

Annex B

Metam-sodium

B.7 Residue data **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.

Introductory note [added in August 2010]

This document is based on the updated version (dated June 2008) of Volume 3 of the DAR-chapter B.7 which was peer-reviewed in July 2008 (PRAPeR 55). Revisions were made following the evaluation of the resubmission dossier introduced according to the legal provisions of Commission Regulation (EC) No. 33/2008 and are highlighted in yellow.

Introduction:

Metam-sodium acts as a soil fumigant (nematicide, fungicide, herbicide and insecticide) through rapid degradation to Methyl Isothiocyanate (MITC), which is active on living organisms present in the soil at the time of the application.

In water or moist soil, Metam-sodium was rapidly and predominantly decomposed into MITC.

The compound is applied before planting. MITC is rapidly degraded in the soil, dissipates through volatilization and is not present in the soil at the moment of planting or sowing the crops.

The product is not aimed being applied on the crop or any other crop part; as a soil fumigant, it must be applied in the soil before planting or sowing occurs.

There are 2 variants to the active substance Metam: Metam-sodium and Metam-potassium.

Based on the chemical similarity, it is expected that hydrolysis, photolysis, octanol-water partition, flammability, explosive and oxidizing properties of Metam-potassium will be comparable to Metam-sodium.

Methyl Isothiocyanate is the main metabolite of both Metam-sodium and Metam-potassium.

The product will control:

- Nematodes: root-knot nematodes (*Meloidogyne* spp.), root-lesion nematodes (*Pratylenchus* spp.), dagger nematodes (*Xiphinema*), cyst nematodes (*Heterodera* spp., *Globodera* spp.), stem nematodes (*Ditylenchus* spp.), free-living nematodes (*Trichostrongylus* spp.).
- Soil fungi: vascular diseases (*Fusarium* spp., *Verticillium* spp.), root rots (*Fusarium* spp., *Rhizoctonia* spp., *Pyrenochaeta lycopersici*, *Phytophthora* sp.).
- Weeds: seeds (*Solanum* spp., *Portulaca oleracea*, *Amaranthus* spp. ...), rhizomes (*Cyperus* sp., *Convolvulus* sp.).
- Insects: insects present in the soil at the time of the application of the product (larvae, eggs, pupae, adults).

The product has no direct effect on the crop. By reducing the level of harmful organisms, it allows a quick set-up of the plant and a vigorous growth.

Methyl Isothiocyanate (MITC) interferes at the level of the enzymatic activity. It disturbs the absorption of oxygen during the process of the cellular respiration by chelating enzymes having a metal radical. The efficacy on nematodes is probably due to the ability of MITC to deactivate the sulfuric groups of essential enzymes.

With a log P_{ow} value below -2.9 at 20 °C, bioaccumulation of Metam-sodium is not expected.

Resistance is unlikely to occur since the product acts on various enzymes involved in the cellular respiration process. Indeed, the appearance of a resistant strain of organisms would mean that such an organism is capable to modify and adapt at the same time numerous of its enzymes, which is known to be practically impossible.

The Metam-sodium aqueous solutions are generally used without further dilution. Only in the case of the drip-irrigation system, the product is applied as a dilution.

Application is done by direct injection or through drip-irrigation system.

- *Soil injection of the undiluted formulation:* Metam-sodium is injected in the field at 15 cm depth and immediately homogenized within the soil by spading or roto-tilling in a depth of 25 cm; this allows a good diffusion of the active substance in the whole mass of soil, thus enabling MITC to reach all infested sites. Soil surface is sealed with a roller in order to keep the fumes longer in the soil (carrots, lamb's lettuce, potato, tomato) in field and in greenhouse.

These results demonstrated that the starting concentration at an application rate of 4 g a.s./m² in the model system is similar to the total residue levels recovered in the open system model determined 7 days after the

critical dose rate of application of 40 g a.s./m² matching the normal field application rate (Dr. R. Hamm, BASF Personal communication).

The bioassay (cress test) uses cress seeds that are very sensitive to volatile phytotoxic compounds. The treated soil samples as well as controls with untreated soil are incubated at room temperature for 2-3 days. If no difference in the germination is observed the culture can be planted. Otherwise the aeration time has to be extended until the cress test showed negative results.

In radish, tomato and Chinese cabbage metabolism studies, the dose rate at time of application, 40 kg a.s./ha was indeed lower than those supported for the here above justified reasons, but anyhow this does not imply differences in the dose in the soil at the time of sowing/transplanting the crop because of the adapted waiting period. These plant metabolism studies should therefore be accepted.

On the other hand, the metabolism study in turnip was carried out at a dose rate of application of 356 kg a.s./ha.

Appendix A to this section contains the respective metabolic pathways in rat, soil and plants. Appendix B includes the structure of metabolites as well as the chemical names of synthetic reference compounds that were used in the metabolism studies.

B.7.0 Storage stability of residue samples

In the individual residue trials performed in the US, the storage stability conditions and intervals of storage (i.e., harvest to extraction interval, extraction to analysis interval) ranged between 30 and 40 days.

This frozen storage period is also valid for the additional supervised residue trials submitted in the framework of the resubmission.

Therefore, no further storage stability data were required.

B.7.1 Metabolism, distribution and expression of residues of Metam-sodium in plants (Annex IIA 6.1)

B.7.1.1 Metabolism, distribution and expression of residues of Metam-sodium in Radishes

-Investigations on the Residues of Metam-sodium in Radishes Grown on Pre-treated Soil (Bieber W.D. and Kröhn R., 1989a)

Guidelines :

EPA –Pesticide Assessment Guidelines, Subdiv. 0, & 171-4 (a) (1) and (2)

GLP :

No GLP compliance stated

Material and Methods :

Test substance: N-methyl-¹⁴C-(Thiocarbonyl)-Metam-Sodium

Radiochemical purity: >99%

Specific activity: 394.2 MBq/mmol.

Log P_{ow} for Metam-sodium: -2.9 at 20 °C.

Reference standards: Metam-sodium, Methyl Isothiocyanate, N-methyl thiourea, N,N'-Dimethyl thiourea, N,N,N'-Trimethyl urea, N,N'-dimethyl urea.

Experimental design:

The test substance was incorporated into the soil (sand/loam/peat-mixture, 1:2:1, w/w/w) at an application rate corresponding to 4 g a.s./m² at 20 cm depth.

In view of protection of the greenhouse workers against radioactivity and due to the stringent restrictions of the competent authority, this dose rate represented only one tenth of the critical application rate supported in the representative use on root and tuber vegetables (carrots) but under the conditions used in this study, the rate of 4 g a.s./m² simulated the commonly used rate of 40 g a.s./m² – see general considerations.

Radish crop was grown in the soil previously treated with the test substance simulating an application rate of about 40 g a.s./m².

At harvest (80 DAT), radish roots and leaves were sampled and stored under frozen storage conditions until analysis.

Extraction procedure:

The total level of radioactive residues in the liquid and extracted solids fractions was determined by Liquid Scintillation counting after radio combustion analysis of the homogenized plant samples.

For trapping possible volatile compounds, a slight stream of nitrogen was passed through the homogenisation vessel and then through 3 absorption flasks containing Ethyl Acetate, sulphuric acid and potassium hydroxide, respectively.

Radish roots and leaves were extracted with a mixture of acetonitrile/water (1:1, v/v) with subsequent partitioning against hexane and Ethyl Acetate in order to fractionate the radioactivity into organo soluble, aqueous soluble and residual radioactive aliquots.

Attempts to separate high molecular substances were performed using ultrafiltration and gel chromatography.

- Using gel chromatography, the acetonitrile/water extracted fraction, after partitioning against n-hexane and Ethyl Acetate, was passed through a Sephadex column (exclusion for Molecular Weight >5,000 or >10,000).

The aqueous soluble phase resulting from the Ethyl acetate partitioning was treated with enzymes (proteinase, β -glucosidase) followed by Ethyl Acetate extraction in order to detect the possible presence of proteins and glucosides.

-The acetonitrile/water extracted phase after lyophilisation was refluxed with Methanolic HCl used as a hydrolysing and methylating agent and after concentration was partitioned between water and Ethyl acetate. This procedure was performed in order to convert the polar radioactive residues into less polar components.

-Treatments respectively with aqueous hydrochloric acid and sodium hydroxide of the extracted solids were performed in order to release further radioactivity from the unextracted radioactive residues followed by partitioning against n-hexane and Ethyl Acetate.

TLC analysis by co-chromatography with reference standards was used to characterize and identify the metabolites of Metam-sodium in radish roots and leaves.

Findings :

Table B.7.1.1-1: Distribution of the radioactive residues and characterization of the nature of the residues of Metam-sodium in radish leaves and roots following pre-emergence soil application of Metam-sodium at a dose rate of 4 g a.s./m². (Residues expressed in % of the total radioactive residues and as mg Metam-sodium equivalents/kg).

	Radish roots			Radish leaves		
Sampling days after soil treatment	63	77	80	63	77	80
Sampling days after planting into the soil	32	46	49	32	46	49
Total radioactive residues (mg ¹⁴ C-Metam-sodium equivalents/kg) ⁽¹⁾						
	0.342	0.164	0.220	0.982	0.505	0.594
Extractability of the total radioactive residues expressed in % of TRR and (in mg ¹⁴ C-Metam-sodium equiv./kg)						
Acetonitrile/water extraction phase	65.0 (0.223)	63.0 (0.103)	59.0 (0.131)	62.0 (0.616)	63.8 (0.322)	61.14 (0.364)
1 st procedure of characterization						
n-hexane soluble partitioned phase	0.7 (0.0024)	0.6 (0.001)	0.4 (0.0009)	0.2 (0.0019)	0.29 (0.0015)	0.3 (0.002)
Ethyl Acetate soluble partitioned phase	2.0 (0.0069)	1.8 (0.003)	1.7 (0.0038)	3.5 (0.0345)	3.86 (0.0195)	3.7 (0.0223)
Aqueous soluble partitioned phase	62.9 (0.215)	60.9 (0.1)	57.4 (0.126)	58.1 (0.570)	59.6 (0.301)	57.4 (0.341)
Volatile losses	Trace level (0.0002)	Trace level (0.0002)	Trace level (0.0002)	Trace level (0.0002)	Trace level (<0.0001)	Trace level (0.0001)
2 nd procedure of characterization						
Ethyl Acetate organo soluble partitioned phase ⁽²⁾	10.0 (0.0341)	15.6 (0.0256)	13.0 (0.0287)	na	na	na
Water soluble partitioned phase ⁽²⁾	58.3 (0.199)	51.2 (0.0842)	50.9 (0.112)	na	na	na
Volatile losses ⁽²⁾	0.4 (0.0014)	1.3 (0.0022)	1.1 (0.0024)	na	na	na
Unextracted radioactive residues expressed in % of TRR and (in mg ¹⁴ C-Metam-sodium equiv./kg)						
	26.0	33.0	35.0	32.0	32.87	35.58

	(0.0905)	(0.055)	(0.0776)	(0.314)	(0.166)	(0.211)
MeOH/HCl extraction by reflux⁽³⁾	11.0 (0.0403)	11.0 (0.0194)	14.0 (0.0317)	15.0 (0.147)	na	na
n-hexane partitioned phase⁽³⁾	0.57 (0.0019)	0.9 (0.0015)	1.0 (0.0022)	1.3 (0.0129)	na	na
Ethyl Acetate partitioned phase⁽³⁾	1.7 (0.0057)	2.1 (0.0036)	3.2 (0.0071)	3.5 (0.0342)	na	na
Aqueous soluble partitioned phase⁽³⁾	8.3 (0.0286)	8.0 (0.0132)	10.1 (0.0222)	9.5 (0.0936)	na	na
Bound residues	16.0 (0.0549)	21.0 (0.0354)	20.0 (0.437)	16.0 (0.158)	na	na
Accountability (Extracted phases + volatile losses + Residual radioactive residues)						
	91.0 (0.313)	96.0 (0.158)	94.0 (0.208)	94.0 (0.93)	96.6 (0.488)	96.7 (0.575)
n.a.: Not analysed.						
Notes:						
⁽¹⁾ : Sum of extracted and residual radioactivity. The amount of radioactivity being volatile during homogenisation of the plant material is not included in these data.						
⁽²⁾ : The acetonitrile/water extraction phase after lyophilisation was refluxed with Methanolic HCl resulting in hydrolysis/methylation of the extracted phase and after concentration, the hydrolysed/methylated fraction was partitioned between water and Ethyl Acetate.						
⁽³⁾ : Treatment of the non-extracted residues with methanolic HCl followed by partitioning against n-hexane and Ethyl Acetate.						

The total radioactive residues in radish roots sampled 63 days and at harvest time (80 DAT) after soil treatment accounted for 0.342 and 0.220 mg Metam-sodium equiv./kg, respectively while in radish leaves, the amount of recovered residue levels were higher and accounted for 0.982 and 0.594 mg Metam-sodium equiv./kg, respectively at 63 and 80 days after soil treatment.

Up to around 65 % of TRR could be extracted with acetonitrile and water for both radish roots and leaves.

After liquid-liquid partitioning, the extractable radioactivity was predominantly found in the aqueous soluble phase for roots and leaves indicating the presence of an important amount of polar compounds.

Up to 63 % and 60 % of the total residues present in the extracted phase of roots and leaves, respectively could be partitioned into the aqueous soluble phase.

The volatile losses were recovered at a trace level (0.0002 mg/kg).

During the second procedure of characterization, the radioactivity being volatile during lyophilisation of the acetonitrile/water extracted phase was not found to exceed 1.3 % of the TRR (0.0022 mg/kg).

Identification of the metabolites was attempted on the aqueous soluble fraction after partitioning through radio-TLC analysis using different TLC systems and by co-chromatography with reference standards (mainly ureas and thioureas).

The acetonitrile/water extracted residues of radish roots were refluxed with methanolic HCl for further characterization. After volatilisation of methanol and partitioning between water and Ethyl Acetate, the major part of the radioactivity was also recovered in the aqueous solution (up to 10 % of the TRR in radish roots – 80 DAT).

The acetonitrile/water extract of the radish roots –63 DAT was passed through a Sephadex column and showed that only 18 % of the radioactivity applied were eluted indicating that most of the radioactive residues were constituted of small molecules. This result was confirmed by ultrafiltration, thereof, more than 54 % of TRR (0.185 mg/kg) showed a molecular weight less than 500.

Data were also provided on gel chromatography and ultrafiltration followed by enzymatic treatment on the acetonitrile/water extracts from radish roots.

Those polar residues could not be cleaved to any significant extent by incubation with proteinase or β -glucosidase.

TLC analysis showed that the radioactivity present in the aqueous soluble fraction spread over a broad peak on the plate.

No information was available on the possible cleavage of the polar compounds by incubation with proteinase or β -glucosidase.

Methanolic HCl extraction of the unextracted radioactive residues solubilized nearly one half of the radioactivity contained in the initial extracted solids fraction.

Data were also provided on the extractability of radioactivity from radish roots after treatment of the extracted solids with Sodium Hydroxide. Alkaline treatment released about 27 % of the TRR (0.059 mg/kg) from the extracted solids of radish roots – 80 DAT.

TLC analysis of the different fractions revealed that no detectable amounts of the reference substances were present and that in most of the analysed fractions, the radioactivity was found remaining at the origin of the plate.

Conclusion :

A degradation pathway of Metam-sodium in radish plants cannot be depicted since no metabolite identification was possible.

Attempts to derivatise the polar radioactive residues by methylation or by means of enzymatic cleavage altered the chromatographic behaviour only to a limited extent.

TLC analysis using different solvent systems attempted to identify the different metabolites but could not contribute to the elucidation of the nature of the residues.

Neither the parent compound nor its metabolite Methyl Isothiocyanate and the methylthiourea/ureas derivatives were detected in the different extracts of the radish roots grown in soil treated with the thiocarbonyl labelling form of Metam-sodium.

TLC analysis of the organic extracts revealed broad zones of radioactivity spreading over the plates.

All the characterized compounds had a rather high polarity as concluded from their extractability in the aqueous soluble partitioned fractions and considering their chromatographic behaviour (most of the radioactivity remained at the origin of the TLC plate).

B.7.1.2 Metabolism, distribution and expression of residues of Metam-sodium in Chinese cabbage

-Investigations on the Residues of Metam-sodium in Chinese Cabbage Grown on Pre treated Soil (Bieber W.D. and Kröhn R., 1989b)

Guidelines:

EPA –Pesticide Assessment Guidelines, Subdiv. 6, & 171-4 (a) (1) and (2)

GLP:

Yes

Material and Methods:

Test substance: ^{14}C -(Thiocarbonyl)-Metam-sodium

Radiochemical purity: >99%.

Specific activity: 394.2 MBq/mmol.

Log P_{ow} for Metam-sodium: -2.9 at 20 °C.

Reference standards: Metam-sodium, Methyl Isothiocyanate, N-methyl thiourea, N, N'-Dimethyl thiourea, N, N, N'-Trimethyl urea, N, N'-dimethyl urea.

Experimental design:

The test substance was incorporated into the soil (sand/loam/peat-mixture, 1:2:1, w/w/w) at an application rate corresponding to 4 g a.s./m² at 20 cm depth.

The residue pattern in Chinese cabbage leaves can cover the intended use on corn salad (lamb's lettuce).

In view of protection of the greenhouse workers against radioactivity and due to the stringent restrictions of the competent authority, this dose rate represented only one tenth of the application rate supported for the representative use on corn salad but under the conditions used in this study, the rate of 4 g a.s./m² simulated the commonly used rate of 40 g a.s./m² – see general considerations.

Chinese cabbage plants were grown in the soil previously treated with ^{14}C -Metam-sodium simulating an application rate of about 40 g a.s./m².

Chinese cabbage leaves were sampled 77 and 104 days after soil treatment and stored under frozen storage conditions until analysis.

Extraction procedure:

The total level of radioactive residues in the liquid and extracted solids fractions was determined by Liquid Scintillation Counting (LSC) after radio combustion analysis of the homogenized plant samples.

For trapping possible volatile compounds, a slight stream of nitrogen was passed through the homogenisation vessel and then through 3 absorption flasks containing Ethyl Acetate, sulphuric acid and potassium hydroxide, respectively.

Cabbage leaves were extracted with a mixture of acetonitrile/water (1:1, v/v) with subsequent partitioning against hexane and Ethyl Acetate in order to fractionate the radioactivity into organo soluble, aqueous soluble and residual radioactive fractions.

-Attempts to separate high molecular substances were performed using ultrafiltration (filtration of the aqueous soluble partitioned fraction through a membrane rated at 500 MW cut off) and gel chromatography (the aqueous soluble partitioned fraction was chromatographed on a column Sephadex G-10 – exclusion for MW>5.000) procedures.

The aqueous soluble phase resulting from the Ethyl acetate partitioning was treated with enzymes (proteinase, β -glucosidase) followed by extraction with Ethyl Acetate in order to detect the possible presence of proteins and glucosides.

-The acetonitrile/water extracted solids phase after lyophilisation was refluxed with Methanolic HCl used as hydrolysing and methylating agent and after concentration was partitioned between water and Ethyl acetate.

-Treatments respectively with aqueous hydrochloric acid and sodium hydroxide of the extracted solids were performed in order to release further radioactivity followed by partitioning against n-hexane and Ethyl Acetate.

An aliquot of the alkaline washing solution was transferred into a flask connected to a trapping system for acid volatile compounds.

The radioactivity in the trapping liquid was determined by LSC.

1D-TLC analysis by co-chromatography with reference standards was used to identify the metabolites of Metam-sodium in cabbage leaves extracts.

Findings:

Table B.7.1.2-1: Distribution of the radioactive residues and characterization of the nature of the residues of Metam-sodium in Chinese cabbage leaves following a pre-emergence soil application of ^{14}C -(Thiocarbonyl)-Metam-sodium at a dose rate of 4 g a.s./m².

(Residues expressed in % of the total radioactive residues and as mg Metam-sodium equivalents /kg).

Chinese cabbage leaves		
Sampling days after soil treatment	77	104
Sampling days after planting into the soil	33	60
Total radioactive residues (mg ^{14}C -Metam-sodium equivalents/kg) ⁽¹⁾		
	0.261	0.108
Extractability of the total radioactive residues expressed in % of TRR and in (mg ^{14}C -Metam-sodium equiv./kg)		
Acetonitrile/water extraction phase	39.0 (0.101)	61.3 (0.0664)
n-hexane soluble partitioned phase	0.1 (0.0003)	0.3 (0.0003)
Ethyl Acetate soluble partitioned phase	5.6 (0.0147)	3.7 (0.004)
Aqueous soluble partitioned phase	33.4 (0.0872)	56.5 (0.0613)
Methanolic washing of the residue	4.1 (0.0108)	2.6 (0.0028)
Volatile losses	<0.1 (<0.0001)	<0.1 (<0.0001)
Unextracted radioactive residues (% of TRR - mg ^{14}C -Metam-sodium equiv./kg)		
	56.8 (0.148)	36.0 (0.0391)
Washing with 0.9 % NaCl	3.3 (0.0085)	np
Methanolic HCl extraction phase ⁽²⁾	23.8 (0.062)	16.5 (0.0179)
n-hexane extraction phase	1.4 (0.0036)	1.6 (0.0018)

Ethyl Acetate partitioned phase	5.8 (0.015)	3.9 (0.0042)
MeOH/water partitioned phase	16.1 (0.0421)	10.4 (0.0113)
Residual radioactive residues	28.3 (0.0739)	17.9 (0.0194)
Accountability (Extracted phases + volatile losses + Methanolic washing fraction + Residual radioactive residues)		
	100.0 (0.261)	100.0 (0.108)
Np : Not performed. (1): Sum of extracted and residual radioactivity. The amount of radioactivity being volatile during homogenisation of the plant material is not included in these data. (2): Treatment with methanolic hydrogen chloride attempted tentative hydrolysis/methylation of potential sensitive groups.		

