MDA in these applications without giving details.

2.2 Alternative techniques

3 RISK-RELATED INFORMATION

Risk-related information for 4,4´-MDA is taken from the Risk Assessment Report, published by the ECB in November 2001 (http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/mdareport008.pdf). The information from the RAR is reduced in this Annex XV document to the most critical endpoint, the carcinogenicity after inhalation and dermal contact. In the table below, all exposure scenarios are listed and compared with the calculated T25 value. The distance between exposure value and T25 is expressed as Margin of Exposure (MOE) values. The higher the value for MOE, the lower is the corresponding risk.

Carcinogenicity

There is no clear evidence of carcinogenicity in humans. The carcinogenicity of MDA was demonstrated in drinking-water studies on rats and mice. MDA caused thyroid and liver tumours in both species. The T25-value of 8.4 mg/kg/d describes the carcinogenic potency in animals (continuous life time exposure). It was calculated for MDA-dihydrochloride (molecular weight: 269.2 g/mol). For MDA (molecular weight: 198.3 g/mol) a T25 of 6.2 mg/kg/d results. The mechanism of tumour formation is discussed in detail in the Risk Assessment Report (RAR). On the one hand the carcinogenicity studies may be interpreted to indicate a nongenotoxic mechanism of action based on nonneoplastic effects. But considering on the other hand the genotoxicity data it has to be assumed that a genotoxic mechanism without a threshold for tumour formation is involved.

Inhalation

The T25-value (6.2 mg/kg/d) is extrapolated to a modified value assumed to be relevant to humans (workplace time schedule, inhalation) by the following steps. Based on the assumption, that a 10-fold higher sensitivity of humans concerning carcinogenicity has to be regarded a value of 0.62 mg/kg/d is calculated for humans. For a route-to-route extrapolation a body weight of 70 kg, a respiratory volume of 10 m^3/8 h and an equivalent inhalatory and oral uptake are assumed. A value of 4.3 mg/m^3 results. A final adjustment to workplace conditions is done below (constants are taken from DECOS, 1995).

$$4.3\ mg/m^3 \times \frac{75\ years \times 52\ weeks \times 7\ days}{40\ years \times 48\ weeks \times 5\ days} = ca.\ 12\ mg/m^3$$

A modified T25-value (inhalation, workplace time schedule) in the range of 12 mg/m^3 is estimated.

For reasons of comparability the modified T25-value without consideration of the anticipated higher human sensitivity is calculated as well: a value in the range of 120 mg/m^3 results. This value is 10-fold higher than the modified T25-value of 12 mg/m^3. There are uncertainties as to the use of a species factor derived from acute toxicity, but there are at present no clear reasons excluding a higher sensitivity of humans concerning carcinogenicity.

Since it has to be assumed that a genotoxic mechanism is involved a linear dose response cannot be excluded.

For purposes of carcinogenic risk assessment a MOE (margin of exposure) is calculated. Assuming a chronic level of inhalation exposure of 0.52 mg/m^3 (chemical industry) a MOE of 23 will result. The MOE for the other exposure scenarios are calculated as well. For details see table 4.1.3.2.2.C.

Assuming the involvement of a genotoxic mechanism most MOE values are of concern. However it should be kept in mind that humans might be less sensitive than assumed.

Conclusion: iiib[1]

Dermal

The T25-value (6.2 mg/kg/d) is extrapolated to a modified value assumed to be relevant to humans (workplace time schedule, dermal) by the following steps. Based on the assumption, that a 10-fold higher sensitivity of humans concerning carcinogenicity has to be regarded a value of 0.62 mg/kg/d is calculated for humans. For a route-to-route extrapolation the factor >2 is used as described under "Acute toxicity (Dermal)". For a body weight of 70 kg results a value >90 mg/person/d. A final adjustment to workplace conditions is done below (constants are taken from DECOS, 1995).

$$> 90 \text{ mg/person/d} \times \frac{75 \text{ years} \times 52 \text{ weeks} \times 7 \text{ days}}{40 \text{ years} \times 48 \text{ weeks} \times 5 \text{ days}} = > 250 \text{ mg/person/d}$$

A modified T25-value (dermal, workplace time schedule) of >250 mg/person/d is estimated.

