



9 December 2011

**Substance Name(s): Formaldehyde, oligomeric reaction products with
aniline**

**EC Number: 500-036-1
CAS Number: 25214-70-4**

SUPPORT DOCUMENT FOR IDENTIFICATION OF

**FORMALDEHYDE, OLIGOMERIC REACTION PRODUCTS
WITH ANILINE**

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS
CMR PROPERTIES**

NOTE

During the public consultation, in accordance with Article 59 (4) of the REACH Regulation, on the proposed identification of “formaldehyde, oligomeric reaction products with aniline” as a Substance of Very High Concern (SVHC) on the basis of its classification as carcinogenic category 1B no comments were received objecting the conclusion that the substance meets criteria set out in Article 57(a). Therefore, in accordance with Article 59 (6), “formaldehyde, oligomeric reaction products with aniline” has been included in the Candidate List by ECHA.

The present support document comprises Part I (Justification) of the Annex XV dossier for identification of “formaldehyde, oligomeric reaction products with aniline” as SVHC on the basis of Article 57(a) of REACH.

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Substance Name(s): Formaldehyde, oligomeric reaction products with aniline

EC Number: 500-036-1

CAS number: 25214-70-4

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1 B¹ which corresponds to classification as carcinogen category 2².

Summary of how the substance(s) meet(s) the CMR (Cat 1A or 1B) criteria

The structurally related substance 4,4'-diaminodiphenylmethane is listed by index number 612-051-00-1 of Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as carcinogenic: Carc. 1B (H 350: "May cause cancer."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is Carc. Cat. 2; R45 ("May cause cancer.").

4,4'-diaminodiphenylmethane is a major constituent of the UVCB substance *formaldehyde, oligomeric reaction products with aniline* (CAS-No. 25214-70-4) and therefore the classification for 4,4'-diaminodiphenylmethane applies also for this UVCB substance. The classification of 4,4'-diaminodiphenylmethane in Regulation (EC) No 1272/2008 shows that also the UVCB substance *formaldehyde, oligomeric reaction products with aniline* meets the criteria for classification as carcinogenic in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substance? Yes

¹ Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

² Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	500-036-1
EC name:	Formaldehyde, oligomeric reaction products with aniline
CAS number (in the EC inventory):	25214-70-4
CAS number:	25214-70-4
CAS name:	Formaldehyde, polymer with benzenamine
IUPAC name:	Formaldehyde, oligomeric reaction products with aniline
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$(C_6H_7N.CH_2O)_x$
Molecular weight range:	> 168 g/mol
Synonyms:	polymeric MDA ³ PMDA MDA, technical grade crude MDA

³ In Kirk-Othmer [1991] the substance is named polymeric MDA and this name is used in this dossier to refer to Formaldehyde, oligomeric reaction products with aniline. The name is abbreviated as PMDA.

Structural formula:

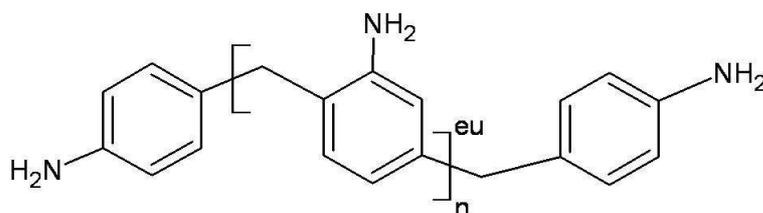


Figure 1: Structural formula with n = 1-5 (according to registration dossiers received) and eu = either unknown

1.2 Composition of the substance

Name: Formaldehyde, oligomeric reaction products with aniline

Description:

Degree of purity: 100%

Formaldehyde, oligomeric reaction product with aniline (Technical-grade MDA) is a UVCB substance with a varying content of tri- and polynuclear amines (so-called „polymers“). A typical standard product with a content of 4,4'-MDA between ca. 47 and < 65 % (w/w) is liquid at room temperature and comprises the following:

Table 2: Generic composition (based on registration dossiers received)

Impurity	Content range ⁴ % w/w	CAS no.	EC no.	Molecular formular
4,4'-MDA	ca. 47 to < 65	101-77-9	202-974-4	C ₁₃ H ₁₄ N ₂
2,4'-MDA	< 1.4 to ca. 10	1208-52-2	214-900-8	C ₁₃ H ₁₄ N ₂
2,2'-MDA	ca. 0.2 to 3	6582-52-1	229-512-4	C ₁₃ H ₁₄ N ₂
Higher Oligomers of MDA	ca. 38.4 to < 65	-	-	(C ₆ H ₇ N) ₂ (CH ₂) _(x+1) (C ₆ H ₆ N) _x or C _(7x+13) H _(6x+13) N _(x+2)
Water	< 1	7732-18-5	231-791-2	H ₂ O
Aniline	< 0.1	62-53-3	200-539-3	C ₆ H ₇ N

The separate identities indicated in the registration dossiers received are confidential and were included in the technical dossier.