Table B.7.1.2-2: Ultrafiltration of the aqueous soluble fraction after partitioning against Ethyl Acetate from the Chinese cabbage leaves followed by enzymatic treatment (proteinase, β -glucosidase)- (Residues expressed in % of the total radioactive residues and as mg Metam-sodium equivalents/kg).

Sampling days after soil treatment	Chinese cabbage leaves	
	77	104
Total radioactive residues (mg ^{14}C-Metam-sodium equivalents/kg)		
	0.261	0.108
Extractability of the total radioactive residues expressed in % of TRR and in (mg ^{14}C-Metam-sodium equiv./kg)		
Acetonitrile/water extraction phase	39.6 (0.101)	61.3 (0.0664)
n-hexane partitioned phase	0.1 (0.0003)	0.3 (0.0003)
Ethyl Acetate soluble partitioned phase	5.6 (0.0147)	3.7 (0.004)
Aqueous soluble partitioned phase	33.4 (0.0872)	56.5 (0.0613)
Ultrafiltration of the aqueous soluble partitioned extract from Chinese cabbage leaves (Residues expressed as mg ^{14}C-Metam-sodium equivalents/kg)		
Residue fraction	8.2 (0.0213)	14.6 (0.0159)
Filtrate	27.8 (0.0725)	47.8 (0.0518)
Water soluble partitioned phase (1)	22.2 (0.0579)	39.6 (0.0429)
Ethyl Acetate partitioned phase (1)	5.6 (0.0145)	8.4 (0.0092)
Water soluble partitioned phase (2)	21.8 (0.0568)	39.4 (0.0427)
Ethyl Acetate partitioned phase (2)	5.6 (0.0147)	9.2 (0.01)
(1): After proteinase treatment (2): After β -glucosidase treatment Remark: The process used an ultrafiltration membrane rated 500 MW cut-off.		

The level of total radioactive residues recovered in Chinese cabbage leaves amounted for 0.261 and 0.108 mg Metam-sodium equiv./kg 77 and 104 days after soil treatment, respectively (Table B.7.1.2-1).

43 % to 64 % of the TRR could be extracted with acetonitrile/water and by washing the residue fraction with methanol.

During the extraction procedure, only <0.1 % of the total residues was lost as volatile compounds.

The n-hexane and Ethyl Acetate partitioning extracted each 5.7 % and 4 % of the TRR for the Chinese cabbage leaves sampled 77 days and 104 days after soil treatment, respectively.

Partitioning of the acetonitrile/water extracted phase against n-hexane and Ethyl Acetate revealed that the radioactivity was recovered mainly in the aqueous soluble phase with up to 56.5 % of TRR for cabbage leaves samples – 104 DAT. Radio-TLC analysis by co-chromatography with reference standards characterized the total residues as rather polar substances.

Following ultrafiltration of the aqueous soluble fraction, most of the radioactivity was recovered in the filtrate (27.8 % and 47.8 % of TRR, respectively for the 77 and 104 days cabbage samples – Table B.7.1.2-2) indicating that this fraction was related to smaller molecules (Molecular Weight < 500).

These polar residues were not cleaved to any significant extent by incubation with proteinase or β -glucosidase. After treatment of the unextracted radioactive residues with methanolic HCL followed by partitioning against n-hexane and Ethyl Acetate, up to 16 % of TRR partitioned into the MeOH/water soluble phase and most of the radioactivity in the aqueous solution remained at the origin of the TLC plate during analysis. No peak could be assigned to the reference compounds.

After treatment of the extracted residues with 10 % aqueous NaOH, 30 % of the TRR were released from the extracted solids and the lignin fraction obtained by precipitation contained radioactivity at a trace level in cabbage leaves at 77 days and 104 days (0.8 % and 1.1 % of TRR, respectively).

Conclusion :

A degradation pathway of Metam-sodium in Chinese cabbage cannot be depicted since no metabolite identification was possible.

Neither parent compound nor MITC or methylureas/methylthioureas could be identified in the different extracts of Chinese cabbage by radio-TLC analysis.

Radio-TLC analysis of the organic extracts revealed broad zones of radioactivity spreading over the TLC plates. Most of the radioactivity was characterized as highly polar based on its extractability design and its behaviour on the TLC plates (most of the radioactivity in the aqueous solution remained at the origin of the TLC plate).

As shown by ultrafiltration, a non negligible amount of radioactivity exhibited a molecular weight less than 500 but these polar radioactive residues were not cleaved by enzymatic incubation (proteinase, β -glucosidase).

Attempts to derivatise the polar radioactive residues by methylation or by enzymatic cleavage refined the chromatographic behaviour only to a limited extent.

B.7.1.3 Metabolism, distribution and expression of residues of Metam-sodium in Tomatoes

-Investigations on the Residues of Metam-sodium in Tomatoes Grown on Pre treated Soil (Bieber W.D. and Kröhn R., 1989c)

Guidelines:

EPA –Pesticide Assessment Guidelines, Subdivision 0, & 171-4 (a) (1) and (2)

GLP:

Yes

Material and Methods:

Test substance: ^{14}C -(Thiocarbonyl)-Metam-sodium

Radiochemical purity: >99%

Specific activity: 394.2 MBq/mmol.

Log P_{ow} for Metam-sodium: -2.9 at 20 °C.

Reference standards: Metam-sodium, Methyl Isothiocyanate, N-methyl thiourea, N, N'-Dimethyl thiourea, N, N'-Trimethyl urea, N, N'-dimethyl urea.

Experimental design:

The test substance was incorporated into the soil (sand/loam/peat-mixture, 1:2:1, w/w/w) at an application rate corresponding to 4 g a.s./m² at 20 cm depth simulating an application rate of about 40 g a.s./m² (In view of protection of the greenhouse workers against radioactivity and due to the stringent restrictions of the competent authority – see general considerations).

Tomato fruits (mature and immature) and green plant parts were harvested 102 days after soil treatment and stored under frozen storage conditions until analysis.

Extraction procedure:

The total level of radioactive residues in the liquid and extracted solids fractions was determined by Liquid Scintillation Counting after radio combustion analysis of the homogenized plant samples.

For trapping possible volatile compounds, a slight stream of nitrogen was passed through the homogenisation vessel and then through 3 absorption flasks containing Ethyl Acetate, sulphuric acid and potassium hydroxide, respectively.

Tomato fruit and green plant parts were extracted with a mixture of acetonitrile/water (1:1, v/v) with a subsequent extraction with n-hexane followed by partitioning against Ethyl Acetate in order to fractionate the radioactivity in organo soluble, aqueous soluble and residual radioactive fractions.

-Attempts to separate high molecular substances were performed using ultrafiltration (filtration of the aqueous partitioned solution through a membrane rated at 500 MW cut off) and gel chromatography (the aqueous partitioned solution was chromatographed on a column Sephadex G-10 – exclusion for Molecular Weight > 5.000) procedures.

The aqueous soluble phase resulting from the Ethyl Acetate partitioning was treated with enzymes (proteinase, β -glucosidase) followed by extraction again with Ethyl Acetate in order to detect the possible presence of proteins and glucosides.

-The acetonitrile/water extracted phase after lyophilisation was refluxed with Methanolic HCl used as hydrolysing and methylating agent and after concentration; the extracted fraction was partitioned between water and Ethyl acetate.

The unextractable radioactive residues fraction was washed with a sodium chloride solution.

Release of further radioactivity from the extracted solids was attempted through treatment with methanolic HCl, aqueous HCl following by extraction with n-hexane and Ethyl Acetate.

1D-TLC analysis by co-chromatography with reference standards was used to identify the metabolites of Metam-Sodium in tomato fruit and green plant parts.

Findings:

Table B.7.1.3-1: Distribution of the radioactive residues and characterization of the nature of the residues of Metam-sodium in tomato fruit and green plant parts following a pre-emergence soil application of ^{14}C -(Thiocarbonyl)-Metam-sodium at a dose rate of 4 g a.s./m² - (Residues expressed in % of the total radioactive residues and as mg Metam-sodium equivalents /kg).

	Fruit mature	Fruit immature	Green plant parts
Sampling days after soil treatment	102	102	102
Sampling days after planting into the soil	77	77	77
Total radioactive residues (mg ^{14}C-Metam-sodium equivalents/kg) ⁽¹⁾			
	0.241	0.249	1.925
Extractability of the total radioactive residues expressed in % of TRR and in (mg ^{14}C-Metam-sodium equiv./kg)			
Acetonitrile/water extraction phase	58.09 (0.140)	56.8 (0.141)	44.5 (0.857)
n-hexane partitioned phase	0.6 (0.0015)	0.52 (0.0013)	0.1 (0.001)
Ethyl Acetate soluble partitioned phase	1.1 (0.0042)	0.64 (0.0016)	0.8 (0.0145)
Aqueous soluble partitioned phase	52.9 (0.127)	54.4 (0.135)	43.3 (0.834)
Methanolic washing of the residue	8.3 (0.0201)	4.1 (0.0104)	4.0 (0.0762)
Volatile losses	0.1 (0.0002)	<0.1 (0.0001)	<0.1 (0.0001)
Unextracted radioactive residues expressed in % of TRR and in (mg ^{14}C-Metam-sodium equiv./kg)			
	33.6 (0.081)	39.35 (0.098)	51.5 (0.992)
Washing with 0.9 % NaCl	Not analysed	na	2.9 (0.0563)
Buffer solution pH 7		1.5 (0.0037)	3.9 (0.0754)
Methanolic HCl extraction phase ⁽²⁾		19.2 (0.048)	26.8 (0.515)

n-hexane extraction phase		3.5 (0.0088)	1.4 (0.0269)
Ethyl Acetate partitioned phase		3.1 (0.0077)	5.2 (0.1)
MeOH/water partitioned phase		11.9 (0.0296)	19.7 (0.379)
Residual radioactive residues	-	18.2 (0.0455)	17.9 (0.345)
Accountability (Extracted phases + volatile losses + Methanolic fraction + Residual radioactive residues)			
	100.9 (0.241)	100.35 (0.249)	100.1 (1.925)
⁽¹⁾ : Sum of extracted and residual radioactivity. The amount of radioactivity being volatile during homogenisation of the plant material is not included in these data. ⁽²⁾ : Treatment by reflux with methanolic hydrogen chloride as hydrolysing/methylating agents of potential sensitive groups. Na : not analysed.			

Table B.7.1.3-2: Partitioning between water and Ethyl Acetate of the radioactive residues in the acetonitrile/water extraction phase after lyophilisation and acid treatment by reflux with Methanolic HCl - Residues expressed in % of the total radioactive residues and as mg Metam-sodium equivalents/kg).

	Fruit mature	Fruit immature	Green plant parts
Sampling days after soil treatment	102	102	102
Sampling days after planting into the soil	77	77	77
Total radioactive residues (mg ¹⁴C-Metam-sodium equivalents/kg)			
	0.241	0.249	1.925
Extractability of the total radioactive residues expressed in % of TRR and in (mg ¹⁴C-Metam-sodium equiv./kg)			
Acetonitrile/water extraction phase	58.09 (0.140)	56.8 (0.141)	44.5 (0.857)
Volatiles fraction	0.6 (0.0014)	0.4 (0.001)	0.3 (0.0055)
Ethyl Acetate partitioned phase	21.5 (0.0518)	17.9 (0.0446)	23.2 (0.446)
Water partitioned phase	38.0 (0.0916)	37.5 (0.0937)	22.1 (0.425)
Unextracted radioactive residues			
	33.6 (0.081)	39.35 (0.098)	51.5 (0.992)
Accountability (volatile losses + Ethyl Acetate partitioned phase + Water partitioned phase + Unextracted radioactive residues)			
	92.3 (0.222)	96.5 (0.24)	96.3 (1.854)

Table B.7.1.3-3: Ultrafiltration of the aqueous soluble fraction after partitioning against Ethyl Acetate from tomato mature fruit and green plant parts followed by enzymatic treatment (proteinase, β -glucosidase) - Residues expressed in % of the total radioactive residues and as mg ¹⁴C-Metam-sodium equivalents/kg.

	Tomato fruit mature	Tomato green plant parts
Sampling days after soil treatment	102	102
Total radioactive residues (mg ¹⁴C-Metam-sodium equivalents/kg)		
	0.241	1.925
Extractability of the total radioactive residues expressed in % of TRR - (mg ¹⁴C-Metam-sodium equiv./kg)		
Acetonitrile/water extraction phase	58.09 (0.140)	44.5 (0.857)

n-hexane soluble partitioned phase	0.6 (0.0015)	0.1 (0.001)
Ethyl Acetate soluble partitioned phase	1.1 (0.0042)	0.8 (0.0145)
Aqueous soluble partitioned phase	52.9 (0.127)	43.3 (0.834)
Ultrafiltration of the aqueous soluble partitioned extract from tomato fruit and tops (Residues expressed in % of the TRR and as mg ¹⁴C-Metam-sodium equiv./kg)		
Residue fraction	Nd	12.4 (0.244)
Filtrate	46.1 (0.111)	31.1 (0.598)
Water soluble partitioned phase (1)	41.3 (0.099)	25.0 (0.481)
Ethyl Acetate partitioned phase (1)	1.3 (0.0031)	1.6 (0.0309)
Water soluble partitioned phase (2)	43.2 (0.104)	29.1 (0.560)
Ethyl Acetate partitioned phase (2)	1.4 (0.0035)	1.2 (0.0235)
(1): After proteinase treatment (2): After β -glucosidase treatment <i>Remark:</i> The process used an ultrafiltration membrane rated 500 MW cut-off. Nd: not radiodetected.		

The uptake of Metam-sodium from the treated soil resulted in the radioactive residue level of 0.241 and 1.925 mg Metam-sodium equiv./kg in harvested tomato fruit mature and green plant parts, respectively (Table B.7.1.3-1).

Up to 58 % and 44.5 % of the TRR could be extracted into the acetonitrile/water phase both in tomato mature fruit and green plant parts, respectively.

Further 8.3 % of TRR could be eluted by Methanolic washing of the residue in fruit mature.

During the extraction procedure of the mature fruit, only 0.1 % of the TRR was lost as volatile compounds.

Partitioning of the acetonitrile/water extracted phase against n-hexane and Ethyl Acetate revealed that the radioactivity was recovered mainly in the aqueous soluble phase (53 % of TRR in fruit mature, 54.4 % of TRR in fruit immature and 43.3 % of TRR in green plant parts) and was characterized therefore as highly polar substances - Table B.7.1.3-1.

The highly polar character of the radioactive residues was confirmed by their chromatographic behaviour.

A non negligible part of the radioactive residues could be converted into less polar components after lyophilisation and acid treatment by reflux with methanolic HCl that was used as a hydrolysing and methylating agent (21.5 % of TRR and 23.2 % of TRR respectively in fruit mature and green plant parts against up to 38 % of TRR recovered in the aqueous soluble fraction for fruit mature and 22.1 % of the TRR in tomato green plant parts) – Table B.7.1.3-2.

The acetonitrile/water extracted fraction was lyophilised, during which process about only 0.6 % of the TRR was volatilised for tomato fruit mature.

Following ultrafiltration of the aqueous soluble partitioned fraction, most of the radioactivity was recovered in the filtrate (46.1 % and 31.1 % of TRR, respectively for fruit mature and green plant parts samples) indicating that this fraction was related to smaller molecules (Molecular Weight < 500) - Table B.7.1.3-3.

These polar components could not be cleaved by incubation with proteinase or β –glucosidase.

After treatment by reflux of the unextracted radioactive residues with methanolic HCL followed by extraction with n-hexane and partitioning against Ethyl Acetate, a non negligible part of the radioactivity partitioned into the water soluble phase (12 % of TRR and 19.7 % of TRR for tomato fruit immature and green plant parts, respectively - Table B.7.1.3-1).

Most of the radioactivity in the aqueous solution remained at the origin of the TLC plate confirming the polarity of the radioactivity.

Neither parent compound nor its metabolite MITC was present in detectable amounts.

No other metabolite could be detected since TLC analysis of the extracts demonstrated that sufficient isolation of the different fractions was impossible. In most cases, the radioactivity was spread widely over the plates.

Conclusion :

A degradation pathway of Metam-sodium in tomato fruit cannot be depicted since no metabolite identification was possible.

Neither parent compound nor MITC or methylureas/methylthioureas could be identified in the different extracts of tomato fruit and green plant parts by radio-TLC analysis.

Radio-TLC analysis of the organic extracts revealed broad zones of radioactivity spreading over the TLC plates.

The radioactivity was characterized as highly polar based on its extractability design and its behaviour on the TLC plates (most of the radioactivity remained at the origin of the TLC plate).

As shown by ultrafiltration, a non negligible amount of radioactivity exhibited a molecular weight less than 500 but further characterization was not possible as these polar radioactive residues couldn't be cleaved by enzymatic incubation (proteinase, β -glucosidase).

B.7.1.4 Metabolism, distribution and expression of residues of Metam-sodium in Turnip

-Nature of the Residue of ^{14}C -Metam-sodium in Turnip (Davis M.L., Campbell L.A.; 1995)

Guidelines:

US EPA Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry Series 171-4(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

GLP:

Yes

Material and Methods:

Test substance: ^{14}C -(Thiocarbonyl)-Metam-sodium

Radiochemical purity: 90.1 % - 95.4 %

Specific activity: 26.5 $\mu\text{Ci/mg}$

Log P_{ow} for Metam-sodium: - 2.9 at 20°C.

Reference standards: Metam-sodium, Methyl Isothiocyanate (MITC), N-methyl thiourea (1-M-2-TU), N, N'-Dimethyl thiourea (1,3-DMTU), N, N, N'-Trimethyl urea (1,1,3-TMU), N, N'-Dimethyl urea (1,3-DMU), N, N-Dimethyl urea (1,1-DMU), ^{14}C -Metam-Sodium.

Formulation of the ^{14}C -(Thiocarbonyl)-Metam-sodium:

The test substance (43.9 g or approximately 36 mL of aqueous solution containing 45.02 % ^{14}C -Metam - sodium by weight; density 1.23 g/mL) was diluted in water within minutes prior to application to the treated plot.

Experimental design:

The test substance was applied as a soil drench at a rate of application of 356 kg a.s./ha to the entire plot area.

The test dose rate of application in this study reflected the critical supported dose of application for root and tuber vegetables in order to maximize potential uptake for residue analysis.

Due to the volatility of the test substance and its phytotoxicity to the tested crop (turnips), the maximum dose was used with multiple plantings to get the earliest surviving crop for maximized residues.

The treated plots received a single application.

The soil used was a sandy loam.

The study was designed to provide a turnip crop at the earliest possible plant-back date to maximise the level of radioactivity in the soil available for uptake.

Due to the inherent phytotoxicity of Metam-sodium to germinating seeds and to establish a turnip crop as soon as possible after application, several plantings were made.

Turnip seeds (*Brassica rapa*) were planted at intervals of 7, 10, 14 and 21 days after soil treatment (DAT).

The 7-DAT crop did not survive. The 10-DAT crop showed symptoms of phytotoxicity but revived, grew to maturity and was used for further analysis.

The 10-DAT-plants were the first to survive and would be expected to have the greatest potential to contain Metam-sodium residues.

Plants from 14-DAT were removed once it was decided the 10-DAT crop would survive.

The 21-DAT crop grew to maturity.

Immature crop samples were collected at 56-DAT and 93-DAT. Mature turnip samples (10-DAT and 21-DAT) were collected by hand when bolting (first stage of flowering) was initiated.

The delay in growth to the 10-DAT crop induced by the phytotoxicity slowed the root growth necessitating bringing the plots indoors to complete root development.

Tops and roots were separated and stored frozen until processing.

Mature tops and roots from the 10-DAT planting were collected at 160-DAT.

Mature tops and roots from the 21-DAT planting were collected at 173-DAT.

Plants from the 21-DAT crops planted were retained to compare uptakes with the 10-DAT crops.

Extraction procedure:

The total level of radioactive residues in liquid and solid fractions was determined by radio combustion analysis and Liquid Scintillation Counting.

Both roots and tops samples were extracted with a mixture of acetonitrile:water (1:1, v/v) followed by partitioning against hexane to provide organo soluble (hexane) fraction, aqueous soluble (Acetonitrile/aqueous) fraction and the extracted solids fraction.

Extraction recoveries were calculated against combustion values of the freshly homogenised turnip roots and tops to determine if any volatiles were lost.

The acetonitrile/water extract was stored at <-20°C and a phase separation with a solid lower aqueous phase and a liquid upper acetonitrile phase occurred by freezing.

The aqueous soluble phases and the post extracted solids of treated turnip tops and roots were subjected to acid and base hydrolysis through acid and base treatment (6 N HCl and NaOH) in parallel to characterize the radioactive components in the hydrolysates.

Aqueous phase roots and tops were also treated under strong acid and base hydrolysis conditions (12 N HCl and NaOH).

The turnip roots aqueous soluble phase was submitted to enzymatic hydrolysis by cellulose digestion, pectin digestion and starch digestion with various enzyme mixtures (cellulase, β -glucosidase, pectinase and α -amylase) to attempt to release the conjugates after cellulose, pectin and starch digestion.

