

ANNEX B

Metam

B.1 Identity

**Update June 2008,
Revision August 2010**

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.1.0 Introductory note [added in August 2010]

This document is based on the updated version (dated June 2008) of Vol.3 B.1 of the DAR, which was peer-reviewed in June 2008 (PRAPeR 51). Revisions were made following the evaluation of the resubmission dossier introduced in 2010 according to the legal provisions of Commission Regulation (EC) No. 33/2008 and are highlighted in yellow.

B.1.1 Identity of the active substance (Annex IIA 1)

B.1.1.1 Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)

Name: Taminco N.V.

Address: Pantserschipstraat 207,
B-9000 Gent
Belgium

Telephone: [REDACTED]
Fax: [REDACTED]

Contact person: [REDACTED]
Telephone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

Alternative
contact person: [REDACTED]
Telephone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

B.1.1.2 Manufacturer(s) of the active substance (Annex IIA 1.2)

Name: Taminco N.V.

Contact: [REDACTED]
Address: [REDACTED]
[REDACTED]
[REDACTED]

Location of plant: [REDACTED]
[REDACTED]
[REDACTED]

Telephone: [REDACTED]
Fax: [REDACTED]

B.1.1.3 ISO common name and synonyms (Annex IIA 1.3)

ISO common name: Metam

Variant 1:

Common name: metam-sodium
synonyms: metham-sodium, metham-Na

Variant 2:

Common name: metam-potassium
synonyms: metham-potassium, metham-K

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC name: methylthiocarbamic acid
CA name: methylthiocarbamic acid

Variant 1: Metam-sodium

IUPAC: sodium N-methylthiocarbamate
CA: Methylthiocarbamic acid sodium salt

Variant 2: Metam-potassium:

IUPAC: potassium N-methylthiocarbamate
CA: Methylthiocarbamic acid potassium salt

B.1.1.5 Manufacturer's development code number(s) (Annex IIA 1.5)

Not applicable

B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS no: 144-54-7
CIPAC: 20

Variant 1: Metam-sodium

CAS no: 137-42-8
EEC: 205-293-0
CIPAC: 20.011

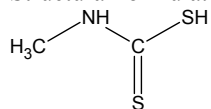
Variant 2: Metam-potassium

CAS no: 137-41-7
EEC: 205-292-5
CIPAC: 20.019

B.1.1.7 Molecular formula, molecular mass and structural formula (Annex IIA 1.7)

Molecular formula: $C_2H_5NS_2$

Structural formula:

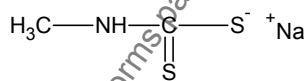


Molecular mass: 107.20 u

Variant 1: Metam-sodium

Molecular formula: $C_2H_4NNaS_2$

Structural formula:

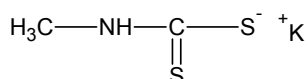


Molecular mass: 129.19 u

Variant 2: Metam-potassium

Molecular formula: C₂H₄KNS₂

Structural formula:



Molecular mass: 145.3 u

B.1.1.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C

B.1.1.9 Specification of purity of the active substance (Annex IIA 1.9)

Metam-sodium TK (Technical concentrate, i.e. SL-formulation):

Declared metam-sodium content: 510 g/L at 20°C (42.1 % w/w)

Metam-sodium content: min. 400 g/kg – max. 442 g/kg (corresponding to range 485 – 536 g/L at 20°C)

→ FAO specification Code 20.1Na/13/S/15, published in AGP:CP/82 (1979), applicable to Metam-sodium aqueous solutions: “The metam-sodium content shall be declared (g/L at 20°C or % w/w). When the combined carbon disulphide is determined and expressed as metam-sodium the content obtained shall not differ from that declared by more than ± 5% of the declared content.”

Min. purity of dry weight basis (calculated): 983 g/kg (cf. Vol.4, C.1.2.2)

Metam-potassium TK (Technical concentrate, i.e. SL-formulation):

Declared metam-potassium content: 690 g/L at 20°C (54.0 % w/w)

Metam-potassium content: min. 520 g/kg – max. 560 g/kg (approximately corresponding to the range 665 – 715 g/L at 20°C, which is in accordance with the FAO tolerance of ± 25 g/L from the declared content 690 g/L)

Min. purity of dry weight basis (calculated): 990 g/kg (cf. Vol.4, C.1.2.2)

B.1.1.10 Identity of isomers, impurities and additives (Annex IIA 1.10)

Confidential information: see Annex C

→ FAO specification Code 20.1Na/13/S/15, published in AGP:CP/82 (1979), applicable to Metam-sodium aqueous solutions: “Insoluble material: maximum 0.2% retained on a 125 µm test sieve.”