For reasons of comparability the modified T25-value without consideration of the anticipated higher human sensitivity is calculated as well: a value of >2500 mg/kg/d results. This value is 10-fold higher than the modified T25-value of >250 mg/kg/d. There are uncertainties as to the use of a species factor derived from acute toxicity, but there are at present no clear reasons excluding a higher sensitivity of humans concerning carcinogenicity.

Since it has to be assumed that a genotoxic mechanism is involved a linear dose response cannot be excluded.

For workplace risk assessment a dermal T25 of greater than 250 mg/person/d was calculated. Again, it was assumed that humans are more sensitive than rats and that there may be a genotoxic mechanism. Repeated dermal exposure is assumed in the chemical industry, in all industrial applications, even in case of use of PPE (see chapter 4.1.1.2).

Most MOE-values calculated for dermal exposure are very low resulting in high concern for carcinogenicity due to dermal contact.

Conclusion: iiib[1]

The MOE for all dermal exposure scenarios are calculated, for details see table 4.1.3.2.2 C.

[1] iiib: there is a need for limiting the risk; risk reduction measures which are already being applied shall be taken into account (the risk for carcinogenicity is considered substantial)

Table: 4.1.3.2.2.c: MOE values of MDA

Exposure scenario	Duration and frequency	Shift average value [mg/m^3]	T 25 [mg/m^3]	MOE	Con-clusion	Shift average value [mg/cm^2/d]	Shift average value [mg/p/d]	T 25 [mg/p/d]	MOE	Con-clusion
Chemical industry										
manufacturing and further processing as a chemical intermediate (methylene diphenyl di-isocyanate, MDI) activity: drumming, transfer, cleaning, maintenance										
– dust	shift length, daily	0.52[1]	12	23	iiib	0,1 - 1[2]	42 - 420	> 250	> 0.6 - 6	iiib
– vapour	shift length, daily	very low[3]	12	very high	iiia	0.06 - 0.6[2]	25 - 252	> 250	> 1 - 10	iiib
production of preparations activity: drumming, transfer, cleaning, maintenance										
imid preparations, max. 10 % MDA										
– dust	batch processing, 2hours/daily	0.05-0.125[2]	12	96 - 240	iiib	0.01 - 0.1[2]	4 - 42	> 250	> 6 - 62	iiib
curing formulations, max. 60 % MDA										
– dust	batch processing, 2hours/daily	lower than above[3]	12	> 96 - 240	iiib	0.06 - 0.6[2]	25 - 252	> 250	> 1 - 10	iiib
max. 5 % MDA										
– dust	batch processing, 2hours/daily	lower than above[3]	12	> 96 - 240	iiib	0.05 - 0.05[2]	2 - 21	> 250	> 12 - 125	iiib

Exposure scenario	Duration and frequency	Shift average value [mg/m^3]	T 25 [mg/m^3]	MOE	Con-clusion	Shift average value [mg/cm^2/d]	Shift average value [mg/p/d]	T 25 [mg/p/d]	MOE	Con-clusion
Industrial area										
manufacturing of formulations using powdering MDA activity: transfer, weighing, filling, drumming:										
– dust	batch processing, 2hours/daily	0.6[1]	12	20	iiib	0.1 - 1[2]	42 - 420	> 250	> 0.6 - 6	iiib
– formulating putties using liquid MDA (approx. 60 %)										
– vapour		very low[3]	12	very high	iiia	0.06 - 0.6[2]	25 - 252	> 250	> 1 - 10	iiib
production of preparations activity: drumming, transfer, cleaning, maintenance										
imid preparations max. 10 % MDA										
– dust	batch processing, 2hours/daily	0.1- 1.25[4]	12	10 - 120	iiib	0.01 - 0.1[2]	4 - 42	> 250	> 6 - 62	iiib
curing formulations max. 60 % MDA										
– dust	batch processing, 2hours/daily	0 - 0.75[4]	12	> 16	iiib	0.06 - 0.6[2]	25 - 252	> 250	> 1 - 10	iiib
max. 5 % MDA										
– dust	batch processing, 2hours/daily	0 - 0.08[4]	12	> 150	iiib	0.005 - 0.05[2]	2 - 21	> 250	> 12 - 125	iiib