The respective root hydrolysates were concentrated for further TLC analysis.

The post extraction solids (PES) of each matrix were submitted to mild acid and base hydrolysis treatments (1 N HCl and NaOH).

No further chromatographic analysis was attempted on those hydrolysates.

The post extraction solids (PES) from roots and tops were also submitted to sequential enzymatic hydrolysis by cell wall digestion (cellulase, β -glucosidase), pectin digestion (pectinase), starch digestion (α -amylase and α -glucosidase) and protein digestion (Pronase E).

Controls were also run using both boiled enzyme and buffer only for comparison.

The lignin remaining in the pectin hydrolysed fraction was extracted with Dioxane/2N HCl from roots and tops PES following enzyme hydrolysis.

To maximize the release of further radioactivity from this fraction, the PES enzymatic extraction procedure was initiated by cell wall digestion and proceeded sequentially with starch, protein and other digestions.

Tentative identification of the Metam-sodium metabolites was performed using 1D-TLC and HPLC analysis as a confirmatory method by co-chromatography with reference standards.

Findings:

Table B.7.1.4-1: Material balance, extractabilities of the total radioactive residues, characterization, identification and magnitude of the radioactive residues recovered in turnip roots and tops after a soil treatment by drenching with ^{14}C -(Thiocarbonyl)-Metam-sodium at a rate of application of 356 kg a.s./ha. – (Residues expressed as mg ^{14}C -Metam-sodium equivalents/kg).

	Mature turnip roots	Mature turnip tops	Mature turnip roots	Mature turnip tops
Days after soil treatment	160	160	173	173
Total radioactive residues (mg ¹⁴ C-Metam-sodium equivalents/kg)				
	2.36	2.83	3.18	4.81
Extractability of the total radioactive residues expressed in % of TRR and in (mg ¹⁴ C-Metam-sodium equiv./kg)				
Acetonitrile/water extraction phase	66.5 (1.57)	81.2 (2.30)	Analysis not performed.	
Hexane organo soluble partitioned phase	0.9 (0.022)	0.1 (0.004)		
Acetonitrile/water soluble partitioned phase	65.5 (1.55)	81.1 (2.29)		
Acetonitrile upper phase	4.5 (0.11)	8.5 (0.24)		
Aqueous lower phase	61.1 (1.44)	72.6 (2.06)		
Characterization of the radioactive residues both in the upper Acetonitrile and lower aqueous phases expressed in % of the TRR and in (mg ¹⁴ C-Metam-sodium equiv./kg)				
Exocon released by acid	6.2	11.0		

hydrolysis-containing metabolites 1,2,3,4,7⁽¹⁾.	(0.146)	(0.311)		
Sugars⁽²⁾-Metabolite 10	11.0 (0.260)	27.8 (0.787)		
Complex of carbohydrates⁽³⁾-Metabolite 11	25.4 (0.599)	13.6 (0.385)		
Total characterized residues in % of the TRR and in (mg ¹⁴C-Metam-sodium equiv./kg)				
	42.6 (1.005)	52.4 (1.482)		
3 resolved unknown compounds⁽⁴⁾-Metabolites 5,8,9	21.8 (0.514)	32.0 (0.905)		
Post extraction solids in % of the TRR and in (mg ¹⁴C-Metam-sodium equiv./kg)				
	38.1 (0.901)	21.1 (0.597)		
Extraction of total radioactive residues using sequential enzyme hydrolysis in % of the TRR and in (mg ¹⁴C-Metam-sodium equiv./kg)				
System A⁽⁵⁾: Cellulose/hemicelluloses	7.1 (0.168)	7.8 (0.221)		
System B⁽⁵⁾: Starch	3.4 (0.080)	4.2 (0.119)		
System C⁽⁵⁾: Protein	8.0 (0.189)	4.4 (0.125)		
System D⁽⁵⁾: Pectin	2.9 (0.068)	1.7 (0.048)		
System E⁽⁵⁾: Lignin	6.3 (0.149)	1.1 (0.031)		
Total released radioactivity	27.7 (0.654)	19.2 (0.543)		
Bound residues	9.1 (0.214)	1.9 (0.053)		
Accountability (extracted phases + unextracted radioactive residues)				
	104.0 (2.454)	105.6 (2.99)		

Remarks:

Only the 10-DAT turnip samples were used for metabolite analysis.

TLC analysis using solvent system referenced SS1 for polar metabolites since in SS1 Rf values for parent related standards are all >0.4, while polar natural products (sugars and starch) have Rf values <0.4, providing a convenient break between the two groups.

(1): Only the metabolites 1 and 7 were recovered in both the acetonitrile and aqueous phases of the mature turnip roots.

(2): Total radioactive residues recovered both in acetonitrile and aqueous phases.

This fraction could be a mixture of sugars (monosaccharides and disaccharides), and/or amino acids (L-alanine). This fraction was hydrolysed and derivatized with phenylhydrazine to check for osazone derivatives indicative of sugars. The presence of radioactivity in the chromatographed osazones confirmed its incorporation into sugars.

(3): This fraction is a mixture of very polar components that co-chromatographed with the ^{14}C -starch, the only available oligosaccharide ^{14}C -standard. This fraction was partially hydrolysed under both acidic and basic conditions with a corresponding increase into the sugars fraction. This fraction was enzymatically hydrolysed with cellulose, pectinase and α -amylase indicating the presence of a mixture of carbohydrates.

Derivatization with phenylhydrazine to check for the osazone derivatives indicative of reducing sugars was achieved. The presence of radioactivity in the chromatographed zones confirmed the incorporation of radioactivity into those reducing sugars.

(4): This fraction had no similar chromatographic properties as the parent and the other reference standards.

(5): Specificity of the enzymatic system:

System A: contained cellulase/hemicellulase and β -glucosidase

System B: contained α -amylase and α -glucosidase

System C: contained pronase E

System D: contained pectinase

System E: contained no enzyme but was a lignin solubilization/chemical hydrolysis using dioxane : 2 N HCl (9:1).

Nd : not radiodetected.

The combined radioactivity in the extracted fractions and post extraction solids accounted for 104.0 % of TRR (roots) and 105.6 % of TRR (tops) indicating no loss by volatilisation of radioactivity. The total radioactive residue levels raised 2.36 and 2.83 mg ^{14}C -Metam-sodium equiv./kg in mature 10-DAT turnip roots and tops, respectively.

The mature 21-DAT turnips contained a higher total residue level (4.81 and 3.18 mg ^{14}C -Metam-sodium equiv./kg, respectively for tops and roots). According to the notifier, this was probably due to a more vigorous uptake due to healthier plants after 21 days of dissipation of the test substance.

Turnip tops contained a higher level of radioactive residues than in the roots in both the 10-DAT and 21-DAT turnip samples. Since the treatment with the test substance was a pre-plant soil application and not a foliar application, this indicated a non-negligible translocation by the plant to the tops.

The extractability of turnip roots and tops with acetonitrile/water yielded 65.5 % and 81.1 % of the TRR, respectively.

Partitioning against hexane of these extracts partitioned only 0.9 % and 0.1 % of the TRR into the organo soluble phase, respectively for turnip roots and tops while a major part of the radioactivity was recovered as aqueous soluble compounds (65 % and 81 % of the TRR for roots and tops, respectively).

The acetonitrile/water soluble partitioned phase was separated into 2 phases under frozen storage process (acetonitrile upper and aqueous lower phases) and showed that most of the extracted radioactivity remained in the aqueous lower phase (61 % and 72.6 % of TRR for roots and tops, respectively) indicating that the majority of the extractable residues had a very polar character.

The total level of characterized metabolites accounted for 42.6 % of TRR and 52.4 % of TRR in turnip roots and tops, respectively.

TLC analysis of the root hydrolysates extracts indicated a significant digestion of polar oligomers (radioactivity retained at the origin) and an increase in the level of sugar residues.

Sugars and a complex of carbohydrates were tentatively characterized (Table B.7.1.4-1).

In the aqueous phase, the major part of the radioactivity (51.0 % of TRR-root and 60.4 % of TRR-tops) was recovered under 3 major polar bands for each matrix (corresponding to metabolites 9, 10 and 11); each

metabolite fraction accounting for more than 10 % of TRR (ranging from 13.6 % of TRR to 26.9 % of TRR for tops and from 10.7 % of TRR to 25.4 % of TRR for roots).

One polar band was stable to carbohydrate and pectin specific enzyme digestions, degrading only under strong base hydrolysis conditions sufficient for peptide hydrolysis.

The other metabolite fractions were converted to ^{14}C -osazones after acid hydrolysis and derivatization confirming their nature of carbohydrates containing ^{14}C -reducing sugars.

In the acetonitrile upper phase, TLC analysis revealed several peaks that accounted for a maximum of 2.1 % of TRR (0.059 mg/kg) for turnip tops and 1.7 % of TRR (0.04 mg/kg) for turnip roots. It is possible that those peaks could be multiple components but without any further analytical investigation.

A few radioactive residues in turnip roots and tops (6.2 % and 11.0 % of TRR, respectively) were also characterized as acid hydrolysed exocon or conjugates that were hydrolysed under strong acid conditions (metabolites 1,2,3,4 and 7).

None of the different metabolites fractions separated by TLC analysis co-chromatographed with either the parent or the parent related metabolites including MITC.

The post extraction solids (PES) fraction accounted for 38.1 % and 21.1 % of TRR for turnip roots and tops, respectively.

Acid hydrolysis of the PES fraction released less than 10 % of the radioactivity for both tops and roots.

Only the pronase hydrolysate fraction (4.4 % and 8 % of TRR for tops and roots, respectively) showed some migration of the radioactivity from the origin indicating that a few amino acids or peptides were released and suggested an incorporation of the radioactivity into proteins.

Lignin remaining in the post-enzyme hydrolysed fraction amounted up to 6.3 % of TRR and 1.1 % TRR for turnip roots and tops, respectively.

Bound residues accounted for 9.1 % of TRR and 1.9 % of TRR in turnip roots and tops, respectively.

Conclusion:

No parent Metam-sodium or its primary metabolite, MITC was found in either turnip root or top matrices.

No degradation of the parent compound into its substituted thioureas or methylated –ureas was observed.

The extractable radioactive residues consisted mainly in polar components under reducing sugars suggesting the incorporation of the radioactivity into the carbon pool through the glucose metabolism.

The sequential hydrolysis of the post extraction solids with enzymes selective for cellulose, starch, protein and pectin and finally lignin extraction showed the distribution of the radioactive residues over a variety of natural products such as cellulose, hemicellulose, starch, proteins, pectin and lignin.

The radioactive residues of Metam-sodium were mainly characterized as natural products and the identification of glucose in the extractable residues suggested a complete incorporation of this compound into the carbon pool of the turnip crop.

B.7.2 Metabolism, distribution and expression of residues in livestock (Annex IIA 6.2)

Studies are not required since no significant residues (>0.1 mg/kg total diet) occurred in livestock feed.

B.7.3 Definition of the residue

B.7.3.1 Definition of the residues in plant products

The metabolism of Metam-sodium has been investigated in various crops (radishes, Chinese cabbage, tomatoes and turnips).

These studies were representative of the following categories of crops: root and tuber vegetables, leafy brassica and fruiting vegetables and therefore can be considered as sufficient to cover the supported uses on carrots, corn salad, cucumber, eggplant, pepper, potato, strawberry, tomato and grapes by soil injection or drip-irrigation of Metam-sodium on the planting row.

In radish roots and leaves, neither the parent compound nor its metabolite Methyl Isothiocyanate and the methylthiourea/ureas derivatives were detected in the different extracts. The TLC analysis of the organic extracts revealed broad zones of radioactivity spreading over the plates.

All the characterized compounds had a rather high polarity as concluded from their extractability into the aqueous soluble partitioned fractions and considering their chromatographic behaviour.

In Chinese cabbage leaves, partitioning of the extracted fractions revealed that the radioactivity was recovered mainly in the aqueous soluble phase.

The radioactive residues in Chinese cabbage leaves were found to have a highly polar character based on the extractability design and its behaviour on the TLC plates.

Neither the parent compound nor its metabolites Methyl Isothiocyanate or the methylureas/methylthioureas could be identified in the different extracts.

Ultrafiltration performed on the aqueous soluble fraction demonstrated that this fraction was related to very small molecules.

In tomatoes, the highly polar character of the radioactive residues in the extracted fractions was confirmed by their chromatographic behaviour.

Neither parent compound nor its metabolite MITC was present in detectable amounts.

No other metabolite could be detected since TLC analysis of the extracts demonstrated that sufficient isolation of the different fractions was impossible. In most cases, the radioactivity was spread widely over the plates.

As shown by ultrafiltration, a non-negligible amount of radioactivity exhibited a molecular weight less than 500 but further characterization was not possible as these polar radioactive residues could not be cleaved by enzymatic incubation (proteinase, β -glucosidase).

In turnip roots, TLC analysis of the hydrolysates extracts indicated a significant digestion of polar oligomers (radioactivity retained at the origin) and an increase in sugar and carbohydrate residues in the aqueous soluble fractions.

No Metam-sodium or its primary metabolite, MITC was found in either turnip root or top matrices.

No degradation of the parent compound into its substituted thioureas or methylated –ureas was observed.

The sequential hydrolysis of the post extraction solids with enzymes selective for cellulose, starch, protein and pectin and finally lignin extraction showed the distribution of the radioactive residues over a variety of natural products such as cellulose, hemicellulose, starch, proteins, pectin and lignin.

The radioactive residues of Metam-sodium were mainly characterized as natural products and the identification of glucose in the extractable residues suggested a complete incorporation of this compound into the carbon pool of the turnip crop.

The available metabolism studies showed that most of the radioactivity had been metabolised extensively and to a large extent incorporated into natural compounds such as sugars, starch, proteins, pectins, lignin and cellulose.

~~The metabolic pathway of Metam sodium in plants can be considered as sufficiently investigated in radish, Chinese cabbage, tomato and turnip although tentative metabolites identification failed in all the metabolism studies.~~

New data gap identified at PRAPeR 55 (July 2008):

“The relevance of the 2 significant organic impurities in the technical material should be addressed with regard to the consumer exposure given the high dose rate of application of Metam-sodium.”

The notifier submitted an overview of the main impurities present in the technical material, which was presented in an addendum dated June 2008 (peer reviewed in July 2008). In the resubmission dossier, a further elaborated statement was provided.

DMTU (*N,N'*-dimethylthiourea) is an impurity that has a maximum content of 3.5 g/L in metam-sodium (0.29 % w/w in TK and 0.68 % w/w in TC) and 3.7 g/L in metam-potassium (0.29 % w/w in TK and 0.53% w/w in TC).

DMTU has also been observed as a metabolite in the MITC hydrolysis study and in the Metam water/sediment study. Also in the soil degradation study of metam, peaks of DMTU were observed in the chromatograms.

Despite formation of DMTU as a metabolite in the environment, no DMTU has been detected in the plant metabolism studies carried out with radiolabelled metam. This leads to the conclusion that DMTU is not likely to be translocated into plant material and therefore residues of DMTU are not to be expected.”

[As the rest of the notifier's statement contains confidential information, the reader is referred to the confidential part C (Vol.4) of the DAR, point C.1.2.2, where the relevance of impurities is discussed in detail taking into account the argumentation provided by the applicant Taminco.]

New data gap identified at PRAPeR 55 (July 2008):

“Due to the high rate of application, a large amount of the impurity DMTU can be released in the environment and can therefore be recovered in the crops at harvest. However, due to inadequate residues studies and lack of information on a toxicologically relevant impurity, N,N'-dimethylthiourea (DMTU), the consumer risk assessment could not be finalized.”

Based on toxicological information, RMS considers DMTU as being potentially a toxicologically relevant compound. DMTU is also a metabolite/degradation product formed in the environment after application of metam-sodium (or metam-potassium) aqueous solution (cf. observation of DMTU in MITC hydrolysis study [Vol.3 B.2.1.14] and in metam water/sediment study [Vol.3 B.8.4.4]). DMTU may be formed by reaction of MITC with methylamine (CH_3NH_2).

Furthermore, the results of the additional supervised residue trials performed on pepper, tomato, carrot, eggplants and cucumber showed a no-residue situation both for MITC and DMTU (respective residue levels below the LOQ of 0.01 mg/kg) (point B.7.6).

During PRAPeR 55, a concern was also raised whether as if the metabolism studies on radish, Chinese cabbage and tomato had been performed in compliance with the critical dose rate of application, maybe some metabolites could have been identified.

Therefore it was concluded that as long as the Environmental Fate and Behaviour section confirms that there are no other significant metabolites in soil, the metabolism of Metam in the different plants groups can be considered as sufficiently investigated. In view of the data gaps in this section, it was not possible to conclude on this point and mainly on the fate of DMTU in soil.

Should the E-fate studies confirm that there are no other significant metabolites in soil than MITC then further plant metabolism studies are not required (cf. Vol.3, B.8.1).

Therefore, the meeting of experts proposed to maintain the residue definition both for monitoring and risk assessment as provisional.

However, based on the discussions regarding the toxicological relevance of the different impurities of the technical active substance (mainly DMTU) and also the outcome of the additional supervised residue trials showing no uptake either of MITC or DMTU (below the LOQ of 0.01 mg/kg) in edible parts of the crops (lettuce, pepper, tomato, carrots, cucumber and eggplants) according to the representative uses, RMS considers that DMTU is not a relevant residue occurring after Metam application and that a robust residue definition both for monitoring and risk assessment can be proposed as follows:

The residue definition for MRL enforcement purposes is proposed as MITC alone, as Metam-sodium is completely degraded in soil in its metabolite MITC, which shows biological activity.

The same residue definition applies for consumer exposure risk assessment, as the effects of DMTU are covered by the available toxicological data package.

The following analytical method for the determination of the residues of Methyl Isothiocyanate in crops was provided: “Determination of Methyl Isothiocyanate (MITC) in crops (Meyers, 1988 – Report No. WRC 88-43)”

This method does not meet the requirements of the EU document SANCO/825/00 rev.7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement methodology has to be submitted (see chapter B.5.2.1).

In the framework of the resubmission according to Commission Regulation (EC) No. 33/2008, completely validated analytical methods for the determination of the residues of MITC and DMTU in crops were provided (see point B.7.6).

7.3.2 Definition of the residues in animal products

No metabolism and feeding studies in livestock were required and therefore no residue definition was proposed for animal matrices.

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B.7.4 Use pattern

Table B.7.4-1: Intended uses of Metam-sodium in the EU – Soil treatment

Added in August 2010

Crop and/ or situation (a)	Member state or country	Pr od uct na me	F G or I (b)	Pests or Group of pests controlle d (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max	n.a.	
Carrot	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		F	Soil fumigant	SL	510 g/L	Soil injection + incorporatio n at 25 cm by rotavation	April- June	1	n.a.	n.a.	No dilution	408	n.a.	
Carrot	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		F	Soil fumigant	SL	510 g/L	Soil injection + incorporatio n at 25 cm by rotavation	Oct-Dec	1	n.a.	n.a.	No dilution	408	n.a.	

Crop and/or situation (a)	Member state or country	P r o d u c t n a m e	F o r I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Corn salad (=lamb's lettuce)	FR, ES, BE, DE, IT		F	Soil fumigant	SL	510 g/L	Soil injection + incorporation at 15 cm by rotavation	April-Aug	1	n.a.	n.a.	No dilution	306	n.a.	
Cucumber	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		G	Soil fumigant	SL	510 g/L	Drip-irrigation under a plastic film on the planting row	June-Aug	1	n.a.	n.a.	No dilution 45000-180000 ⁽¹⁾	459	n.a.	
Eggplant / aubergine	CY, ES, FR, EL, IT, MT, NL, PT		G	Soil fumigant	SL	510 g/L	Drip-irrigation under a plastic film on the planting row	June-Aug	1	n.a.	n.a.	No dilution 60000-240000 ⁽¹⁾	612	n.a.	

Crop and/ or situation (a)	Member state or country	Pr od uct na me	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Pepper	BE, CY, ES, FR, EL, HU, IT, MT, NL, PL, PT, UK		G	Soil fumigant	SL	510 g/L	Drip- irrigation under a plastic film on the planting row	June- Aug	1	n.a.	n.a.	No dilution 60000- 240000 ⁽¹⁾	612	n.a.	
Potato	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		F	Soil fumigant	SL	510 g/L	Soil injection + incorporatio n at 25 cm by rotavation	Sept- Nov	1	n.a.	No dilution		153	n.a.	

Crop and/ or situation (a)	Member state or country	Pr od uct na me	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Strawberry	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		F	Soil fumigant	SL	510 g/L	Drip irrigation under a plastic film on the planting row	Jul-Oct	1	n.a.	n.a.	No dilution 60000- 240000 ⁽¹⁾	612	n.a.	
Tomato	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		G	Soil fumigant	SL	510 g/L	Drip irrigation under a plastic film on the planting row	Feb- Aug	1	n.a.	n.a.	No dilution 60000- 240000 ⁽¹⁾	612	n.a.	

(a)	Member state or country	Product name	F or G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Tomato	DE, BE, CY, ES, FR, MT, EL, PL, HU, IE, IT, NL, PT, UK		F	Soil fumigant	SL	510 g/L	Soil injection at 5 cm + coverage by 10 cm of soil	March	1	n.a.	n.a.	No dilution	612	n.a.	
Grape	FR, IT, DE, ES, EL, HU, PT		F	Soil fumigant	SL	510 g/L	Soil injection at 40 cm at the site of the de-rooted vine (0,2 l/m ²) "Spot treatment"	Autumn Before replanting	1	n.a.	n.a.	No dilution	1020	n.a.	

