



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

Gelet op artikel 69 en artikel 71, eerste lid, eerste lid Verordening (EG) Nr. 1107/2009 juncto artikel 39 Wet gewasbeschermingsmiddelen en biociden (hierna te noemen: Wgb);

Overwegende dat:

- *het Ctgb (verder: het College) op grond van artikel 4 Wet gewasbeschermingsmiddelen en biociden (verder: Wgb) is aangewezen als de bevoegde autoriteit voor Nederland als bedoeld in artikel 75 Verordening (EG) 1107/2009*
- *artikel 39 Wgb het College de bevoegdheid geeft om het op de markt brengen of het gebruik van een toegelaten gewasbeschermingsmiddel tijdelijk te beperken of te verbieden, indien er duidelijke aanwijzingen bestaan dat het gewasbeschermingsmiddel een ernstig risico inhoudt voor de gezondheid van mens en dier of voor het milieu*
- *de noodzakelijke beperkingen voor de kortst mogelijke duur gesteld dienen te worden*
- *het College de toelatinghouders van de metam-natrium houdende gewasbeschermingsmiddelen:*
 - *Monam (toelatingsnummer 6443 N)*
 - *Monam Cleanstart (toelatingsnummer 6321 N)*
 - *Nemasol (toelatingsnummer 9635 N),*

heeft bericht dat het op grond van artikel 44 Verordening (EG) 1107/2009 aanleiding heeft gezien om de betreffende toelatingen opnieuw te bekijken omdat er sterke aanwijzingen bestaan dat niet langer wordt voldaan aan de toelatingseisen

- *het College de toelatinghouders de mogelijkheid heeft geboden om opmerkingen te formuleren of nadere gegevens te verstrekken in verband met het voornemen van het Ctgb om de toelatingen in te trekken of te wijzigen*
- *tevens gebleken is dat er aanwijzingen zijn dat het gebruik van gewasbeschermingsmiddelen, gebaseerd op de werkzame stof metam natrium waarschijnlijk een ernstig risico inhouden voor de gezondheid van de mens, die of milieu*
- *dit bevestigd is doordat er zich in Nederland de afgelopen jaren een aantal incidenten met metam-natrium houdende gewasbeschermingsmiddelen hebben voorgedaan, waarbij er sterke aanwijzingen zijn dat bij omwonenden acute effecten zijn geweest, ondanks het feit dat volgens rapportage van de NVWA conform de wettelijke voorschriften zou zijn toegepast*
- *de betreffende toelatinghouders bij het Ctgb geen melding hebben gedaan van informatie over mogelijke schadelijke of onaanvaardbare effecten als bedoeld in artikel 56 Gewasbeschermingsverordening*

- *de risico's op basis van de beschikbare gegevens niet voldoende kunnen worden bestreden met passende en adequate maatregelen om een veilig gebruik te kunnen garanderen en de toelatingsvoorschriften mitsdien geen goede bescherming garanderen*
- *het ministerie van Economische Zaken derhalve, mede namens College de Europese Commissie derhalve heeft verzocht om noodmaatregelen te nemen om het gebruik en/of de verkoop van de betrokken gewasbeschermingsmiddelen te beperken of te verbieden*
- *het Ctgb van mening is dat de bevoegdheid om in de lopende toelating in te grijpen op basis van artikel 44 Verordening (EG) 1107/2009, in dit geval onvoldoende soelaas biedt omdat op grond van het Ctgb ten dienste staande informatie duidelijk is geworden dat deze gewasbeschermingsmiddelen op korte termijn in Nederland toegepast gaan worden terwijl op basis van de beschikbare gegevens geen maatregelen kunnen worden bepaald die tot veilig gebruik zullen leiden,*

BESLUIT

1. Schorsing toelatingen en verbod gebruik

Het College besluit om, onder toepassing van artikel 39 Wgb en artikel 71 Verordening (EG) 1107/2009, de toelating van de gewasbeschermingsmiddelen

- Monam (toelatingsnummer 6443 N)
- Monam Cleanstart (toelatingsnummer 6321 N)
- Nemasol (toelatingsnummer 9635 N)

te schorsen, en het gebruik ervan derhalve tijdelijk te verbieden met ingang van inwerkingtreding van dit besluit. De schorsing en het verbod gelden totdat een communautaire maatregel als bedoeld in artikel 71, derde lid Verordening (EG) 1107/2009 is vastgesteld.