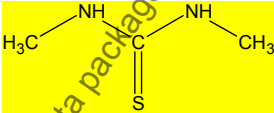
Compliance of the TK with the FAO specification for this parameter has been demonstrated by a wet sieve test: see Vol.3 B.2.2.25, [peer-reviewed in June 2008]

Reference: Re-submission dossier - Doc. J dated June 2010

During the first peer review of metam, the EFSA considered MITC (methyl isothiocyanate) to be a relevant impurity in the technical grade active ingredient and as a consequence, the applicant Taminco was requested to provide a revised specification in which MITC is listed with a maximum content value. The requested specification was presented in the resubmission dossier. The maximum content levels proposed for MITC are based on the 5-batch analysis results (applying the thumb rule ‘mean + 3*SD’).

	MITC
IUPAC name:	Methyl isothiocyanate
CA name :	Methyl isothiocyanate
CAS No.:	556-61-6
EINECS No.:	209-132-5
molecular formula:	C ₂ H ₃ NS
structural formula:	CH ₃ -N=C=S
molecular mass:	73.11 u
max. content:	0.09 g/kg in metam-sodium TK (corresponding to 0.22 g/kg on dry weight basis); 0.22 g/kg in metam-potassium TK (corresponding to 0.42 g/kg on dry weight basis);

Also **DMTU** (N,N'-dimethylthiourea or 1,3-dimethylthiourea) is to be regarded as an impurity of potential toxicological relevance (cf. Vol.4 C.1.2.2):

1	DMTU
IUPAC name:	N,N'-dimethylthiourea
CA name :	Thiourea, N,N'-dimethyl-
CAS No.:	534-13-4
EINECS No.:	208-588-2
molecular formula:	C ₃ H ₈ N ₂ S
structural formula:	
molecular mass:	104.2 u
max. content:	2.9 g/kg in metam-sodium TK (corresponding to 7 g/kg on dry weight basis); 2.9 g/kg in metam-potassium TK (corresponding to 6 g/kg on dry weight basis);

B.1.1.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C

B.1.2 Identity of the plant protection products METAM-SODIUM 510 g/L and METAM-POTASSIUM 690 g/L (Annex IIA 3.1; Annex IIIA 1)

B.1.2.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Metam-sodium 510 g/L:

Different tradenames are used in different EU member states: Solasan, Terrasan, Monam, Nemasol, Traitam Sol, Metam sodio, etc.

Manufacturer's code number: not applicable

Metam-potassium 690 g/L:

Tamifum, Tamifume, Nema K 50

B.1.2.2 Manufacturer or manufacturers of the plant protection products (Annex IIIA 1.2)

Manufacturer of the preparations and the active substances:

Name:	Taminco N.V.
Contact:	[REDACTED]
Address:	[REDACTED] [REDACTED] [REDACTED]
Location of plant:	[REDACTED] [REDACTED] [REDACTED]
Telephone:	[REDACTED]
Fax:	[REDACTED]

B.1.2.3 Type of the preparation and code (Annex IIIA 1.5)

Soluble concentrate (SL)

B.1.2.4 Function (Annex IIIA 1.6)

Soil fumigant (nematicide, fungicide, herbicide, insecticide)

B.1.2.5 Composition of the preparations (Annex IIIA 1.4)

Metam-sodium 510 g/L:

Technical active substance: 100 %
The preparation is identical to the technical grade active ingredient (metam-sodium as manufactured).

Pure active substance: 510 g/L $\pm$ 25 g/L (as determined with CIPAC method 20/13M/1.3)

Additives: see Annex C (Confidential information)

Metam-potassium 690 g/L:

Technical active substance: 100 %
The preparation is identical to the technical grade active ingredient (metam-potassium as manufactured).

Pure active substance: 690 g/L $\pm$ 25 g/L (as determined with CIPAC method 20/13M/1.3)

Additives: see Annex C (Confidential information)

B.1.3 References relied on

none