Remark:

In this table, the term "no dilution" was used in the sense that Metam is not diluted *prior* to application, contrary to what is common practice for most plant protection products. Metam is not to be loaded and mixed in a tank, so there is no "spray solution". In the case of drip irrigation with Metam the dilution with water takes place during the actual application, not in a tank but in the tubes of the irrigation system with instantaneous application.

(1): Diluted with water directly in the drip irrigation lines at concentration 0.5 - 2.0 % v/v.

- Remarks:
- (a) For crops, the EU and Codex classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (i): g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

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- | | |
|--|---|
| <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> | <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p> |
|--|---|

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B.7.5 Identification of the critical GAPs

See Table B.7.4-1.

B.7.6 Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.1)

Analytical methods:

Two analytical methods were used to determine respectively the magnitude of the residues of Metam-sodium and its metabolite MITC in the residue trials.

-The first analytical method to determine the residues of MITC (Methyl Isothiocyanate) is entitled “Determination of Methyl Isothiocyanate (MITC) in crops (Meyers, 1988 – Report referenced WRC 88-43)” and is summarized as follows: crop samples were extracted with Ethyl Acetate in the presence of water and sodium chloride. The resulting Ethyl Acetate extract was analysed for Methyl Isothiocyanate using GC/NPD analysis. The Limit of Detection of the analytical method is 0.02 mg/kg and the Limit of Quantification is set at 0.028 mg/kg MITC.

The provided validation data are not in accordance with EU Doc. SANCO/825/00 rev.7: no confirmatory method is provided, ILV was performed for only one matrix (cabbage) with only 2 determinations at each fortification level and linearity was not fully addressed.

-The method for the determination of the residues of Metam-sodium was similar to the analytical method developed for Maneb and referenced as: “H.A. McLeod and K.A. McCully, Head Space Gas procedure for screening Food Samples for Dithiocarbamate Pesticide Residues, JAOAC, Vol 52, N°6, pp. 1226-1230 (1969)”.

This method is summarized as follows:

Metam-sodium present in the sample is converted to carbon disulfide (CS₂) during reaction with Hydrochloric acid/Stannous chloride reagent at 100 °C in a sealed reaction flask.

An aliquot of the headspace is injected into a gas chromatograph by co-chromatography with the Metam-sodium standards.

Carbon disulfide formed by decomposition of Metam-sodium is quantified by using GC/NPD.

According to the report, this method failed for 3 crop categories: Brassica leafy vegetables, bulb vegetables and some tuber vegetables due to large interferences with natural sulphur containing compounds.

The Limit of Detection of the analytical method is 0.05 mg/kg.

The Limit of Quantification of the analytical method was not reported.

This method is not specific. Other dithiocarbamates like maneb, zineb, etc. are also detected by this method, which is based on decomposition into CS₂. Due to decomposition procedure, varying backgrounds of CS₂ occurred in specific crops (e.g., cabbage, broccoli, onions, garlic), thus raising the lower detection limit.

This method is not acceptable. Anyway, this is not critical for monitoring purposes, as Metam-sodium is not included in the residue definition in plants.

Characterization of the residue trials:

Residue trials were performed in North America under outdoor conditions for the following crops: snap beans, cucumbers, potatoes, mustard greens, peppermint, basil, tobacco, cantaloupe, radishes, leaf lettuce, green onions, head lettuce, spinach, turnip, broccoli, sweet corn, bulb onion, strawberry, tomato fruit, cabbage and garlic and in Germany for the Baby-leaf lettuce crop.

3 methods of application of Metam-sodium were used:

-Sprinkling cans method:

The active substance is placed in a sprinkling can and filled with water and sprinkled uniformly over the soil.

-Soil injection using shanks:

The active substance is injected into the soil via injection shanks.

-Sprinkler injection:

Use only with sprinkler systems that give large water droplets.

The plots were immediately tamped for ca 96 hours followed by a period of aeration of the soil.

Depending on the nature of the soil, a waiting period prior to planting of 21 days (sand, sandy loams) or 30 days (loams or clay loams) was required.

Metam-sodium was applied once pre-plant to the soil at a dose rate of application ranging between 153 and 413.6 kg a.s./ha. The crops were harvested at maturity. The supervised residue trials were conducted under GLP standards and Standard Operating Procedure was followed.

Since the analytical method for the determination of the residues of MITC showed numerous gaps in the validation data package, the Limit of Quantification of the a completely validated analytical method that should be provided to generate the future residue trials will be used as MRL proposal to reflect the no residue situation in the following supported crops.

Added in August 2010 (Peer reviewed in PRAPeR 51 - June 2008)

Taminco NV has obtained co-ownership with Kanesho Soil Treatment sprl/bvba of their analytical methods for MITC in crops. A summary of the validation data was pasted from the assessment of the residue analytical methods under point B.5.2.1 and is presented here below.

References:

- Validation of the analytical method 234/2: Determination of methyl iso-thiocyanate (MITC, Reg. No. 250285) in various plant matrices and soil (Benz and Mackenroth, 2003 – Report No. 2002/1004118)
- Independent laboratory validation of analytical methodology for the determination of methyl iso-thiocyanate in lettuce and lemons (Wormald, 2005 – Report No. KST 2005/001)

GLP:

GLP-compliance stated

Principle of the method: BASF method 234/2

Methyl isothiocyanate (MITC) is distilled from aqueous solution into a cooled reservoir containing a known amount of ethyl acetate. The aqueous distillate collected is saturated with sodium chloride and the analyte extracted into the ethyl acetate layer. The final determination of MITC is performed by GC-MS (DB-17, 30m, 0.32mm i.d., 0.25µm film; monitoring m/z: 73, 72, 70).

Findings:

Specificity – interferences :

- GC-MS is a highly specific technique. However, due to MW of MITC, use of 3 fragment ions with m/z > 100 is not possible.
- In the ILV-study report, confirmation of residue (identity) is demonstrated by comparison of ion ratios (m/z 73/72 and 70/72) in calibration standards with those in samples.
- Blank values < 30% of LOQ (demonstrated by representative chromatograms)

Linearity : Primary validation: Linear range: 0.01 µg/mL (corresponds to residue conc. 0.0005 mg/kg) – 2.5 µg/mL; $r^2 > 0.99$ (n = 7-8);

ILV: Linear range: 0.01 µg/mL – 2.5 µg/mL; $r^2 > 0.99$ (n ≥ 8); Representative calibration graphs provided

Recovery – precision : see table here below on the recovery rates.

Validation by an independent laboratory (ILV) : Same methodology as the primary validation (only minor modifications); Acceptable recoveries and precision: see second table here below.

Limit of quantification (LOQ) : 0.01 mg/kg (MITC)

Recovery rates and limits of quantification for MITC in various plant matrices (Benz and Mackenroth, 2003)

Matrix	Compound	Detection method	Fortification level [mg/kg]	n	Recovery rates [%]	
					Range	Mean values $\pm$ RSD
Oilseed rape seed	MITC	GC-MSD	0.01*	5	66 – 84	72.5 $\pm$ 10.9
			0.1	5	69 – 75	72.2 $\pm$ 3.5
Strawberry fruit	MITC	GC-MSD	0.01*	5	72 – 81	78.4 $\pm$ 5.1
			0.1	5	87 – 97	92.2 $\pm$ 4.7
Tomato fruit	MITC	GC-MSD	0.01*	5	78 – 89	85.2 $\pm$ 5.1
			0.1	5	88 – 92	88.4 $\pm$ 2.5
Lettuce	MITC	GC-MSD	0.01*	5	79 – 84	81.4 $\pm$ 2.6
			0.1	5	74 – 91	84.4 $\pm$ 7.4
Lemon fruit	MITC	GC-MSD	0.01*	5	73 – 88	81.0 $\pm$ 7.9
			0.1	5	81 – 103	87.1 $\pm$ 10.5
Wheat grain	MITC	GC-MSD	0.01*	5	52 – 63	57.5 $\pm$ 8.8
			0.1	5	57 – 69	61.3 $\pm$ 7.3

* Limit of quantification

Independent laboratory validation data of BASF method 234/2 for the determination of MITC in lettuce and lemons (Wormald, 2005)

Matrix	Compound	Detection method	Fortification level [mg/kg]	n	Recovery rates [%]	
					Range	Mean values $\pm$ RSD
Lettuce	MITC	GC-MSD	0.01*	5	81 – 87	84.6 $\pm$ 3.0
			0.1	5	53 – 85	71.3 $\pm$ 16.2
Lemon fruit	MITC	GC-MSD	0.01*	5	73 – 80	76.8 $\pm$ 3.4
			0.1	5	67 – 74	70.5 $\pm$ 3.7

* Limit of quantification

Conclusion:

The **GC-MS method 234/2** is successfully validated (incl. ILV) for the determination of MITC in food commodities of plant origin with high water content and with high acid content. The LOQ of the method is 0.01 mg/kg.

Besides, it should be noted that the method appears not suitable for the determination of MITC in dry crops, e.g. wheat grain (poor recoveries). For food matrices with high fat content (e.g. oilseed rape seed), recoveries were also relatively low and moreover, no ILV was provided for this matrix.

Added in August 2010 (Not peer reviewed)

Additional validation experiments were performed using the '**BASF method no. 234/2**' for determination of MITC in pepper, carrot, corn salad, cucumber, eggplant and grape.

Reference is made to Appendix 1 in Vol. 3 (B5) [Analytical methods (residue) in support of pre-registration data requirements]. A summary of the relevant validation data was copied from Vol.3 (B.5) and is presented here below.

- Validation of analytical methodology for the determination of methyl isothiocyanate in carrot and corn salad (Wormald, 2009 – Study No. FSGD-052)

- Validation of analytical methodology for the determination of methyl isothiocyanate in cucumber, eggplant and grape (Wormald, 2010 – Study No. FSGD-082)

- Residue of Methyl Isothiocyanate (MITC) in lettuce, pepper, tomato at harvest in protected crop following one application of Tamisol 510 in pre-planting Italy, 2008 (Misericocchi, 2008 – Study No. 08083RMC – Analytical phase report)

GLP: GLP-compliance stated

Principle of the method: **BASF method 234/2**

Methyl isothiocyanate (MITC) is distilled from aqueous solution into a cooled reservoir containing a known amount of ethyl acetate. The aqueous distillate collected is saturated with sodium chloride and the analyte extracted into the ethyl acetate layer. The final determination of MITC is performed by GC-MS (DB-17, 30m, 0.32mm i.d., 0.25µm film; electron ionisation (EI), monitoring ions with m/z: 73 (for quantitation), 72 and 70).

Findings :

Specificity – interferences :

- No significant chromatographic interferences were observed for the quantifier ion m/z = 73, i.e. blank values were < 30% of LOQ (demonstrated by representative chromatograms).
- GC-MS is a highly specific technique. However, due to MW of MITC, use of 3 fragment ions with m/z > 100 is not possible.
- Confirmation of residue (identity) can be done by comparison of ion ratios (m/z 73/72 and 70/72) in samples with those in calibration standards. However, due to a significantly interfering peak observed for ion m/z = 70 in the control samples of corn salad, cucumber, eggplant and grape, confirmation of MITC residues in these matrices appears to be not possible using this technique.

Linearity : Linear range: 0.01 µg/mL (corresponds to residue conc. 0.0005 mg/kg) – 2.5 µg/mL; $r^2 = 0.9988$ (n=8); series of MITC solvent standards

Recovery – precision : see table here below on the recovery rates.

Limit of quantification (LOQ): 0.01 mg/kg (MITC)

Recovery rates and limits of quantification for MITC in various plant matrices (Wormald, 2009; Wormald, 2010)

Matrix	Compound	Type of method	Fortification level [mg/kg]	n	Recovery rates [%]	
					Range	Mean values ± RSD
Carrot	MITC	GC-MSD	0.01*	5	71.1 – 83.7	76.5 ± 6.3
			0.1	5	55.2 – 77.5	71.8 ± 13
Corn salad	MITC	GC-MSD	0.01*	5	65.3 – 83.6	73.5 ± 11.7
			0.1	5	74.1 – 78.9	76.7 ± 2.9
Cucumber	MITC	GC-MSD	0.01*	5	80.9 – 87.1	83.2 ± 3.7
			0.1	5	63.4 – 77.1	71.6 ± 7.4
Eggplant	MITC	GC-MSD	0.01*	5	84.8 – 88.1	86.1 ± 1.5
			0.1	5	75.0 – 83.0	80.5 ± 4.1
Grape	MITC	GC-MSD	0.01*	5	72.8 – 82.9	78.4 ± 5.4
			0.1	5	77.5 – 85.1	82.1 ± 3.8
Pepper	MITC	GC-MSD	0.01*	5	80.1 – 86.0	83.5 ± 2.6
			0.1	5	86.8 – 109.0	93.2 ± 9.8

* Limit of quantification

Conclusion:

The validation data meet the requirements of SANCO/3029/99 rev. 4 and show that the GC-MS method 234/2 is suitable for the quantitative determination of MITC residues in carrot, corn salad, cucumber, eggplant, grape and pepper with a LOQ of 0.01 mg/kg. It is noted that the method does not allow an unequivocal positive confirmation of MITC residues in corn salad, cucumber, eggplant and grape due to the presence of a significant

chromatographic interference in these matrices. However, the method is considered sufficiently validated for the use in residue trials.

Added in August 2010 (Not peer reviewed)

- Validation of analytical methodology for the determination of N,N'-dimethylthiourea in carrot, corn salad, tomato and soil (Wormald, 2009 – Study No. FSGD-051)

- Validation of analytical methodology for the determination of N,N'-dimethylthiourea in cucumber, eggplant, pepper, strawberry, potato and grape (Wormald, 2010 – Study No. FSGD-081)

GLP:

GLP-compliance stated

Principle of the method:

N,N'-dimethylthiourea (DMTU) is extracted from homogenised samples of the commodity (carrot, corn salad, tomato, cucumber, eggplant, pepper, strawberry, potato, grape and soil) using water (with 5% w/w Na₂CO₃ for carrot, cucumber, eggplant, pepper, strawberry, potato and grape). Following centrifugation, the extracts are filtered, collected and diluted with water. Analysis is performed by means of LC-MS/MS (Waters Atlantis dC18, 3µm, 50 x 2.1 mm; isocratic elution with 10 mM ammonium acetate / methanol (95/5); Atmospheric Pressure Chemical Ionisation (APCI); ion transition monitored: m/z 105 → 74). Quantification is based on matrix-matched calibration (for matrices carrot, corn salad, tomato, cucumber and strawberry) or on internal standard calibration with ETU d4 (ethylenethiourea; C₃H₂N₂SD₄) as internal standard (for matrices eggplant, pepper, potato and grape).

Findings:

Specificity – interferences:

- LC-MS/MS is a highly specific technique. Beside the transition monitored for quantification (m/z 105 → 74), an additional transition is suggested for confirmatory purposes (m/z 105 → 59), but data demonstrating the suitability of this second mass transition were not presented in the report.
- No significant chromatographic interferences were observed, i.e. blank values were > 30% of LOQ (demonstrated by representative chromatograms).

Linearity: Series of matrix-matched calibration standards showed a linear response within the concentration range 0.00015 µg/mL – 0.01 µg/mL (corresponding to residue conc. 0.003 – 0.2 mg/kg); r² ≥ 0.99 (n=3 to 5; duplicate determinations).

Where internal standard (IS) was used, peak area ratio (DMTU vs. IS) showed a linear correlation with the concentration within at least the range 0.00015 to 0.005 µg/mL; r² ≥ 0.9869 (n=4x2)

Recovery – precision: see table here below on the recovery rates.

Limit of quantification (LOQ): 0.01 mg/kg (DMTU)

Recovery rates and limits of quantification for DMTU in various plant matrices (Wormald, 2009; Wormald, 2010)

Matrix	Compound	Type of method	Fortification level [mg/kg]	n	Recovery rates [%]	
					Range	Mean values $\pm$ RSD
Carrot	DMTU	LC-MS/MS	0.01*	5	91.2 – 100.1	97.1 $\pm$ 4.0
			0.1	5	95.4 – 110.4	104.6 $\pm$ 6.3
Corn salad	DMTU	LC-MS/MS	0.01*	5	67.3 – 84.1	75.2 $\pm$ 8.1
			0.1	5	76.5 – 89.0	84.5 $\pm$ 6.0
Tomato	DMTU	LC-MS/MS	0.01*	5	98.8 – 103.6	101.7 $\pm$ 2.0
			0.1	5	104.0 – 107.0	105.0 $\pm$ 1.1
Cucumber	DMTU	LC-MS/MS	0.01*	5	82.8 – 89.8	86.6 $\pm$ 3.3
			0.1	5	82.6 – 92.8	88.1 $\pm$ 5.1
Eggplant	DMTU	LC-MS/MS	0.01*	5	64.4 – 95.0	78.4 $\pm$ 17.9
			0.1	5	64.7 – 80.0	70.8 $\pm$ 8.1
Pepper	DMTU	LC-MS/MS	0.01*	5	70.6 – 102.4	81.5 $\pm$ 16.1
			0.1	5	81.4 – 95.4	88.6 $\pm$ 6.2
Strawberry	DMTU	LC-MS/MS	0.01*	5	81.0 – 97.8	91.6 $\pm$ 7.3
			0.1	5	85.2 – 110.0	93.4 $\pm$ 10.9
Potato	DMTU	LC-MS/MS	0.01*	5	73.4 – 81.6	77.1 $\pm$ 4.0
			0.1	5	87.5 – 100.8	92.5 $\pm$ 5.7
Grape	DMTU	LC-MS/MS	0.01*	5	70.8 – 78.2	72.7 $\pm$ 4.3
			0.1	5	86.9 – 96.6	92.9 $\pm$ 4.3

* Limit of quantification

Conclusion:

The validation data meet the requirements of SANCO/3029/99 rev. 4 and show that the LC-MS/MS method is suitable for the quantitative determination of DMTU residues in carrot, corn salad, tomato, cucumber, eggplant, pepper, strawberry, potato and grape with a LOQ of 0.01 mg/kg. The method is considered sufficiently validated for the use in residue trials.

The residue data are summarized according to the standard summary sheets and are presented in Appendix C. The figures selected for MRLs proposals are underlined in the summary sheets.

B.7.6.1 Residues resulting from supervised trials

Table B.7.6.1-1: Characterization of the supervised residue trials and MRLs estimated from the selected trials according to the representative uses of Metam-sodium.

Crop	Zone/Field or glasshouse conditions	Trials results relevant to the representative uses	MRL estimated from trials according to the representative uses.
Snap beans (Legume vegetables-fresh)	USA/Field	3 trials available: 1 application at 356.45 kg a.s./ha. Residue values: -Metam-sodium: 3 x <0.05 mg/kg for seeds -MITC: 3 x <0.02 mg/kg for seeds	Conclusion: No representative use. No MRL proposal.
Cucumbers (Fruiting vegetables-	USA/Field	2 trials are acceptable. Residue values: -Metam-sodium: 2 x <0.05	No further trial is required. Conclusion: MRL: LOQ of the completely

Crop	Zone/Field or glasshouse conditions	Trials results relevant to the representative uses	MRL estimated from trials according to the representative uses.
Cucurbits, edible peel)		mg/kg -MITC: 2 x <0.02 mg/kg	validated analytical method ⁽²⁾ .
Potatoes (Root and tuber vegetables)	USA/Field	4 trials are acceptable. Residue values: - Metam-sodium: 4 x <0.05 mg/kg in tuber -MITC: 4 x <0.02 mg/kg in tuber.	<u>Conclusion:</u> MRL: LOQ of the completely validated analytical method ⁽²⁾ .
Mustard greens (Leafy brassica)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 3.54-1.24 ⁽¹⁾ mg/kg in greens -MITC: <0.02 mg/kg in greens.	<u>Conclusion:</u> No representative use. No MRL proposal.
Peppermint (Herbs)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: <0.05 mg/kg in hays -MITC: <0.02 mg/kg in hays.	<u>Conclusion:</u> No representative use. No MRL proposal.
Basil (Herbs)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: <0.05 mg/kg -MITC: <0.02 mg/kg	<u>Conclusion:</u> No representative use. No MRL proposal.
Tobacco	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: <0.05 mg/kg -MITC: <0.02 mg/kg	<u>Conclusion:</u> No representative use. No MRL proposal.
Cantaloupe (fruiting vegetables- Cucurbits, inedible peel)	USA/Field	2 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 2 x <0.05 mg/kg -MITC: 2 x <0.02 mg/kg	<u>Conclusion:</u> No representative use. No MRL proposal.
Radishes (Root and tuber vegetables)	USA/Field	2 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 0.64-0.80; 1.20-0.76 ⁽¹⁾ mg/kg in roots -MITC: 2 x <0.02 mg/kg in roots.	<u>Conclusion:</u> No representative use. No MRL proposal.