2. Geen respijperiode

Aangezien dit besluit zijn grondslag vindt in artikel 71 Verordening (EG) 1107/2009, kan van het toekennen van een respijperiode als bedoeld in artikel 46 van Verordening (EG) 1107/2009 geen sprake zijn. Een respijtermijn wordt derhalve niet toegekend.

2. Motivering

Metam-natrium is de werkzame stof van een aantal grondontsmettingsmiddelen. Metam-natrium is een fumigant die werkt doordat het in de bodem wordt omzet in de gasvormige vorm MITC. Er zijn in Nederland drie middelen toegelaten (een moedertoelating, met twee afgeleiden), die voornamelijk worden ingezet om nematoden (aaltjes) in de grond te bestrijden.

Sommige van deze nematodensoorten zijn in de EU als quarantaine-organismen aangemerkt, die op grond van Europese regelgeving door lidstaten bestreden moeten worden.

Zoals uit het onderstaande en bijlage I bij dit besluit blijkt, is het duidelijk dat het gebruik van de onderhavige gewasbeschermingsmiddelen op basis van metam-natrium waarschijnlijk een ernstig risico inhoudt voor de gezondheid van de mens, aangezien bij gebruik volgens de huidige toelating de blootstelling zodanig is dat voor omwonenden concentraties te verwachten zijn die aanzienlijk boven de humane norm liggen. De vastgestelde veiligheidsnorm wordt voor omwonenden en met name omwonende kinderen, zo blijkt uit de voor het stofdossier aangeleverde veldstudies, met een factor 10 overschreden.

De geleverde veldstudies geven een zeer wisselend beeld mbt de luchtconcentraties en in de

belangrijkste studie, met de hoogste piekconcentratie is een veel lagere dosering gebruikt (300 l/ha) dan de maximaal toegelaten dosering (750 L/ha).

Het is derhalve niet uit te sluiten, dat in de praktijk omwonenden kunnen worden blootgesteld aan hogere luchtconcentraties dan waar de risicobeoordeling in bijlage I vanuit gaat. Dit sluit aan bij de acute oogklachten en ademhalingsproblemen van omwonenden; vanuit het stofdossier waren deze klachten niet te verwachten bij de gemeten luchtconcentraties. Bovendien blijkt uit eerdere incidenten in Nederland dat ook onder bijzondere omstandigheden, zoals windstil of mistig weer, de concentraties tot zodanige hoogte kunnen oplopen dat omwonenden acute oogklachten en ademhalingsproblemen rapporteren. Onder deze bijzondere omstandigheden kan kennelijk niet worden uitgesloten dat de concentratie MITC waar omwonenden mee in aanraking kunnen komen, de humane norm zodanig wordt overschreden dat er een geenszins als denkbeeldig te verwaarlozen mogelijkheid bestaat dat daadwerkelijk gezondheidsschade optreedt.

In de humane norm zit een veiligheidsfactor van 100. In de risicobeoordeling in bijlage I is een overschrijding van 10 berekend, zodat de afstand tot de veilige norm nog maar 10 is. Gezien de onzekerheden en variatie in de gemeten luchtconcentraties, en de in de praktijk veelal hogere doseringen, geeft deze factor 10 onvoldoende bescherming, met name aan gevoelige groepen zoals kinderen met luchtwegproblemen (astma etc).

Mede gezien de tekst van preambule nr. 8 van de Gewasbeschermingsverordening kwalificeert het Ctgb deze mogelijkheid als een potentieel ernstig risico als bedoeld in artikel 71 Gewasbeschermingsverordening.

Het College stelt daarnaast vast dat het bepaalde in artikel 71 Gewasbeschermingsverordening met zich meebrengt dat een lidstaat voorlopige beschermende noodmaatregelen kan nemen indien het de Europese Commissie officieel in kennis stelt van de noodzaak daartoe, er (nog) geen noodmaatregel is genomen door de Commissie en er duidelijke aanwijzingen zijn dat de toelatingsvoorschriften geen goede bescherming bieden voor kwetsbare groepen, zoals kinderen.