Exposure scenario	Duration and frequency	Shift average value [mg/m^3]	T 25 [mg/m^3]	MOE	Con-clusion	Shift average value [mg/cm^2/d]	Shift average value [mg/p/d]	T 25 [mg/p/d]	MOE	Con-clusion
mixing curing formulations (max. 60 % MDA) with resin for epoxies activity: transfer, weighing, filling										
– dust	short term (0.5 h), daily	0 - 0.2[4]	12	> 60	iiib	0.06 - 0.6[2]	50 -504	> 250	> 0.5 - 5	iiib
– vapour	short term (0.5 h), daily	very low[3]	12	very high	iiia	0.06 - 0.6[2]	50 -504	> 250	> 0.5 - 5	iiib
handling of formulations containing MDA and epoxide resins (4.5 - 30 %)										
– vapour	shift length, daily	very low[3]	12	very high	iiia	0.03 - 0.3[2]	25 - 252	> 250	> 1 - 10	iiib
mixing curing formulations (max. 5 % MDA) with resin for polyurethanes activity: transfer, weighing, filling										
– dust	short term (0.5 h), daily	0 - 0.02[4]	12	> 600	iiib	0.005 - 0.05[2]	4.2 - 42	> 250	> 6 - 60	iiib
handling of formulations containing MDA and polyurethane (2 - 3 %)										
– vapour	shift length, daily	very low[3]	12	very high	iiia	0.003 - 0.03[2]	2.5 -25	> 250	> 10 - 100	iiib

Exposure scenario	Duration and frequency	Shift average value [mg/m^3]	T 25 [mg/m^3]	MOE	Con-clusion	Shift average value [mg/cm^2/d]	Shift average value [mg/p/d]	T 25 [mg/p/d]	MOE	Con-clusion
handling of formulations containing MDA (0.1-10 %) and imid resins activity: weighing, filling										
– dust	short term (0.5 h), daily	0.03 - 0.3[2]	12	40 - 400	iiib	0.01 - 0.1[2]	8.4 - 84	> 250	> 3 - 30	iiib
– vapour	shift length, daily	very low[3]	12	very high	iiia	0.01 - 0.1[2]	8.4 - 84	> 250	> 3 - 30	iiib
Skilled trade										
mixing formulations containing MDA (9 - 60 %) with epoxide resins activity: transfer, weighing, filling, drumming										
– dust	short term (0.5 h), not daily[5]	0 - 0.2[4]	12	> 60	iiib	0.6 - 3[2]	504 - 2 520	> 250	> 0.1 - 0.5	iiib
handling of formulations containing MDA and epoxide resins (4 - 30 %)										
vapour	duration and frequency not known, assumed: not daily[5]	very low[3]	12	very high	iiia	0.3 - 1.5[2]	252 - 1 260	> 250	> 0.2 -1	iiib

[1] workplace measurements [2] EASE [3] expert judgement [4] EASE (without LEV) [5] information about frequency of exposure not available

iiia: negligible risk for carcinogenicity is applied

iiib: there is a need for limiting the risk; risk reduction measures which are already being applied shall be taken into account (the risk for carcinogenicity is considered substantial)

OTHER INFORMATION

(It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e. g. Technical Dossiers, CSRs, other published sources) used for the dossier could also be indicated here).

The following uses should be exempted form authorisation:

Production and further use of MDA as an intermediate in the chemical industry, mixing and handling formulations containing MDA in the industrial area.

With respect to inhalative exposure most scenarios in these sectors showed only negligible concern according to the criteria used under Directive 793/93. For those scenarios that indicated a need for additional measures the framework of worker protection is regarded sufficient for adequate control of inhalative exposure.

With regard to dermal exposure all scenarios resulted in concern according to the criteria used under Directive 793/93. Exposures were assessed under the assumption that PPE (gloves) were not used because at that time there was no evidence about the availability of efficient gloves. Later, industry launched studies and could provide information that effective gloves are available. It is generally accepted, that gloves will eliminate 90% of dermal exposure of the hands. Residual dermal exposure can be tolerated except for scenarios in skilled trade.

http://ecb.jrc.it/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ON_HUMAN_EXPOSURE/TNsG%20-Human-Exposure-2007.pdf p. 16ff (espec. p. 17 footnote): Protection factor of "gloves" see table 2 on page 19.