Crop	Zone/Field or glasshouse conditions	Trials results relevant to the representative uses	MRL estimated from trials according to the representative uses.
Leaf lettuce (Leafy vegetables)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: <0.05 mg/kg in leaves. -MITC: <0.02 mg/kg in leaves.	<u>Conclusion:</u> No representative use. No MRL proposal.
Head lettuce (Leafy vegetables)	USA/Field	3 trials available: 1 application at 356.4 kg a.s./ha. Residue values: -Metam-sodium: 3 x <0.05 mg/kg in leaves. -MITC: 3 x <0.02 mg/kg in leaves.	<u>Conclusion:</u> No representative use. No MRL proposal.
Baby-leaf lettuce/corn salad (Leafy vegetables)	Germany/Field	3 trials available: 1 application at 153 kg a.s./ha. Residue values: -MITC: 3 x <0.02 mg/kg in leaves.	<u>Conclusion:</u> MRL: LOQ of the completely validated analytical method ⁽²⁾ .
Green onions (Bulb vegetables)	USA/Field	3 trials available: 1 application at 352.2 kg a.s./ha. Residue values: - Metam-sodium: 0.38-0.401;0.319-0.391;0.603-1.18 ⁽¹⁾ mg/kg whole plant -MITC: 3 x<0.02 mg/kg whole plant.	<u>Conclusion:</u> No representative use. No MRL proposal.
Bulb onions (Bulb vegetables)	USA/Field	3 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 0.565-0.84;0.351-0.49;0.219-0.304 ⁽¹⁾ mg/kg in bulb -MITC: 3 x<0.02 mg/kg in bulb	<u>Conclusion:</u> No representative use. No MRL proposal.
Garlic (Bulb vegetables)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: <0.05 mg/kg in bulb. -MITC: <0.02 mg/kg in bulb.	<u>Conclusion:</u> No representative use. No MRL proposal.
Spinach (Leafy vegetables)	USA/Field	2 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 2x<0.05 mg/kg in greens. -MITC: 2 x<0.02 mg/kg in greens.	<u>Conclusion:</u> No representative use. No MRL proposal.
Turnip (Root and tuber)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha.	<u>Conclusion:</u> No representative use.

Crop	Zone/Field or glasshouse conditions	Trials results relevant to the representative uses	MRL estimated from trials according to the representative uses.
vegetables)		Residue values: - Metam-sodium: 0.295-0.380 ⁽¹⁾ mg/kg in roots. -MITC: <0.02 mg/kg in roots.	No MRL proposal.
Broccoli (Flowering brassica)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 0.191-0.279 ⁽¹⁾ mg/kg in heads -MITC: <0.02 mg/kg in heads	<u>Conclusion:</u> No representative use. No MRL proposal.
Sweet corn (Fruiting vegetables)	USA/Field	4 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 4x<0.05 mg/kg in corn ears. -MITC: 4x<0.02 mg/kg in corn ears.	<u>Conclusion:</u> No representative use. No MRL proposal.
Strawberry (Berries and small fruit)	USA/Field	3 trials available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 3 x <0.05 mg/kg in berries -MITC: 3 x <0.02 mg/kg in berries.	<u>Conclusion:</u> MRL: LOQ of the completely validated analytical method ⁽²⁾ .
Tomato (Fruiting vegetables)	USA/Field	3 trials available: 1 application at 356.4 kg a.s./ha. Residue values: -Metam-sodium: 3 x <0.05 mg/kg in fruit -MITC: 3 x <0.02 mg/kg in fruit.	<u>Conclusion:</u> MRL: LOQ of the completely validated analytical method ⁽²⁾ .
Cabbage (Head brassica)	USA/Field	1 trial available: 1 application at 356.4 kg a.s./ha. Residue values: - Metam-sodium: 0.194-0.338 ⁽¹⁾ mg/kg -MITC: <0.02 mg/kg	<u>Conclusion:</u> No representative use. No MRL proposal.
Carrots (Root and tuber vegetables)	No residue data provided. MRL: LOQ of the completely validated analytical method ⁽²⁾ .		
Eggplant (Fruiting vegetables)	No residue data provided. MRL: LOQ of the completely validated analytical method ⁽²⁾ .		
Peppers (Fruiting vegetables)	No residue data provided. MRL: LOQ of the completely validated analytical method ⁽²⁾ .		

Crop	Zone/Field or glasshouse conditions	Trials results relevant to the representative uses	MRL estimated from trials according to the representative uses.
Grapes (Berries and small fruit)	No residue data provided. MRL: LOQ of the completely validated analytical method ⁽²⁾ .		
Remarks: ⁽¹⁾ : Method failure- It is highly likely that the analytical method used in the residue trials to determine the level of sulfur of Metam-sodium as CS ₂ actually also includes the sulfur of a multitude of sulfur-containing compounds contained in broccoli, cabbage, mustard greens, onions, radishes and turnips. ⁽²⁾ : The analytical method does not meet the requirements of EU Doc. SANCO/825/00 rev. 7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement analytical method has to be submitted (see chapter B.5.2.1).			

Conclusion:

The available plant metabolism studies in radishes, Chinese cabbage, tomatoes and turnip clearly indicated that neither Metam-sodium nor its metabolite MITC were recovered in the edible parts of these crops when the active substance is applied once to the soil at pre-emergence according to the representative use.

Moreover, the residue trials performed on numerous crops and presented in Table B.7.6.1-1 showed that the residue levels of MITC were always below the Limit of Quantification of the available analytical method (0.028 mg/kg).

This situation of no residue can be extrapolated to the supported crops for which no residue trial or an incomplete database was provided.

This assumption can be re-enforced by the following argumentation:

The metabolite MITC is phytotoxic and damage to plants is noticeable rapidly making the edible parts of the plants not suitable for use. In order to avoid the risk of phytotoxicity, soil fumigation occurs usually 3-4 weeks prior to planting.

Labels require a period of 3 week after Metam-sodium application to allow for dissipation of phytotoxic MITC before planting a crop.

Residues of Metam-sodium or MITC in the crops are therefore not expected.

Added in August 2010 (Not peer reviewed)

New data gap identified at PRAPeR 55:

Sufficient residue trials performed in compliance with the Good Agricultural Practices to support the no-residue situation of MITC should be provided. A sufficiently sensitive analytical method should be used and given that MITC is volatile, the samples should be analysed as soon as possible after harvest.

Additional supervised residue trials were conducted on lettuce, pepper, tomato, cucumber and aubergines (indoor/plastic tunnel conditions) and on carrots (outdoor conditions) and were characterized by 1 application at pre-planting at dose rates ranging between 373 kg a.s./ha and 630 kg a.s./ha with an interval of 14 and 21 days between application and crop planting.

Analytical methods:

-The analytical method had originally been validated for the determination of **MITC** in high water and high acid content matrices by BASF (DocID 2002/1004118) with a LOQ of 0.01 mg/kg.

Additional validation experiments were performed using the '**BASF method no. 234/2**' for determination of MITC in pepper, carrot, corn salad, cucumber, eggplant and grape [cf. Vol.3 (B.5) – appendix 1].

-The analytical method for the determination of **DMTU** was validated in carrot, corn salad, tomato and soil (Study No. FSGD-051) and in cucumber, eggplant, pepper, strawberry, potato and grape (Study No. FSGD-081) with a LOQ of 0.01 mg/kg [cf. Vol.3 (B.5) – appendix 1].

Findings:

Table B.7.6.1-1': Determination of the residues of MITC and DMTU in supervised residue trials carried out on lettuce, pepper, tomato, carrot, cucumber and aubergines using direct soil injection or drip irrigation pre-planting applications.

Report No. Northern/Southern EU	Commodity/Variety	Application rate per treatment			Portion analysed	Residues MITC (mg/kg)	Residues DMTU (mg/kg)	PHI (days)	Remarks:
		kg a.i./hL	formulation (L/ha)	kg a.i./ha					
Trial I132 SE Indoor/plastic tunnel	Lettuce (Impulsion)	0.049	1182.84	577	Lettuce heads	< 0.01	na	42	14 days between application and planting
Trial I132 SE Indoor/plastic tunnel	Pepper (Fenice 1)	0.049	1182.84	577	Pepper fruits	< 0.01	na	91	Frozen storage period from sampling until extraction/ analysis (MITC): max. 13 days.
Trial I132 SE Indoor/plastic tunnel	Tomato (Oskar)	0.049	1182.84	577	Tomato fruits	< 0.01	na	91	
Trial B104 NE Outdoor	Carrot (Laguna)	n.a.	825.36	414.33	Carrot roots	< 0.01	< 0.01	99	21 days between application and crop drilling
Trial GB105 NE Outdoor	Carrot (Autumn King 2)	n.a.	860.00	431.72	Carrot roots	< 0.01	< 0.01	148	
Trial I106 SE Outdoor	Carrot (Nelson)	n.a.	744.96	373.97	Carrot roots	< 0.01	< 0.01	117	Frozen storage period from sampling until extraction/ analysis (DMTU/ MITC): max. 33/34 days.
Trial I107 SE Outdoor	Carrot (Bolero)	n.a.	758.72	380.88	Carrot roots	< 0.01	< 0.01	142	
Trial B112 NE Indoor/plastic tunnel	Tomato (Broderna)	n.a.	1255.68	630.35	Tomato fruits	< 0.01	< 0.01	65	21 days between application and crop drilling
Trial I113 SE Indoor/plastic tunnel	Tomato (Naxos)	n.a.	1200.00	602.40	Tomato fruits	< 0.01	< 0.01	96	Frozen storage period from sampling until
Trial I114 SE Indoor/plastic tunnel	Tomato (Salomone)	n.a.	1200.00	602.40	Tomato fruits	< 0.01	< 0.01	115	

Trial I115 SE Indoor/plastic tunnel	Tomato/ Namanaxos	n.a.	1200.00	602.40	Tomato fruits	< 0.01	< 0.01	107	extraction/ analysis (DMTU/ MITC): max. 30/25 days.
Trial I127 SE Indoor/plastic tunnel	Cucumber (Saring)	n.a.	900.00	451.80	Cucumber fruits	< 0.01	< 0.01	70	21 days between application and crop planting.
Trial S128 SE Indoor/plastic tunnel	Cucumber (Jedida)	n.a.	900.00	451.80	Cucumber fruits	< 0.01	< 0.01	58	Frozen storage period from sampling until extraction/ analysis (DMTU/ MITC): max. 47/42 days.
Trial I129 SE Indoor/plastic tunnel	Green pepper (Valdor)	n.a.	1200.00	602.40	Green pepper fruits	< 0.01	< 0.01	141	21 days between application and crop planting
Trial S130 SE Indoor/plastic tunnel	Green pepper/ (Toscana)	n.a.	1200.00	602.40	Green pepper fruits	< 0.01	< 0.01	67	Frozen storage period from sampling until extraction/ analysis (DMTU/ MITC): max. 58/34 days.
Trial I131 SE Indoor/plastic tunnel	Aubergine (Molfettese)	n.a.	1200.00	602.40	Aubergine fruits	< 0.01	< 0.01	107	21 days between application and crop

Trial S132 SE Indoor/plastic tunnel	Aubergine (Ecavi)	n.a.	1200.00	602.40	Aubergine fruits	< 0.01	< 0.01	100	Planting Frozen storage period from sampling until extraction/ analysis (DMTU/ MITC): max. 38/42 days.
Na: not analysed.									

Conclusion:

The residue database can be considered as complete for carrot, tomato, pepper, cucumber and aubergines.

A no-residue situation both for MITC and DMTU is confirmed for these crops.

No residue trials were provided for strawberry, potato and grapes and only one trial was provided on lettuce with the determination of the residues of MITC only (<0.01 mg/kg).

Provisional MRL proposal: 0.01* mg/kg for all crops pending the submission of further residue trials on strawberries, potato, lettuce and grapes in order to confirm the no-residue situation both for MITC and DMTU in those crops according to the representative uses and to finalise the consumer risk assessment.

Although no residue trial was provided for these crops, a no-residue situation is expected according to the Good Agricultural Practice of Metam.

More specifically for grapes, although the intended use is at the higher dose of 1020 kg a.s./ha, only an occasional and local treatment would be necessary (isolated cases of few trees in a row of vines). The application rate on full field basis would therefore be considerably lower than 1020 kg a.s./ha and the time between disinfection and the harvest of new grapes is expected to be very long. RMS is of the opinion that residue trials on grapes are less relevant.

Therefore RMS suggests that this requirement should be dealt with at MS level post Annex I listing, if deemed necessary.

[illegible]

Mg/kg diet (dry weight basis):	0.036
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Table B.7.8-4: Intake calculations for pig (maximum daily intake of dry matter: 3 kg for 75 kg body weight).

Material	% of total DM/day	Intake of DM from material (kg/animal/day)	% dry matter in material	Intake of fresh material (kg/animal/day)	Residue in material (mg/kg)	Residue intake (mg/animal/day)	Intake by crop
V/Potatoes	60	1.8	15	12	0.028	0.336	0.336
Mg/animal/day:							0.336
Mg/kg bw/day:							0.00448
Mg/kg diet (dry weight basis):							0.112

(Added in August 2010)

No updated livestock dietary intake calculation was performed considering potato and grape pomace as feed items since no residue trial was provided on these crops. Nevertheless, the outcome of this calculation is not expected to be different and livestock feeding studies are not required.

B.7.9 Residues in succeeding or rotational crops (Annex IIA 6.6; Annex IIIA 8.5)**(Added in August 2010)**

Rotational crops studies are not required considering the DT50/DT90 values respectively for Metam-sodium and MITC.

Moreover, given the use pattern of Metam as a soil fumigant before planting, the primary crops metabolism data address the metabolism of Metam in rotational crops.

The rates of degradation of ^{14}C -Metam-sodium and ^{14}C -MITC in soils are given in the table here below.

Table B.7.9-1: Average rate of degradation of ^{14}C -Metam-sodium and ^{14}C -MITC in soils – Laboratory studies.

	Average DT50	Average DT90
^{14}C -Metam-sodium	10-9-17 min.	34 min.
^{14}C -MITC	1.0-2.9 days	7.14 days

It was also demonstrated that DMTU is not persistent, as the average DT50 value of DMTU in soils is 0.24 days.

B.7.10 Proposed pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants and plant products, treated areas or spaces (Annex IIA 7.8; Annex IIIA 8.7)**(Added in August 2010)**

-Pre-harvest interval for the representative uses:
Not relevant

-Re-entry period for livestock:
Not applicable. Metam-sodium is used on bare soil before planting or sowing and not on areas to be grazed.

-Re-entry period for man to crops:

Field

Worker re-entry exposure calculations based on measurements of MITC concentrations in air are below the AOEL proposed by the RMS.

Greenhouse

After soil treatment in glasshouses, workers should not entering the greenhouse shortly after soil injection application and a waiting period of 120-168 h with a respiratory protection is necessary to be below the AOEL.

See point B.6.15.7 in Vol 3 (B6): operator, worker, bystander exposure to MITC after application of Metam.

-Withholding period for animal feeding stuffs:
Not applicable based on the representative uses.

-Waiting period between application and crop sowing or planting the crop to be protected:
The waiting period between treatment and planting or sowing the new crop depends on the temperature, the moisture, the structure and texture of the soil. For soils with mean moisture content the following indicative waiting periods are proposed by the applicant:

Soil temperature at 10 cm depth	Waiting period between application and planting/sowing (days)
15 - 18 °C	13 - 15
12 - 15 °C	16 - 20
8 - 12 °C	21 - 35
6 - 8 °C	36 - 45

To determine if a new crop can be planted or sown without risk of phytotoxicity, a cress test is recommended.

-Waiting period between application and handling:
Not applicable. No residues in crops based on the additional supervised residue trials submitted in the frame of the resubmission.

-Waiting period between last application and sowing or planting succeeding crops:
The waiting period between treatment and planting or sowing the new crop depends on the temperature, the moisture, the structure and texture of the soil. For soils with mean moisture content the following indicative waiting periods are proposed by the applicant:

Soil temperature at 10 cm depth	Waiting period between application and planting/sowing (days)
15 - 18 °C	13 - 15
12 - 15 °C	16 - 20
8 - 12 °C	21 - 35
6 - 8 °C	36 - 45

To determine if a new crop can be planted or sown without risk of phytotoxicity, a cress test is recommended.
See also point B.7.9.

B.7.11 Estimates of the potential and actual exposure through diet and other means (Annex IIA 7.9; Annex IIIA 8.8)

B.7.11.1 Long term consumer risk assessment:

TMDI calculations were carried out using:

-The FAO/WHO cultural diet for the European adult (WHO/FSF/FOS/98.3, GEMS/Food Regional Diets, Revision September 2003 Consumption data)

-Chronic VELS Modell, BfR, Stand 10. April 2006, Version 1.6

-The long term consumer risk assessment using PSD's ten Consumer

-The MRL proposals for individual commodities established in section B.7.6

After long-term exposure (104 weeks) to metam sodium in drinking water, the lowest NOAEL was reported in the rat at 1.5 mg/kg bw/d. In mice, a quite similar result was reported (NOAEL = 1.9 mg/kg bw/d). However, a short-term drinking water study showed lower NOAELs in dogs, and in a 1-year dog study a NOAEL was proposed at 0.1 mg/kg bw/d. Therefore, RMS considers that this dog study is the most appropriate for setting of an ADI for metam sodium. Applying a safety factor of 100 gives an ADI_{Metam-sodium} = 0.001 mg/kg bw/d. For MITC, the lowest NOAEL = 0.04 mg/kg bw/d was reported in the 90-day dog drinking water study. Applying a safety factor of 100 gives an ADI_{MITC} = 0.0004 mg/kg bw/d.

Adult Consumer

Table B.7.11.1-1: TMDI calculation for MITC for an adult based on WHO European diet intake data

Commodity	MRL (mg/kg)	Consumption (kg/person/day)	Intake (mg/person/day)
Carrots	0.028 ^(†)	0.022	0.000616
Lettuce, leaf	0.028 ^(†)	0.0225	0.00063
Peppers	0.028 ^(†)	0.0104	0.00029
Tomato	0.028 ^(†)	0.0666	0.00186
Grapes	0.028 ^(†)	0.0138	0.00038
Strawberries	0.028 ^(†)	0.0053	0.000148
Eggplant	0.028 ^(†)	0.0023	0.000064
Cucumbers	0.028 ^(†)	0.009	0.000252
Potato	0.028 ^(†)	0.2048	0.00674
Total Theoretical intake			0.0109
mg/kg bw/day			0.000182
ADI (mg/kg bw/day)			0.0004
TMDI as % of ADI			45.7
^(†) : The analytical method does not meet the requirements of EU Doc. SANCO/825/00rev.7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement methodology has to be submitted (see chapter B.5.2.1).			

[†] Assumes 60 kg body weight.

German 3-5 years old children

Table B.7.11.1 2: TMDI calculations for MITC for German children based on the Chronic VELS Modell, BfR, Stand 10. April 2006, Version 1.6

Commodity	HR (mg/kg)	Average processing factor	Consumption (kg/person/day)	Intake (mg/person/day)
Table grapes, total	0.028 ^(†)	-	0.0205	0.00057
Strawberries, total	0.028 ^(†)	-	0.0079	0.000221
Carrots, total	0.028 ^(†)	-	0.0166	0.00046
Peppers, total	0.028 ^(†)	-	0.0047	0.00013
Eggplants	0.028 ^(†)	-	0.0001	0.0000028
Tomato, total	0.028 ^(†)	-	0.0156	0.000436
Cucumbers, total	0.028 ^(†)	-	0.0095	0.000266
Corn salad (Lamb's lettuce), raw	0.028 ^(†)	-	0.0001	0.0000028
Potatoes	0.028 ^(†)	-	0.0414	0.00115
Total theoretical intake			0.00324	
Mg/kg body weight/day			0.0002	
ADI (mg/kg bw/day)			0.0004	
TMDI as % of ADI			50.27	

^(†): The analytical method does not meet the requirements of EU Doc. SANCO/825/00rev.7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement methodology has to be submitted (see chapter B.5.2.1).

[†]-Assumes 16.15 kg body weight.

~~Adults, school children, infants, toddlers, vegetarians and elderly from United Kingdom~~

Table B.7.11.1-3: Commodities intakes and TMDI calculations for MITC for the different categories of UK consumers based on 97.5th percentile with the PSD's ten Consumer Model.

		TOTAL INTAKE based on 97.5th percentile									
		ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day		0,00039	0,00043	0,00043	0,00033	0,00030	0,00020	0,00025	0,00041	0,00030	0,00019
% of ADI		98%	107%	108%	83%	75%	51%	62%	102%	75%	37%

STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)	(mg/kg bw/day)									
Table grapes	0,028 ⁽⁺⁾	0,00004	0,00005	0,00013	0,00006	0,00007	0,00003	0,00002	0,00006	0,00004	0,00001
Wine grapes	0,028 ⁽⁺⁾	0,00028	0,00003	0,00002	0,00003	0,00001	0,00003	0,00010	0,00027	0,00019	0,00004
Strawberries	0,028 ⁽⁺⁾	0,00002	0,00005	0,00006	0,00004	0,00003	0,00002	0,00001	0,00003	0,00003	0,00001
Carrots	0,028 ⁽⁺⁾	0,00002	0,00010	0,00007	0,00005	0,00003	0,00002	0,00003	0,00002	0,00003	0,00002
Tomatoes	0,028 ⁽⁺⁾	0,00004	0,00005	0,00007	0,00005	0,00005	0,00003	0,00004	0,00005	0,00004	0,00004
Peppers	0,028 ⁽⁺⁾	0,00001	L/C	0,00002	0,00001	0,00002	0,00001	0,00001	0,00002	0,00002	0,00001
Aubergines	0,028 ⁽⁺⁾	0,00001	L/C	0,00004	0,00002	0,00001	0,00001	0,00001	0,00002	0,00001	L/C
Cucumbers	0,028 ⁽⁺⁾	0,00001	0,00001	0,00007	0,00004	0,00003	0,00001	0,00001	0,00002	0,00001	0,00001
Lettuce	0,028 ⁽⁺⁾	0,00002	0,00001	0,00002	0,00002	0,00002	0,00001	0,00001	0,00002	0,00001	0,00001
Potatoes	0,028 ⁽⁺⁾	0,00009	0,00031	0,00026	0,00023	0,00020	0,00015	0,00013	0,00010	0,00009	0,00009

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

⁽⁺⁾: The analytical method does not meet the requirements of EU Doc. SANCO/825/00rev.7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement methodology has to be submitted (see chapter B.5.2.1).