⁴ Based on registration dossiers received

1.3 Physico-chemical properties

Table 3: Overview of physicochemical properties⁵

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	olig. MDA is a yellow, clear, high viscous liquid/wax	
Melting/freezing point	30 — 70 °C	
Boiling point	410.6 °C at 1013.25 hPa	
Vapour pressure	< 0.000001 hPa; 20 °C 0.000016 hPa; 50 °C	
Water solubility	0.36 g/L, Temp. 20 °C; pH 7.1 — 7.4; Remarks: 1 g test item per one liter of water 1.22 g/L, Temp. 20 °C; pH 7.5 — 7.6 Remarks: 10 g test item per one liter of water	
Partition coefficient n-octanol/water (log value)	1.3 - 2.5 at 23°C/pH = 6.2 1.2 -2.7 at 23°C/pH = 10	Key value for chemical safety assessment: Log K _{ow} (Log P _{ow}) 2.5, 23 °C
Dissociation constant	The test item consists of substances with a number of different amine groups. For each of these groups a discrete dissociation constant can be defined, but not determined by titration. The determination of the dissociation constant of an aqueous preparation of the test item is not possible.	

⁵ The references of the values reported in Table 3 will be available in the technical dossier. In case references need to be included an additional column could be added manually in Table 3.

2 HARMONISED CLASSIFICATION AND LABELLING

The UVCB substance *formaldehyde, oligomeric reaction products with aniline* is covered by the entry of 4,4'-diaminodiphenylmethane under index number 612-051-00-1 in Annex VI, Part 3 of Regulation (EC) No 1272/2008. as provided in Table 4 and Table 5.

Table 4: Classification for MDA according to part 3 of Annex VI, Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
4,4'-diamino-diphenylmethane; 4,4'-methylene-dianiline	202-974-4	101-77-9	Carc. 1B Muta. 2 STOT SE 1 STOT RE 2 * Skin Sens. 1 Aquatic Chronic 2	H350 H341 H370 ** H373 ** H317 H411	GHS08 GHS07 GHS09 Dgr	H350 H341 H370 ** H373 ** H317 H411			

Table 5: Classification for MDA according to part 3 of Annex VI, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	Chemical name	Notes related to substances	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes related to preparations
ANNEX I								
612-051-00-1	4,4'-diamino-diphenylmethane; 4,4'-methylene-dianiline		202-974-4	101-77-9	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R39/23/24/25 Xn; R48/20/21/22 R43 N; R51-53	R: 45-39/23/24/25-43-48/20/21/22-68-51/53 S: 53-45-61		

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant

6.2 CMR assessment

The structurally related substance 4,4'-diaminodiphenylmethane is listed by index number 612-051-00-1 of Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as carcinogenic: Carc. 1B (H 350: "May cause cancer."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is Carc. Cat. 2; R45 ("May cause cancer.").

4,4'-diaminodiphenylmethane is a major constituent of the UVCB substance *formaldehyde, oligomeric reaction products with aniline* (CAS-No. 25214-70-4) and therefore the classification for 4,4'-diaminodiphenylmethane applies also for this UVCB substance. The classification of ,4'-diaminodiphenylmethane in Regulation (EC) No 1272/2008 shows that also the UVCB substance *formaldehyde, oligomeric reaction products with aniline* meets the criteria for classification as carcinogenic in accordance with Article 57 (a) of REACH.

6.3 Substances of equivalent level of concern assessment

Not relevant

REFERENCES

ECHA report (2008): Data on manufacture, import, export, uses and releases of 4,4'-diaminodiphenylmethane as well as information on potential alternatives to its use (specific contract ECHA/2008/02/SR5/ECA.227).

ECHA website, 22.08.2011: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d99d110-026b-3a79-e044-00144f67d249/AGGR-5f11a3d8-0a0f-4285-9924-40641866f705_DISS-9d99d110-026b-3a79-e044-00144f67d249.html#AGGR-5f11a3d8-0a0f-4285-9924-40641866f705

Kirk-Othmer (Edt.,1991): Encyclopedia of Chemical Technology, Vol. 2, 4th Ed., New York, John Wiley, pp. 461–473.

ABBREVIATIONS

ECB	(Ex-)European Chemicals Bureau.
ERB	exposure-risk-relationship
LOQ	limit of quantification
T25	tumourigenic dose at which 25 % additional incidence is expected
tpa	tons per anno
UVCB substances	substances of u nknown or, v ariable, complex composition or b iological origin