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.7.11.2 Short term consumer risk assessment:

The National Estimates of Short Term Intake were calculated using the PSD's ten consumer model. The HR values for individual commodities established in section B.7.6 (corresponding to the Limit of Quantification of the analytical method for the determination of the MITC residues in crops). Developmental toxicity was reported for metam sodium. In each of the reported studies, single cases of rare anomalies were reported at maternal toxic doses and detected in both rat and rabbit developmental studies. At maternal toxic doses, increased post implantation losses were reported. RMS proposes to set an ARfD for metam sodium at 0.05 mg/kg bw/d, based on the NOAEL for developmental toxicity in rats at 5 mg/kg bw/d. For MITC, an ARfD can be based on the developmental toxicity NOAEL = 10 mg/kg bw/day reported in the rat study where pups showed a reduced body weight at 30 mg/kg bw/day. **ARfD_{MITC} = 0.4 mg/kg bw/d**

Table B.7.11.2-1: Acute consumption (97.5th percentile)

	Adult			Infant			Toddler			4-6 year old child			7-10 year old child		
Commodities	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Potatoes	0,531	0,513	0,550	0,191	0,170	0,216	0,246	0,234	0,262	0,346	0,327	0,456	0,405	0,394	0,497
Wine grapes	1,803	1,630	2,165	0,068	0,013	0,163	0,068	0,036	0,095	0,130	0,043	0,137	0,057	0,016	0,230
Strawberries	0,200	0,187	0,236	0,039	0,039	0,041	0,071	0,054	0,087	0,142	0,095	0,192	0,149	0,110	0,250
Carrots	0,179	0,169	0,200	0,079	0,072	0,093	0,090	0,080	0,096	0,124	0,101	0,156	0,111	0,106	0,148
Tomatoes	0,283	0,265	0,339	0,060	0,059	0,075	0,091	0,085	0,102	0,127	0,111	0,175	0,174	0,157	0,195
Peppers	0,143	0,120	0,160	0,000	0,000	0,000	0,034	0,028	0,060	0,034	0,031	0,080	0,073	0,060	0,146
Aubergines	0,149	0,090	0,225	0,000	0,000	0,000	0,062	0,037	0,062	0,103	0,071	0,109	0,058	0,035	0,064
Cucumbers	0,108	0,095	0,120	0,013	0,008	0,014	0,086	0,063	0,109	0,096	0,067	0,210	0,109	0,085	0,154
Lettuce	0,150	0,107	0,139	0,022	0,004	0,024	0,035	0,025	0,040	0,073	0,040	0,095	0,083	0,069	0,279

	11-14 year old child			15-18 year old child			Vegetarians			Elderly - own home			Elderly - residential		
Commodities	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Potatoes	0,573	0,473	0,612	0,559	0,524	0,799	0,694	0,552	0,868	0,386	0,358	0,406	0,304	0,282	0,381
Wine grapes	0,339	0,176	0,813	1,209	0,818	2,008	1,426	1,232	1,901	0,927	0,760	2,972	0,206	0,106	0,417
Strawberries	0,143	0,116	0,277	0,148	0,129	0,250	0,226	0,189	0,275	0,186	0,150	0,215	0,072	0,065	0,103
Carrots	0,134	0,120	0,182	0,192	0,166	0,237	0,177	0,160	0,202	0,151	0,136	0,165	0,100	0,093	0,120
Tomatoes	0,168	0,156	0,188	0,251	0,235	0,362	0,397	0,284	0,460	0,200	0,187	0,245	0,218	0,160	0,240
Peppers	0,072	0,055	0,130	0,091	0,069	0,181	0,156	0,123	0,242	0,097	0,080	0,237	0,046	0,025	0,065
Aubergines	0,119	0,056	0,135	0,102	0,042	0,156	0,236	0,174	0,296	0,095	0,074	0,097	0,000	0,000	0,000
Cucumbers	0,093	0,063	0,220	0,117	0,085	0,524	0,115	0,093	0,193	0,092	0,075	0,120	0,035	0,028	0,071
Lettuce	0,080	0,066	0,100	0,102	0,077	0,135	0,147	0,125	0,275	0,100	0,084	0,114	0,049	0,036	0,080

Table B.7.11.2-2: Acute intakes (97.5th percentile)

			Adult		Infant		Toddler		4-6 year old child		7-10 year old child	
commodities	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Potatoes	0,03		0,00067	0,7	0,00431	4,3	0,00298	3,0	0,00224	2,2	0,00154	1,5
Wine grapes	0,03		0,00066	0,7	0,00022	0,2	0,00013	0,1	0,00018	0,2	0,00005	0,1
Strawberries	0,03		0,00007	0,1	0,00013	0,1	0,00014	0,1	0,00019	0,2	0,00014	0,1
Carrots	0,03		0,00024	0,2	0,00178	1,8	0,00110	1,1	0,00083	0,8	0,00054	0,5
Tomatoes	0,03		0,00029	0,3	0,00135	1,4	0,00116	1,2	0,00087	0,9	0,00062	0,6
Peppers	0,03		0,00037	0,4	0,00000	0,0	0,00046	0,5	0,00033	0,3	0,00046	0,5
Aubergines	0,03		0,00027	0,3	0,00000	0,0	0,00060	0,6	0,00070	0,7	0,00026	0,3
Cucumbers	0,03		0,00020	0,2	0,00021	0,2	0,00083	0,8	0,00066	0,7	0,00050	0,5

Lettuce	0,03	0,00028	0,3	0,00035	0,4	0,00034	0,3	0,00050	0,5	0,00038	0,4
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commodities	HR	P	11-14 year-old child		15-18 year-old child		Vegetarians		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Potatoes	0,03		0,00109	1,1	0,00081	0,8	0,00084	0,8	0,00067	0,7	0,00073	0,7
Wine grapes	0,03		0,00020	0,2	0,00053	0,5	0,00060	0,6	0,00037	0,4	0,00009	0,1
Strawberries	0,03		0,00008	0,1	0,00007	0,1	0,00009	0,1	0,00007	0,1	0,00003	0,0
Carrots	0,03		0,00036	0,4	0,00030	0,3	0,00028	0,3	0,00025	0,2	0,00026	0,3
Tomatoes	0,03		0,00040	0,4	0,00033	0,3	0,00038	0,4	0,00028	0,3	0,00033	0,3
Peppers	0,03		0,00029	0,3	0,00028	0,3	0,00046	0,5	0,00027	0,3	0,00015	0,1
Aubergines	0,03		0,00035	0,3	0,00022	0,2	0,00050	0,5	0,00019	0,2	0,00000	0,0
Cucumbers	0,03		0,00027	0,3	0,00026	0,3	0,00024	0,2	0,00018	0,2	0,00008	0,1
Lettuce	0,03		0,00023	0,2	0,00022	0,2	0,00031	0,3	0,00020	0,2	0,00011	0,1

Added in August 2010 (Not peer reviewed)

Metam			
Status of the active substance:		Code no.	
LOQ (mg/kg bw)(MITC)	0,01	proposed LOQ:	
Toxicological end points (MITC)			
ADI (mg/kg bw/day):	0,004	ARfD (mg/kg bw):	0,03
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2010	Year of evaluation:	2010

Note: The toxicological reference values are related to MITC (Proposed residue definition for monitoring and risk assessment in plants).

Chronic risk assessment									
			TMDI (range) in % of ADI minimum - maximum						
			1		2				
			No of diets exceeding ADI:						
	Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
	2,5	PT General population	1,3	Potatoes	0,7	Table and wine grapes	0,2	Tomatoes	2,5
	2,3	WHO Cluster diet B	0,8	Tomatoes	0,7	Potatoes	0,5	Table and wine grapes	2,3
	2,3	FR toddler	1,3	Potatoes	0,6	Carrots	0,2	Tomatoes	2,3
	2,1	NL child	1,5	Potatoes	0,2	Table and wine grapes	0,2	Tomatoes	2,1
	1,9	FR infant	1,0	Potatoes	0,7	Carrots	0,1	Strawberries	1,9
	1,8	DE child	0,6	Potatoes	0,3	Table and wine grapes	0,3	Carrots	1,8
	1,7	WHO cluster diet E	1,0	Potatoes	0,4	Table and wine grapes	0,1	Tomatoes	1,7
	1,7	SE general population 90th percentile	1,0	Potatoes	0,2	Carrots	0,2	Tomatoes	1,7
	1,6	DK child	0,6	Potatoes	0,4	Cucumbers	0,3	Carrots	1,6

1,6	WHO regional European diet	1,0	Potatoes	0,3	Tomatoes	0,1	Table and wine grapes	1,6
1,6	FR all population	1,0	Table and wine grapes	0,3	Potatoes	0,1	Tomatoes	1,6
1,6	WHO cluster diet D	1,0	Potatoes	0,3	Tomatoes	0,1	Table and wine grapes	1,6
1,4	WHO Cluster diet F	0,9	Potatoes	0,2	Table and wine grapes	0,2	Tomatoes	1,4
1,3	UK Toddler	0,9	Potatoes	0,1	Tomatoes	0,1	Carrots	1,3
1,3	UK Infant	0,8	Potatoes	0,3	Carrots	0,1	Tomatoes	1,3
1,3	PL general population	0,9	Potatoes	0,2	Tomatoes	0,1	Table and wine grapes	1,3
1,2	IE adult	0,6	Potatoes	0,3	Table and wine grapes	0,1	Tomatoes	1,2
1,1	NL general	0,7	Potatoes	0,2	Table and wine grapes	0,1	Tomatoes	1,1
1,1	LT adult	0,8	Potatoes	0,2	Tomatoes	0,1	Cucumbers	1,1
1,1	DK adult	0,4	Table and wine grapes	0,4	Potatoes	0,1	Carrots	1,1
0,9	UK vegetarian	0,3	Potatoes	0,2	Table and wine grapes	0,2	Tomatoes	0,9
0,8	UK Adult	0,3	Potatoes	0,3	Table and wine grapes	0,1	Tomatoes	0,8
0,8	ES child	0,5	Potatoes	0,2	Tomatoes	0,0	Carrots	0,8
0,7	IT kids/toddler	0,4	Tomatoes	0,2	Potatoes	0,0	Carrots	0,7
0,7	ES adult	0,2	Potatoes	0,2	Tomatoes	0,1	Table and wine grapes	0,7
0,6	FI adult	0,3	Potatoes	0,1	Tomatoes	0,1	Table and wine grapes	0,6
0,6	IT adult	0,3	Tomatoes	0,2	Potatoes	0,0	Carrots	0,6
Acute risk assessment /children				Acute risk assessment / adults / general population				

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level that would lead to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1 *) **)			IESTI 2 *) **)			IESTI 1 *) **)			IESTI 2 *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	5,1	Potatoes	0,01 / -	3,7	Potatoes	0,01 / -	1,1	Table grapes	0,01 / -	1,1	Table grapes	0,01 / -
	2,2	Table grapes	0,01 / -	2,2	Table grapes	0,01 / -	1,0	Potatoes	0,01 / -	0,8	Aubergines (egg plants)	0,01 / -
	2,1	Carrots	0,01 / -	1,9	Cucumbers	0,01 / -	0,8	Aubergines (egg plants)	0,01 / -	0,8	Wine grapes	0,01 / -
	2,1	Peppers	0,01 / -	1,5	Carrots	0,01 / -	0,8	Wine grapes	0,01 / -	0,8	Potatoes	0,01 / -
	1,9	Cucumbers	0,01 / -	1,5	Peppers	0,01 / -	0,7	Cucumbers	0,01 / -	0,7	Cucumbers	0,01 / -

Conclusion:

A slight exceedance of the ADI was observed for the UK infants, toddlers and vegetarians (102-108 % of the ADI).

RMS considers that there is no chronic concern for the most sensitive categories of consumers based on the situation of no MITC residues that characterize the supervised residue trials.

There is no acute intake concern for all the categories of the consumers.

There is no safety concern for the different categories of consumers according to EFSA PRIMo Model rev.2A.

Furthermore, the results of the modelling, undertaken to predict potential leaching of DMTU in the groundwater (based on the presence of DMTU at a high application rate of 7 kg/ha at the maximum application rate of 1020 kg a.s./ha according to the GAP table of intended uses) indicated that the predicted environmental concentrations of DMTU at 1 m soil depth would not exceed 0.1 µg/L for all crops and scenario simulations.

B.7.12 Community MRLs and MRLs in the EU Member States

There is currently no specific Community MRLs for MITC.

Table B.7.12-1: EU member state MRLs for MITC and CAC MRLs

	Commodity	MRL mg/kg	Residue Definition
EU Member States			
Spain	All crops	0.10	MITC
Belgium	Potatoes	0.20	MITC
	All other crops	0.05*	MITC
Germany	All crops	0.05	MITC
CAC MRLs			
None			

(Added in August 2010)

Reference is made to Commission Regulation (EC) No. 149/2008 amending Regulation (EC) No.396/2005 by establishing Annexes II, III and IV setting MRLs for products covered by Annex I thereto.

B.7.13 Proposed MRLs and justification for the acceptability of those residues (Annex IIA; Annex IIIA)

(Modified in August 2010)

Expression of the residue	Crops	MRLs (mg/kg)
MITC	Carrots	0.01*
	Corn salad (lamb's lettuce)	0.01* (provisional) ⁽¹⁾
	Cucumber (G)	0.01*
	Eggplant (G)	0.01*
	Pepper (G)	0.01*
	Potato	0.01* (provisional) ⁽¹⁾
	Strawberry	0.01* (provisional) ⁽¹⁾
	Tomato (F/G)	0.01*
	Grapes	0.01* (provisional) ⁽¹⁾
⁽¹⁾ : Provisional MRL pending submission of residue trials, if deemed necessary.		

B.7.14 Summary and evaluation of residue behaviour (revised in August 2010)

Metabolism in plants

The metabolism of Metam-sodium has been investigated in various crops (radish, Chinese cabbage, tomato and turnip).

These crops are representative of the following categories: root and tuber vegetables, leafy brassica and fruiting vegetables and can therefore be considered as sufficient to cover the supported uses on carrots, corn salad, cucumber, eggplant, pepper, potato, strawberry, tomato and grapes by soil injection or drip-irrigation of Metam-sodium in/on the planting row.

The available metabolism studies showed that most of the radioactivity had been metabolised extensively and to a large extent incorporated into natural compounds such as sugars, starch, proteins, pectins, lignin and cellulose.

During PRAPeR 55, a concern was also raised whether as if the metabolism studies on radish, Chinese cabbage and tomato had been performed in compliance with the critical dose rate of application, maybe some metabolites could have been identified.

Therefore it was concluded that as long as the Environmental Fate and Behaviour section confirms that there are no other significant metabolites in soil, the metabolism of Metam in the different plant groups can be considered as sufficiently investigated. In view of the data gaps in this section, it was not possible to conclude on this point and mainly on the fate of DMTU in soil.

As the E-fate studies from the resubmission dossier (cf. Vol.3, B.8.1) confirm that there are no other significant metabolites in soil than MITC, further plant metabolism studies are not deemed to be required.

Metabolism in livestock

Not required.

Definition of the residue

The residue definition for MRL enforcement purposes is proposed as MITC alone as Metam-sodium is completely degraded in its metabolite MITC in soil that shows biological activity.

The same residue definition applies for consumer exposure risk assessment.

The following analytical method for the determination of the residues of Methyl Isothiocyanate in crops was provided: "Determination of Methyl Isothiocyanate (MITC) in crops (Meyers, 1988 – Report No. WRC 88-43)"

This method does not meet the requirements of SANCO/825/00 rev.7 and can thus not be recommended for enforcement purposes. Therefore, a fully validated enforcement methodology has to be submitted (see also chapter B.5.2.1).

In the framework of the resubmission according to Commission Regulation (EC) No. 33/2008, completely validated analytical methods for the determination of the residues of MITC and DMTU in crops were provided (see point B.7.6).

Supervised residue trials

US field residue trials were provided for a wide range of crops including the supported uses on cucumber, potato, corn salad, strawberry and tomato.

No residue trials were provided on carrot, eggplant, pepper and grapes.

However, residues of Metam-sodium or MITC in those crops are not expected. Indeed, the metabolite MITC is phytotoxic and damage to plants is noticeable rapidly making the edible parts of the plants not suitable for use.

In order to avoid the risk of phytotoxicity, soil fumigation occurs usually 3-4 weeks prior to planting to allow total dissipation of MITC.

The residue database can be considered as complete for carrot, tomato, pepper, cucumber and aubergines.

A no-residue situation both for MITC and DMTU is confirmed for these crops.

No residue trials were provided for strawberry, potato and grapes and only one trial was provided on lettuce with the determination of the residues of MITC only (<0.01 mg/kg).

Provisional MRL proposal: 0.01* mg/kg for all crops pending the submission of further residue trials on strawberries, potato, lettuce and grapes in order to confirm the no residue situation both for MITC and DMTU in those crops according to the representative uses and to finalise the consumer risk assessment.

Although no residue trial was provided for these crops, a no-residue situation is expected according to the Good Agricultural Practice of Metam.

More specifically for grapes, although the intended use is at the higher dose of 1020 kg a.s./ha, only an occasional and local treatment would be necessary (isolated cases of few trees in a row of vines). The application rate on full field basis would therefore be considerably lower than 1020 kg a.s./ha and the time between disinfection and the harvest of new grapes is expected to be very long. RMS is of the opinion that residue trials on grapes are less relevant.

Therefore RMS suggests that this requirement should be dealt with at MS level post Annex I listing, if deemed necessary.

Storage stability of residue samples

Storage stability data are not required.

Industrial or household processing studies

Not required.

Livestock feeding studies

Not required.

Residues in rotational crops

Not required.

Consumer safety

Although a slight exceedance of the ADI was observed for the UK infants, toddlers and vegetarians, there is no chronic concern for the most sensitive categories of consumers.

The short term consumer risk assessment was not required.

There is no safety concern for the different categories of consumers according to EFSA PRIMo Model rev.2A. Furthermore, the results of the modelling, undertaken to predict potential leaching of DMTU in the groundwater (based on the presence of DMTU at a high application rate of 7 kg/ha at the maximum application rate of 1020 kg a.s./ha according to the GAP table of intended uses) indicated that the predicted environmental concentrations of DMTU at 9m soil depth would not exceed 0.1 µg/L for all crops and scenario simulations.

B.7.15 References relied on (Updated in August 2010)**B.7.15.1 Residue data for the active substance (Annex IIA 6)**

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 6.1 /01	Bieber WD, Krohn R	1989-01a	Investigations on the residues of metam-sodium in radishes grown on pretreated soil NATEC Institute, 89/0036 GLP Not published	Y	USA TF
IIA 6.1 /02	Bieber WD, Krohn R	1989-01b	Investigations on the residues of metam-sodium in chinese cabbage grown on pretreated soil NATEC Institute, 89/0037 GLP Not published	Y	USA TF
IIA 6.1 /03	Bieber WD, Krohn R	1989-01c	Investigations on the residues of metam-sodium in tomatoes grown on pretreated soil NATEC Institute, 89/0038 GLP Not published	Y	USA TF
IIA 6.1 /04	Davis ML, Campbell LA	1995-03-10	Nature of the residue of 14C-Metam-Sodium in turnip Battelle, SC920140 GLP Not published	Y	USA TF
IIA 6.3 /01	Jones PA	1988-11-28a	The magnitude of Metam-Sodium residues on Snap Beans Morse laboratories, Inc., PAL-ME-ICI-01 GLP Not published	Y	USA TF
IIA 6.3 /02	Jones PA	1988-12-05b	The magnitude of Metam-Sodium residues on Cucumbers Morse laboratories, Inc., PAL-ME-ICI-02 GLP Not published	Y	USA TF
IIA 6.3 /03	Jones PA	1988-11-18c	The magnitude of Metam-Sodium residues on Potatoes Morse laboratories, Inc., PAL-ME-ICI-03 GLP Not published	Y	USA TF
IIA 6.3 /04	Jones PA	1988-12-06d	The magnitude of Metam-Sodium residues on Mustard Greens Morse laboratories, Inc., PAL-ME-ICI-04 GLP Not published	Y	USA TF
IIA 6.3 /05	Jones PA	1988-12-07e	The magnitude of Metam-Sodium residues on Peppermint Morse laboratories, Inc., PAL-ME-ICI-05 GLP Not published	Y	USA TF

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 6.3 /06	Zick MA	1988-12-14a	The magnitude of Metam-Sodium residues on Basil Morse laboratories, Inc., PAL-ME-ICI-06 GLP Not published	Y	USA TF
IIA 6.3 /07	Zick MA	1988-12-13b	The magnitude of Metam-Sodium residues on Tobacco Morse laboratories, Inc., PAL-ME-ICI-07 GLP Not published	Y	USA TF
IIA 6.3 /08	Zick MA	1988-12-13c	The magnitude of Metam-Sodium residues on Cantaloupes Morse laboratories, Inc., PAL-ME-ICI-08 GLP Not published	Y	USA TF
IIA 6.3 /09	Jones PA	1988-12-13f	The magnitude of Metam-Sodium residues on Radish Morse laboratories, Inc., PAL-ME-ICI-09 GLP Not published	Y	USA TF
IIA 6.3 /10	Jones PA	1989-04-03a	The magnitude of Metam-Sodium residues on Leaf Lettuce Morse laboratories, Inc., PAL-ME-ICI-10 GLP Not published	Y	USA TF
IIA 6.3 /11	Cañez VM	1989-06-28a	The magnitude of Metam-Sodium residues on Green Onion Morse laboratories, Inc., PAL-ME-ICI-11 GLP Not published	Y	USA TF
IIA 6.3 /12	Cañez VM	1989-05-03b	The magnitude of Metam-Sodium residues on Head Lettuce Morse laboratories, Inc., PAL-ME-ICI-12 GLP Not published	Y	USA TF
IIA 6.3 /13	Jones PA	1989-04-03b	The magnitude of Metam-Sodium residues on Spinach Morse laboratories, Inc., PAL-ME-ICI-13 GLP Not published	Y	USA TF
IIA 6.3 /14	Jones PA	1989-04-03c	The magnitude of Metam-Sodium residues on Turnip Morse laboratories, Inc., PAL-ME-ICI-14 GLP Not published	Y	USA TF
IIA 6.3 /15	Cañez VM	1989-05-03c	The magnitude of Metam-Sodium residues on Broccoli Morse laboratories, Inc., PAL-ME-ICI-15 GLP Not published	Y	USA TF

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 6.3 /16	Cañez VM	1989-06-27d	The magnitude of Metam-Sodium residues on Sweet Corn Morse laboratories, Inc., PAL-ME-ICI-16 GLP Not published	Y	USA TF
IIA 6.3 /17	Cañez VM	1989-06-28e	The magnitude of Metam-Sodium residues on Bulb Onion Morse laboratories, Inc., PAL-ME-ICI-17 GLP Not published	Y	USA TF
IIA 6.3 /18	Cañez VM	1989-05-03f	The magnitude of Metam-Sodium residues on Strawberry Morse laboratories, Inc., PAL-ME-ICI-18 GLP Not published	Y	USA TF
IIA 6.3 /19	Cañez VM	1989-05-09g	The magnitude of Metam-Sodium residues on Tomato Fruit Morse laboratories, Inc., PAL-ME-ICI-19 GLP Not published	Y	USA TF
IIA 6.3 /20	Cañez VM	1989-07-28h	The magnitude of Metam-Sodium residues on Cabbage Morse laboratories, Inc., PAL-ME-ICI-20 GLP Not published	Y	USA TF
IIA 6.3 /21	Cañez VM	1989-08-18i	The Magnitude of Metam Sodium Residues on Garlic Morse laboratories, Inc., PAL-ME-ICI-21 GLP Not published	Y	USA TF
IIA 6.3/22	Miserocchi G.	2008-10-14	Residue of methyl isothiocyanate (MITC) in lettuce, pepper and tomato at harvest in protected crop following one application of Tamisol 510 in pre-planting, Italy, 2008 S.P.F. GAB Italia s.r.l., Ferrara, Italy Report No. 08083RMC - I132 GLP: yes Not published	Y	Taminco
IIA 6.3/23	Miserocchi G.	2010-01-29	Residue of Methyl isothiocyanate (MITC) and 1,3-dimethylthiourea (DMTU) in carrot at harvest in open field conditions following one pre-drilling application of Tamisol 510/Solasan/Metam 510, , Italy, Belgium, United Kingdom, 2009 SPF S.r.l, Italy Study number 09048RCR, Trials number B104, GB105,I106,I107 GLP: yes Not published	Y	Taminco

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 6.3/24	Miserocchi G.	2010-02-02	Residue of Methyl isothiocyanate (MITC) and 1,3-dimethylthiourea (DMTU) in tomato at harvest in protected crop following one pre-planting application by drip irrigation of Tamisol 510/Solasan, Italy, Belgium, 2009 SPF S.r.l, Italy Study number 09050RTO, Trials number B112, I113, I114, I115 GLP: yes Not published	Y	Taminco
IIA 6.3/25	Miserocchi G.	2010-02-12	Residue of Methyl isothiocyanate (MITC) and 1,3-dimethylthiourea (DMTU) in cucumber at harvest in protected crop following one pre-planting application by drip irrigation of Tamisol 510/Metam sodio 50, Italy, Spain, 2009 SPF S.r.l, Italy Study number 09058RCU, Trials number I127, I128 GLP: yes Not published	Y	Taminco
IIA 6.3/26	Miserocchi G.	2010-02-12	Residue of Methyl isothiocyanate (MITC) and 1,3-dimethylthiourea (DMTU) in green pepper at harvest in protected crop following one pre-planting application by drip irrigation of Tamisol 510/Metam sodio 50, Italy, Spain, 2009 SPF S.r.l, Italy Study number 09059RGP, Trials number I129, I130 GLP: yes Not published	Y	Taminco
IIA 6.3/27	Miserocchi G.	2010-02-12	Residue of Methyl isothiocyanate (MITC) and 1,3-dimethylthiourea (DMTU) in aubergine at harvest in protected crop following one pre-planting application by drip irrigation of Tamisol 510/Metam sodio 50, Italy, Spain, 2009 SPF S.r.l, Italy Study number 09060RAU, Trials number I131, S132 GLP: yes Not published	Y	Taminco

ANNEX B

Metam-sodium

APPENDIX A: METABOLIC PATHWAY IN PLANTS

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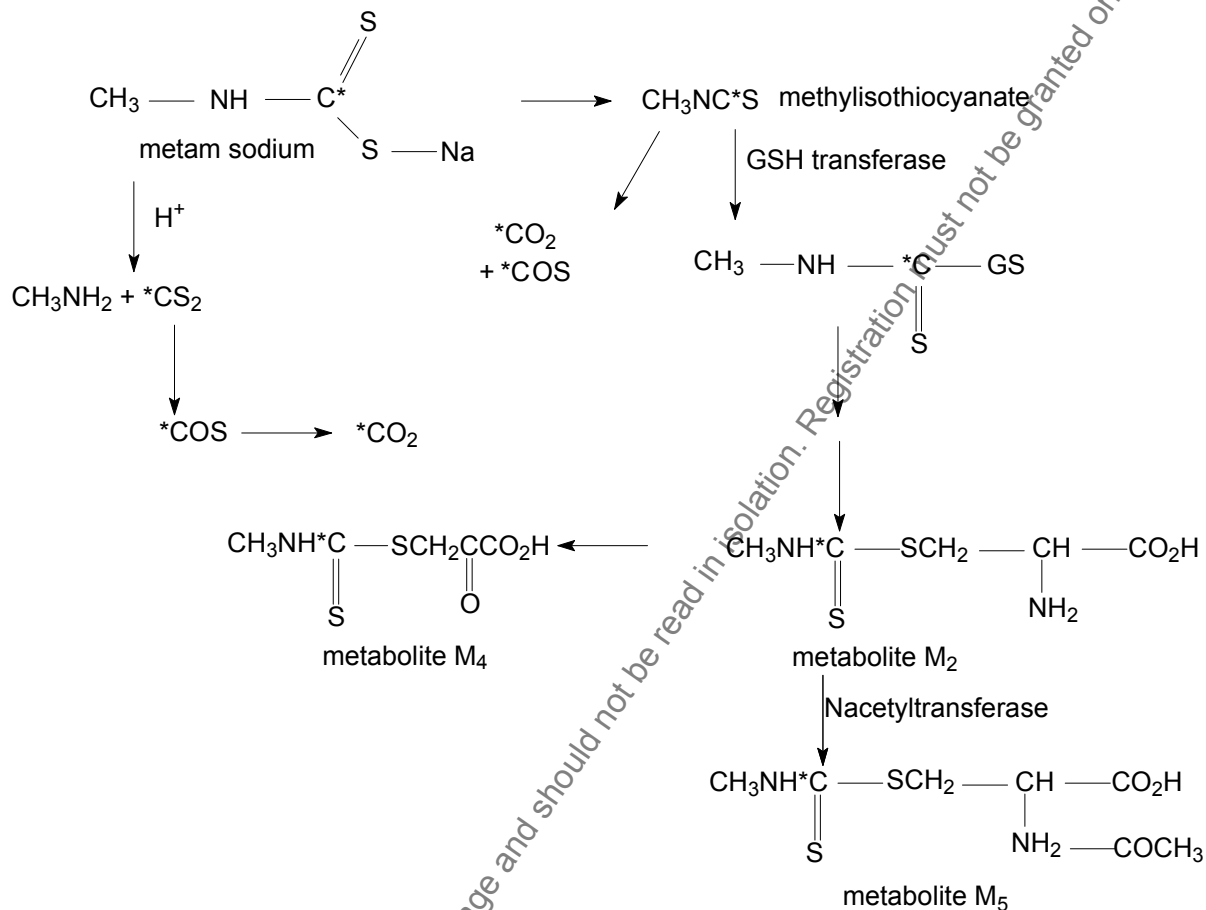
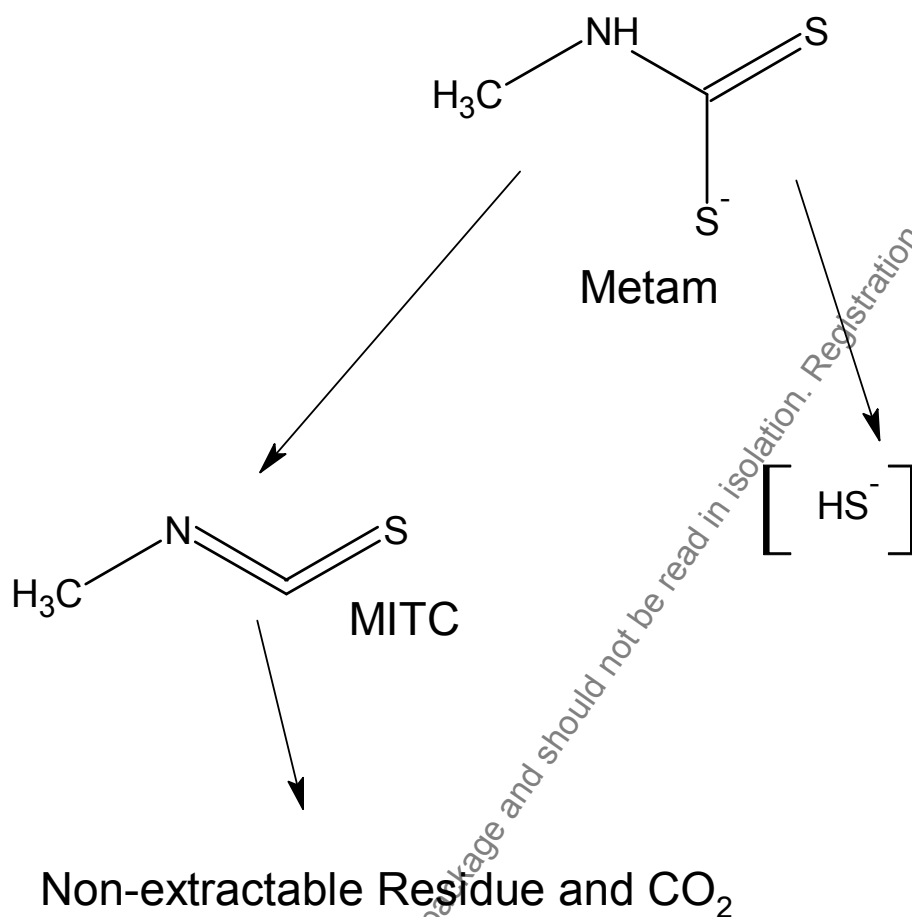
Figure 1: Postulated metabolic pathway for ^{14}C -metam-sodium and methyl isothiocyanate in the rat.

Figure 2: Proposed metabolic pathway of ^{14}C -Metam-sodium in soil and in plants*Remark:*

Mainly in the metabolism of turnip crop, it was demonstrated that sequential hydrolysis of the post extraction solids with enzymes selective for cellulose, starch, proteins and pectins and also lignin extraction showed the distribution of the radioactive residues over a variety of natural products such as cellulose, hemicelluloses, starch, proteins, pectin and lignin.

ANNEX B

Metam-sodium

APPENDIX B:

CHEMICAL NAMES AND STRUCTURES OF SYNTHETIC REFERENCE COMPOUNDS

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Code/Trivial name	Chemical name	Structural formula
Metam-sodium	sodium N-methyldithiocarbamate	$\begin{array}{c} \text{H}_3\text{C}-\text{NH}-\text{C}-\text{S}^+ \text{Na} \\ \parallel \\ \text{S} \end{array}$
MITC	Methylisothiocyanate	$\text{H}_3\text{C}-\text{N}=\text{C}=\text{S}$
MTU	N-methyl-thiourea	$\begin{array}{c} \text{H}_3\text{C}-\text{NH}-\text{C}-\text{NH}_2 \\ \parallel \\ \text{S} \end{array}$
DMTU	N,N'-dimethylthiourea	$\begin{array}{c} \text{H}_3\text{C}-\text{NH}-\text{C}-\text{NH}-\text{CH}_3 \\ \parallel \\ \text{S} \end{array}$
TMTU	N-methyl-N'-dimethyl-thiourea	$\begin{array}{c} \text{H}_3\text{C}-\text{NH}-\text{C}-\text{N}(\text{CH}_3)_2 \\ \parallel \\ \text{S} \end{array}$

ANNEX B

Metam-sodium

APPENDIX C:

RESIDUE DATA FROM SUPERVISED TRIALS

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(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-01 Oregon Hillsboro Washington	Ramono	a) 08/07/88 b) 12/09/88	38.1	935.4 (*)	356.45	09/06/88	Pre plant	Seed + Pod	Metam: < 0.05 MITC: < 0.02	95	Sprinkler
		a) 08/07/88 b) 12/09/88						Vines	Metam: <0.05 MITC: <0.02	95	
		a) 08/07/88 b) 15/09/88						Hay	Metam: <0.05 MITC: <0.02	98	

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date					Application method
PAL-ME-ICI-01 Wisconsin Union Grove Racine	Ego	a) 14/06/88 b) 16/08/88 a) 14/06/88 b) 16/08/88 a) 14/06/88 b) 22/08/88	38.1	935.4 (*)	356.45	14/05/88	Pre plant	Seed + Pod Vines Hay	Metam: < 0.05 MITC: < 0.02 Metam: <0.05 MITC: <0.02 Metam: 0.06-0.06* MITC: <0.02 *: method failure	94 94 100	Water can
MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : -MITC :75 - 121 %. -Metam-sodium : 74-112 %											

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Cucumbers (fruiting vegetables –cucurbits, edible peel)** Other active
substance in the formulation
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.** (common name and content) : -
32380 Avenue 10, Madera, California, USA Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-02 California Madera Madera	Super size	a) 01/07/88 b) 12/09/88	38.1	935.4 (*)	356.45	10/06/88	Pre plant	Fruit	Metam: ≤ 0.05 MITC: ≤ 0.02	94	Soil inject

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-02 Wisconsin Union Grove Racine	Score	a) 14/06/88 b) 12/09/88	38.1	935.4 (*)	356.45	14/05/88	Pre plant	Fruit	Metam: <u>< 0.05</u> MITC: <u>< 0.02</u>	121	Water can
	MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : MITC : 93-103 %; Metam-sodium : 68-94 %										

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Potatoes (Root and tuber vegetables)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
 (common name and content) : -
 32380 Avenue 10, Madera, California, USA Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHl (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-03 Idaho Minidoka Blaine	Russet Burbank	a) 09/06/88 b) 19/09/88	38.1	935.4 (*)	356.4	13/05/88	Pre plant	Tuber	Metam: ≤ 0.05 MITC: ≤ 0.02	129	Sprinkler inject
PAL-ME-ICI-03 Washington Ephrata Grant	Russet Burbank	a) 02/06/88 b) 03/10/88	38.1	935.4 (*)	356.4	14/05/88	Pre plant	Tuber	Metam: ≤ 0.05 MITC: ≤ 0.02	142	Sprinkler inject

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-03 Wisconsin Union Grove Racine	Burbank	a) 14/06/88 b) 10/10/88	38.1	935.4 (*)	356.4	14/05/88	Pre plant	Tuber	Metam: <u>< 0.05</u> MITC: <u>< 0.02</u>	149	Water can
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1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pH (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-03 Minnesota Hollandale Freeborn	Pontiac	a) 11/06/88 b) 28/09/88	38.1	935.4 (*)	356.4	13/05/88	Pre plant	Tuber	Metam: <u>< 0.05</u> MITC: <u>< 0.02</u>	138	Sprinkler inject
MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : MITC : 79-114 %; Metam-sodium : 66-102 %											

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Mustard greens (Leafy brassica)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : **Metam**
Residues calculated as : **MITC**
Country : **USA**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-04 Texas Center point Kerr	Florida broadleaf	a) 25/06/88 b) 22/08/88	38.1	935.4 (*)	356.4	27/05/88	Pre plant	Greens	Metam: 3.54-1.24* MITC: < 0.02 *method failure	87	Soil injection using shanks. No supported use.

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Peppermint (herbs)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
 Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						Application method
PAL-ME-ICI-05 Washington Ephrata Grant	Mirhem	a) 06/03/88 b) 15/08/88	38.1	935.4 (*)	356.4	13/05/88	Pre plant	Hay	Metam: <0.05 MITC: < 0.02	94	Soil injection Not a supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm
Recoveries : MITC : 82-89 %; Metam-sodium : 76-100 %

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Basil (Herbs)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : **Metam**
 Residues calculated as : **MITC**
 Country : **USA**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date	treatment or date				Application method
PAL-ME-ICI-06 California Madera Madera	Large green leaf	a) 01/07/88 b) 31/08/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Fresh	Metam: <0.05 MITC: < 0.02	82	Soil injection Not a supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm
 Recoveries : MITC : 96-104 %; Metam-sodium : 82-140 %

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Tobacco** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
 Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-07 North Carolina Laurinburg Scotland	K-326	a) 16/06/88 b) 19/09/88	38.1	935.4 (*)	356.4	26/05/88	Pre plant	Whole leaves	Metam: <0.05 MITC: < 0.02	116	Sprayer Not a supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm
 Recoveries : MITC : 86-100 %; Metam-sodium : 81-112 %

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Cantaloupe(Cucurbits-inedible peel)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-08 Texas Center Point Kerr	Perlita	a) 23/06/88 b) 11/10/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	138	Water can

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-08 California Madera Madera	Planters jumbo	a) 01/07/88 b) 27/09/88	38.1	935.4 ^(*)	356.4	26/05/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	109	Sprinkler Not a supported use.
MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : MITC : 60-104 %; Metam-sodium : 76-100 %											

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(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-09 Florida Lakeland Polk	Early Scarlet Globe	a) 02/10/88 b) 31/10/88	38.1	1087 (*)	413.6	11/09/88	Pre plant	Roots	Metam: 1.20-0.76* MITC: < 0.02	50	Water can
								Tops	Metam: 0.70-1.05* MITC: < 0.02 *: method failure	50	Water can Not a supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Leaf lettuce** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pH (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-10 California Madera Madera	Red Sails	a) 09/09/88 b) 08/11/88	38.1	935.4^(*)	356.4	19/08/88	Pre plant	Leaves	Metam: <u><0.05</u> MITC: <u><0.02</u>	81	Sprinkler inject

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

Recoveries : MITC : 100-114 %; Metam-sodium : 86-124 %

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Green onion (Bulb vegetables)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : **Metam**
 Country : **USA** Residues calculated as : **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-11 California Madera Madera	Southport white globe	a) 01/07/88 b) 12/09/88	38.1	924.2 (*)	352.2	10/06/88	Pre plant	Whole plant	Metam: 0.380-0.401 MITC: < 0.02	94	Shank injector (Soil inject) Not a supported use.

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-11 New York Phelps Ontario	Southport white bunching	a) 23/06/88 b) 18/10/88	38.1	935.4 (*)	356.4	01/06/88	Pre plant	Whole plant	Metam: 0.319-0.391 MITC: < 0.02	139	Sprinkler head Not a supported use.
PAL-ME-ICI-11 Oregon Hillsboro Washington	White knight	a) 08/07/88 b) 12/09/88	38.1	935.4 (*)	356.4	09/06/88	Pre plant	Whole plant	Metam: 0.603-1.180 MITC: < 0.02	95	Sprinkler injection Not a supported use.

MITC: LOQ: 0.028 ppm; LOD: 0.02 ppm

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Head lettuce** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHl (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-12 California Madera Madera	Empire	a) 09/09/88 b) 03/01/89	38.1	935.4 (*)	356.4	19/08/88	Pre plant	Lettuce heads - with wrapper leaves - without wrapper leaves	Metam: <0.05 MITC: < 0.02 Metam: <0.05 MITC: < 0.02	137	Sprinkler injection

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-12 6.2 Florida Lakeland Polk	Great lakes	a) 02/10/88 b) 09/01/89	38.1	935.4 (*)	356.4	11/09/88	Pre plant	Lettuce heads - with wrapper leaves - without wrapper leaves	Metam: <u>≤0.05</u> MITC: <u>≤ 0.02</u>	120	Water can
									Metam: <u>≤0.05</u> MITC: <u>≤ 0.02</u>		
									MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm		

Indoor / outdoor	:	Outdoor
Other active substance in the formulation (common name and content)	:	-
Residues calculated as	:	Metam MITC

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm
Recoveries : MITC : 71-110 %; Metam-sodium : 72-114 %

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.

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Spinach (Leafy vegetables)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHl (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-13 California Madera Madera	St. Helens	a) 09/09/88 b) 08/11/88	38.1	935.4 (*)	356.4	19/08/88	Pre plant	Greens	Metam: <0.05 MITC: < 0.02	81	Sprinkler injection Not a supported use

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-13 Texas Center Point Kerr	Dixie Market	a) 07/09/88 b) 09/11/88	38.1	935.4 ^(*)	356.4	08/08/88	Pre plant	Greens	Metam: <0.05 MITC: < 0.02	93	Shank injector (soil injection)
											Not a supported use
											MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : MITC : 76-103 %; Metam-sodium : 74-100 %

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Turnip (root and tuber vegetables)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : **Metam**
 Residues calculated as : **MITC**
 Country : **USA**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date					Application method
PAL-ME-ICI-14 California Madera Madera	White Globe	a) 09/09/88 b) 08/11/88	38.1	935.4 (*)	356.4	19/08/88	Pre plant	Roots Greens	Metam: 0.295-0.380 MITC: < 0.02 Metam: 0.135-0.175 MITC: < 0.02	81	Shank injector (soil injection) Not supported use

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Broccoli (Flowering brassica)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-15 California Madera Madera	Broccoli	a) 09/09/88 b) 01/02/89	38.1	935.4 (*)	356.4	19/08/88	Pre plant	Heads and stalks	Metam: 0.191-0.279 MITC: < 0.02	166	Shank injector (soil injection)

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Sweet corn (Fruiting vegetables)** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
 Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date	treatment or date				Application method
PAL-ME-ICI-16 Florida Loxahatchee Palm Beach	7210	a) 25/10/88 b) 09/01/89	38.1	935.4 (*)	356.4	04/10/88	Pre plant	Corn Ears Forage	Metam: <0.05 MITC: < 0.02 Metam: <0.05 MITC: < 0.02	97	Sprinkler injection Not supported use

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-16 California Madera Madera	How sweet it is	a) 01/07/88 b) 21/09/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Corn Ears Forage	Metam: <0.05 MITC: < 0.02 Metam: <0.05 MITC: < 0.02	134	Sprinkler injection Not supported use
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1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date					Application method
PAL-ME-ICI-16 Illinois Geneso Henry	Secota medium	a) 27/06/88 b) 13/09/88	38.1	935.4 (*)	356.4	26/05/88	Pre plant	Corn Ears Forage	Metam: <0.05 MITC: < 0.02 Metam: <0.05 MITC: < 0.02	110	Water can Not supported use
PAL-ME-ICI-16 New York Phelps Ontario	Jubilee	a) 18/06/88 b) 12/09/88	38.1	935.4 (*)	356.4	28/05/88	Pre plant	Corn Ears Forage	Metam: <0.05 MITC: < 0.02 Metam: <0.05 MITC: < 0.02	107	Shank injector (Soil injection) Not supported use
MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm Recoveries : MITC : 70-109 %; Metam-sodium : 77-106 %											

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Bulb onion** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
 Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-17 California Madera Madera	Early Stockton Yellow	a) 01/07/88 b) 08/11/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Bulb	Metam: 0.565-0.840 MITC: < 0.02	151	Soil injection Not supported use

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

PAL-ME-ICI-17 New York Phelps Ontario	Buffalo	a) 22/06/88 b) 07/11/88	38.1	935.4 (*)	356.4	01/06/88	Pre plant	Bulb	Metam: 0.351-0.490 MITC: < 0.02	159	Hand held sprinkler head Not supported use
PAL-ME-ICI-17 Washington Ephrata Grant	Yellow Spanish	a) 04/06/88 b) 03/10/88	38.1	935.4 (*)	356.4	04/05/88	Pre plant	Bulb	Metam: 0.219-0.304 MITC: < 0.02	142	Sprinkler injection Not supported use

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm
Recoveries : MITC : 86-116 %; Metam-sodium : -

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Strawberry (Berries and small fruit)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.** (common name and content) : -
32380 Avenue 10, Madera, California, USA Residues calculated as : **Metam**
Country : **USA** **MITC**
Content of active substance (g/kg or g/l) : **381 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Vapam**

1	2	3	4	5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment	Dates of treatment(s)	Growth stage at last	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks

Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date	treatment or date				Application method
PAL-ME-ICI-18 California Madera Madera	Fern	a) 01/07/88 b) 12/09/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	94	Shank injector (soil injection) Supported use.
PAL-ME-ICI-18 Florida Lakeland Polk	Chandellor	a) 23/10/88 b) 18/01/89	38.1	935.4 (*)	356.4	02/10/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	108	Watering can Supported use.
PAL-ME-ICI-18 Washington Ephrata Grant	Shuksan	a) 04/06/88 b) 15/08/88	38.1	935.4 (*)	356.4	14/05/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	93	Sprinkler injection Supported use.
This study is not acceptable: The rate of application exceeds the rule of 25 % based on the supported dose rate.											

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name)	: Metam sodium	Indoor / outdoor	: Outdoor
Crop / crop group	: Tomato fruit	Other active substance in the formulation	
Responsible body for reporting (name, address)	: Pan-Agricultural Laboratories, Inc.	(common name and content)	: -
	: 32380 Avenue 10, Madera, California, USA	Residues calculated as	: Metam
Country	: USA		: MITC
Content of active substance (g/kg or g/l)	: 381 g/l		
Formulation (e.g. WP)	: aqueous solution		
Commercial Product (name)	: Vapam		

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-19 California Madera Madera	Roma	a) 01/07/88 b) 08/11/88	38.1	935.4 (*)	356.4	10/06/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	151	Soil injection Supported use.
PAL-ME-ICI-19 Florida Lakeland Polk	Walter	a) 02/10/88 b) 18/01/89	38.1	935.4 (*)	356.4	11/09/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	129	Watering can Supported use.
PAL-ME-ICI-19 Pennsylvania Orefield Lehigh	Roma	a) 14/07/88 b) 04/10/88	38.1	935.4 (*)	356.4	14/06/88	Pre plant	Fruit	Metam: <0.05 MITC: < 0.02	112	Sprinkler injection Supported use.
This study is not acceptable: The rate of application exceeds the rule of 25 % based on the supported dose rate (612 kg a.s./ha).											

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

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Belgium

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Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Cabbage** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
32380 Avenue 10, Madera, California, USA (common name and content) : -
 Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date	treatment or date				Application method
PAL-ME-ICI-20 New York Phelps Ontario	King Cole	a) 18/06/88 b) 18/10/88	38.1	935.4 (*)	356.4	28/05/88	Pre plant	Cabbage with wrapper leaves Without wrapper leaves	Metam: 0.194-0.338 MITC: < 0.02 Metam: 0.304-0.395 MITC: <0.02	143	Shank injector (soil injection) Not supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
 Crop / crop group : **Garlic** Other active substance in the formulation : -
 Responsible body for reporting (name, address) : **Pan-Agricultural Laboratories, Inc.**
 (common name and content) : -
 32380 Avenue 10, Madera, California, USA Residues calculated as : **Metam**
 Country : **USA** **MITC**
 Content of active substance (g/kg or g/l) : **381 g/l**
 Formulation (e.g. WP) : **aqueous solution**
 Commercial Product (name) : **Vapam**

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHl (days)	Remarks Application method
Location : State City County			kg a.s./hl	Water (l/ha)	kg a.s./ha						
PAL-ME-ICI-21 California Madera Madera	Christopher Jumbo	c) 09/09/88 d) 25/05/89	38.1	935.4 (*)	356.4	19/08/88	Pre plant	Bulbs	Metam: <0.05 MITC: < 0.02	279	Soil injection Not supported use.

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

(*) No further dilution with water, this is the quantity of Metam-sodium aqueous solution

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Baby-leaf lettuce (Schnittsalat)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **PTRL Europe, Ulm** (common name and content) : -
Residues calculated as : **MITC**
Country : **Germany**
Content of active substance (g/kg or g/l) : **510 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Metam-Fluid**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
B712-4G RU-I-2303 NW BN 6/1 Bonn Germany	Lollo Madison BL	a) 26/06/03 b) 31/07/03	11.7	1000 + 300	153	26/05/03	Pre plant	Leaves	MITC: < 0.02	n.a.	Spraying (300 l product in 1000 l water) + incorporation 5-10 cm + 5 mm water seal

1	2	3	4			5	6	7	8	9	10
Report No.	Commodity / Variety	Date of	Application rate per treatment			Dates of treatment(s)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks
Location : State City County		a) planting b) harvest	kg a.s./hl	Water (l/ha)	kg a.s./ha	or no of treatment(s) and last date					Application method
B712-4G RU-I-2303 NW BN 6/2 Bonn Germany	Lollo Madison BL	a) 18/07/03 b) 15/08/03	11.7	1000 + 300	153	27/06/03	Pre plant	Leaves	MITC: < 0.02	n.a.	Spraying (300 l product in 1000 l water) + incorporation 5-10 cm + 5 mm water seal

MITC : LOQ : 0.028 ppm; LOD : 0.02 ppm

Active ingredient (common name) : **Metam sodium** Indoor / outdoor : **Outdoor**
Crop / crop group : **Baby-leaf lettuce (Feldsalat / Corn salad)** Other active substance in the formulation : -
Responsible body for reporting (name, address) : **PTRL Europe, Ulm** (common name and content) : -
Residues calculated as : **MITC**
Country : **Germany**
Content of active substance (g/kg or g/l) : **510 g/l**
Formulation (e.g. WP) : **aqueous solution**
Commercial Product (name) : **Metam-Fluid**

1	2	3	4			5	6	7	8	9	10
Report No. Location : State City County	Commodity / Variety	Date of a) planting b) harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	pHI (days)	Remarks Application method
			kg a.s./hl	Water (l/ha)	kg a.s./ha						
B712-4G RU-I-0603 NW BN 2/2 Bonn Germany	Favor	a) 18/07/03 b) 15/08/03	11.7	1000 + 300	153	27/06/03	Pre plant	Leaves	MITC: < 0.02	n.a.	Spraying (300 l product in 1000 l water) + incorporation 5-10 cm + 5 mm water seal

This study is not acceptable: The rate of application exceeds the rule of 25 % based on the supported dose rate (306 kg a.s./ha).

Added in August 2010 (Not peer reviewed)**RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)**

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Lettuce/Leaf vegetables Group			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO Italia S.r.l. Via Cornalia, 26 I-20124 Milano, Italy									
Country:			Northern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC, mg/kg			
1	2	3	4	5		6	7	8	9	10	11	
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:	
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)					
Trial I132 I-37063 Isola della Scala (VR), Veneto Region, Italy	Lettuce/Impu lsion	1) 10 Jun 2008 2) n.a. 3) 08 Jul 2008	Broadcast application using a direct soil injection machine	0.049	1182.84	577	27 May 2008	Pre planting	Lettuce heads	< 0.01	42	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND=not detected (<0.003 mg/kg)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Pepper/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO Italia S.r.l. Via Cornalia, 26 I-20124 Milano, Italy									
Country:			Northern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC, mg/kg			
1	2	3	4	5		6	7	8	9	10	11	
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:	
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)					
Trial I132 I-37063 Isola della Scala (VR), Veneto Region, Italy	Pepper/ Fenice 1	1)10 Jun 2008 2) 30 Jun/15 Jul 08 3) 26 Aug 2008	Broadcast application using a direct soil injection machine	0.049	1182.84	577	27 May 2008	Pre planting	Pepper fruits	< 0.01	91	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND=not detected (<0.003 mg/kg)

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Tomato/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO Italia S.r.l. Via Cornalia, 26 I-20124 Milano, Italy									
Country:			Northern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC, mg/kg			
1	2	3	4	5		6	7	8	9	10	11	
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:	
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)					
Trial II 32 I-37063 Isola della Scala (VR), Veneto Region, Italy	Tomato/ Oskar	1) 10 Jun 2008 2) 30 Jun till July 3) 26 Aug 2008	Broadcast application using a direct soil injection machine	0.049	1182.84	577	27 May 2008	Pre planting	Tomato fruits	< 0.01	91	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND=not detected (<0.003 mg/kg)

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):				Solasan	
Crop/crop group:			Carrot/root and tuber vegetables Group			Producer of commercial product				Taminco N.V.	
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium								
Country:			Belgium (EU Northern Zone)			Indoor/Glasshouse/Outdoor:				Outdoor	
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):				None	
Formulation:			Aqueous solution			Residues calculated as:				MITC and DMTU, mg/kg	
1	2	3	4	5		6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)				
Trial B104 B-6210 Villers- Perwin, Belgium	Carrot/ Laguna	1) 30 Jun 2009 2) n.a. 3) 17 Sep 2009	Application by soil injection machine	n.a.	825.36	414.33	10 Jun 2009	Pre drilling	Carrot roots	< 0.01 (MITC) < 0.01 (DMTU)	99 n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Metam 510			
Crop/crop group:			Carrot/root and tuber vegetables Group			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			United Kingdom (EU Northern Zone)			Indoor/Glasshouse/Outdoor:			Outdoor			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial GB105 UK OX279AS Stratton Audley, Bicester, UK	Carrot/ Autumn King 2	1) 22 Jul 2009 2) n.a. 3) 26 Nov 2009	Application by soil injection machine	n.a.	860.00	431.72	01 Jul 2009	Pre drilling	Carrot roots	< 0.01 (MITC) < 0.01 (DMTU)	148	n.a.

- (a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 0-8263-3152-4
(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

- (c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Carrot/root and tuber vegetables Group			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			Centre Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Outdoor			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial I106 I-00056 Maccarese (Rome), Lazio Region, Italy	Carrot/ Nelson	1) 09 Jul 2009 2) n.a. 3) 13 Oct 2009	Application by soil injection machine	n.a.	744.96	373.97	18 Jun 2009	Pre drilling	Carrot roots	< 0.01 (MITC) < 0.01 (DMTU)	117	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Carrot/root and tuber vegetables Group			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Outdoor			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial I107 I-71030 Zapponeta (Foggia), Puglia Region, Italy	Carrot/ Bolero	1) 11 Aug 2009 2) n.a. 3) 11 Dec 2009	Application by soil injection machine	n.a.	758.72	380.88	22 Jul 2009	Pre drilling	Carrot roots	< 0.01 (MITC) < 0.01 (DMTU)	142	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Solasan			
Crop/crop group:			Tomato/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			Belgium (EU Northern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial B112 B-6210 Villers- Perwin, Belgium	Tomato/ Brodena	1) 29 Jun 2009 2) 05 Jun-20 Jul 09 3) 13 Aug 2009	Application by drip irrigation system	n.a.	1255.68	630.35	09 Jun 2009	Pre planting	Tomato fruits	< 0.01 (MITC) < 0.01 (DMTU)	65	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510		
Crop/crop group:			Tomato/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.		
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium								
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel		
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None		
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg		
1	2	3	4	5		6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)				
Trial II13 I-70054 Giovinazzo (Bari), Puglia Region, Italy	Tomato/ Naxos	1) 16 Jul 2009 2) Aug to Oct 09 3) 30 Sep 2009	Application by drip irrigation system	n.a.	1200.00	602.40	26 Jun 2009	Pre planting	Tomato fruits	< 0.01 (MITC) < 0.01 (DMTU)	96

- (a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
 (b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

- (c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Tomato/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial II 14 I-70056 Molfetta (Bari), Puglia Region, Italy	Tomato/ Salomone	1) 27 Jul 2009 2) Aug till Oct 09 3) 29 Oct 2009	Application by drip irrigation system	n.a.	1200.00	602.40	06 Jul 2009	Pre planting	Tomato fruits	< 0.01 (MITC) < 0.01 (DMTU)	115	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510			
Crop/crop group:			Tomato/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Belgium									
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial II15 I-71030 Zapponeta (Foggia), Puglia Region, Italy	Tomato/ Namanaxos	1) 04 Aug 2009 2) Sep till Oct 09 3) 29 Oct 2009	Application by drip irrigation system	n.a.	1200.00	602.40	14 Jul 2009	Pre planting	Tomato fruits	< 0.01 (MITC) < 0.01 (DMTU)	107	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):				metam-sodium			Commercial Product (name):				Tamisol 510	
Crop/crop group:				Cucumber/Fruiting vegetables Group (edible skin)			Producer of commercial product				Taminco N.V.	
Responsible body for reporting (name & address):				TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain								
Country:				Southern Italy (EU Southern Zone)								
Content of active substance (g/kg or g/l):				510 g a.i./L nominal			Indoor/Glasshouse/Outdoor:				Indoor/Plastic tunnel	
							Other active substance in the formulation (common name and content):				None	
Formulation:				Aqueous solution			Residues calculated as:				MITC and DMTU, mg/kg	
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial I127 I-70056 Molfetta BA Puglia Region Italy	Cucumber/ Saring	1) 26 Jul 2009 2) Aug/Sep 2009 3) 14 Sep 2009	Application by drip irrigation system	n.a.	900.00	451.80	06 Jul 2009	Pre planting	Cucumber fruits	< 0.01 (MITC) < 0.01 (DMTU)	70	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Metam Sodio 50			
Crop/crop group:			Cucumber/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain									
Country:			Southern Spain (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			500 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial S128 Barbate, Cadiz, Spain	Cucumber/ Jedida	1) 07 Sep 2009 2) 23 Sep 2009 3) 14 Oct 2009	Application by drip irrigation system	n.a.	900.00	451.80	17 Aug 2009	Pre planting	Cucumber fruits	< 0.01 (MITC) < 0.01 (DMTU)	58	n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510		
Crop/crop group:			Green pepper/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.		
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain								
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel		
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None		
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg		
1	2	3	4	5		6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date (a)	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha					
Trial II 29 I-70054 Giovinazzo (Bari) Puglia Region Italy	Green pepper/ Valdor	1) 29 Jul 2009 2) Oct/Dec 2009 3) 26 Nov 2009	Application by drip irrigation system	n.a.	1200.00	602.40	08 Jul 2009	Pre planting	Green pepper fruits	< 0.01 (MITC) < 0.01 (DMTU)	141 n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium				Commercial Product (name):				Metam Sodio 50	
Crop/crop group:			Green pepper/Fruiting vegetables Group (edible skin)				Producer of commercial product				Taminco N.V.	
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain									
Country:			Southern Spain (EU Southern Zone)				Indoor/Glasshouse/Outdoor:				Indoor/Plastic tunnel	
Content of active substance (g/kg or g/l):			500 g a.i./L nominal				Other active substance in the formulation (common name and content):				None	
Formulation:			Aqueous solution				Residues calculated as:				MITC and DMTU, mg/kg	
1	2	3	4	5			6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha		(a)				
Trial S130 Barbate, Cadiz, Spain	Green pepper/ Toscana	1) 07 Sep 2009 2) 30 Sep 2009 3) 23 Oct 2009	Application by drip irrigation system	n.a.	1200.00	602.40	17 Aug 2009	Pre planting	Green pepper fruits	< 0.01 (MITC) < 0.01 (DMTU)	67	n.a.

- (a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 0-8263-3152-4
 (b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

- (c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Tamisol 510		
Crop/crop group:			Aubergine/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.		
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain								
Country:			Southern Italy (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel		
Content of active substance (g/kg or g/l):			510 g a.i./L nominal			Other active substance in the formulation (common name and content):			None		
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg		
1	2	3	4	5		6	7	8	9	10	11
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date (a)	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:
				kg a.i./hL	formulation (L/ha)	kg a.i./ha					
Trial II131 I-70032 Bitonto (Bari) Puglia Region Italy	Aubergine/ Molfettese	1) 15 Sep 2009 2) Nov/Dec 2009 3) 11 Dec 2009	Application by drip irrigation system	n.a.	1200.00	602.40	26 Aug 2009	Pre planting	Aubergine fruits	< 0.01 (MITC) < 0.01 (DMTU)	107 n.a.

(a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

(c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

WARNING: This document contains preliminary data. It is not to be used for regulatory purposes. Registration must not be granted on the basis of this document.

RESIDUES DATA FROM SUPERVISED TRIAL (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):			metam-sodium			Commercial Product (name):			Metam Sodio 50			
Crop/crop group:			Aubergine/Fruiting vegetables Group (edible skin)			Producer of commercial product			Taminco N.V.			
Responsible body for reporting (name & address):			TAMINCO N.V. Panterschipstraat 207 B-9000 Gent, Spain									
Country:			Southern Spain (EU Southern Zone)			Indoor/Glasshouse/Outdoor:			Indoor/Plastic tunnel			
Content of active substance (g/kg or g/l):			500 g a.i./L nominal			Other active substance in the formulation (common name and content):			None			
Formulation:			Aqueous solution			Residues calculated as:			MITC and DMTU, mg/kg			
1	2	3	4	5		6	7	8	9	10	11	
Report No. Location (region)	Commodity/ Variety	Date/Year of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment		Dates of Treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg) (b)	PHI (days) (c)	Remarks:	
				kg a.i./hL	formulation (L/ha)	kg a.i./ha	(a)					
Trial S132 S-41720 Los Palacios y Villafranca, Sevilla, Spain	Aubergine/ Ecavi	1) 08 Sep 2009 2) 02 Nov 2009 3) 26 Nov 2009	Application by drip irrigation system	n.a.	1200.00	602.40	17 Aug 2009	Pre planting	Aubergine fruits	< 0.01 (MITC) < 0.01 (DMTU)	100	n.a.

- (a) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
 (b) Values between 0.003 (30% of the limit of quantification) and 0.01 (limit of quantification) mg/kg are reported as <0.01 mg/kg. ND = not detected (< 0.003 mg/kg).

- (c) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

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