Uit het voorgaande komt tevens naar voren dat, waar er aanwijzingen zijn dat er een geenszins als denkbeeldig te verwaarlozen mogelijkheid bestaat dat zich onder praktijkomstandigheden daadwerkelijk risico's voor kinderen voor kunnen doen, een afweging tussen (enerzijds) het belang bij de mogelijkheid om de betreffende middelen te verkopen en te gebruiken en (anderzijds) het belang dat kinderen gevrijwaard worden van mogelijke schadelijke effecten op de gezondheid, het laatstgenoemde belang dient te prevaleren.

Wageningen, 28 mei 2014

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN
BIOCIDEN,



ir. J.F. de Leeuw
voorzitter

Bijlage 1- Risicobeoordeling

Monam cleanstart voor omwonenden - bufferzone

ASPECT BEOORDELING GEWASBESCHERMING TOXICOLOGIE

Naar aanleiding van de signalen omtrent MITC is er een herbeoordeling uitgevoerd voor omwonenden. Voor de operator, omstander en werker is geen herbeoordeling gedaan.

1. Mammalian toxicology

List of Endpoints

Metam sodium is an existing active substance that is approved for inclusion in Annex I. The final List of Endpoints presented below is taken from the EFSA Scientific Report on Metam (2011); 9(9) 2334. Where relevant, some additional remarks/information are given in italics.

The representative formulated product for the evaluation was "Metam sodium 510 g/L", soluble concentrate (SL), registered under different trade names in Europe. Metam sodium acts as fumigant through rapid degradation to methylisothiocyanate (MITC), which is active on living organisms present in the soil at the time of the application.

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1) metam and MITC

Rate and extent of oral absorption ‡	85 % (based on urinary (50%) and expired air (35%) excretion within 48 h)
Distribution ‡	Uniformly distributed
Potential for accumulation ‡	Slight potential for accumulation in thyroid
Rate and extent of excretion ‡	Rapid and extensive (app. 85 %) within 48 h, mainly via urine (50 %) within 24 h, 4 % via faeces, 35 % via expired air
Metabolism in animals ‡	Extensive degradation of metam into MITC which is further conjugated with GSH or decomposes into MIC, COS and CO ₂ . Another important metabolic pathway is formation of CS ₂ which is related to acidic conditions of stomach
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound and metabolites: Methylisothiocyanate (MITC) , methylisocyanate (MIC), COS, CS ₂
Toxicologically relevant compounds ‡ (environment)	Methylisothiocyanate (MITC), methylisocyanate (MIC), COS, CS ₂

Acute toxicity (Annex IIA, point 5.2) metam sodium

Rat LD ₅₀ oral ‡	896 mg/kg bw	R22
Rat LD ₅₀ dermal ‡	> 2000 mg/kg bw	-
Rat LC ₅₀ inhalation ‡	2.54 mg/L air /4h (whole body)	R20
Skin irritation ‡	Corrosive	R34
Eye irritation ‡	Non-irritant	-
Skin sensitisation ‡	Sensitising (M & K)	R43

Acute toxicity (Annex IIA, point 5.2) MITC

Rat LD ₅₀ oral ‡	147 mg/kg bw	R25
Rat LD ₅₀ dermal ‡	1290 mg/kg bw	R21
Rat LC ₅₀ inhalation ‡	0.54 mg/L air /4h (whole body)	R23 R37
Skin irritation ‡	Corrosive	R34

Eye irritation ‡	No study required	-
Skin sensitisation ‡	Sensitising (M & K)	R43

Short term toxicity (Annex IIA, point 5.3) metam sodium

Target / critical effect ‡	Nasal cavity (rat), urinary bladder(mice), liver(dog)	
Relevant oral NOAEL ‡	1-year dog: 0.1 mg/kg bw/day 90-day rat: 0.5 mg/kg bw/day 90-day mice: 0.8 mg/kg bw/day	R48/ 22
Relevant dermal NOAEL ‡	21-day, rabbit: 31.2 mg/kg bw/day	
Relevant inhalation NOAEL ‡	90-day rat: 6.5 mg/m ³ corresponding to 1.75 mg/kg bw/d	

Short term toxicity (Annex IIA, point 5.3) MITC

Target / critical effect ‡	Nasal cavity (rat), liver (dog)	
Relevant oral NOAEL ‡	90-day, dog 0.04 mg/kg bw/day	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	28-day rat : 5 mg/m ³ (1.35 mg/kg bw/d)	

Genotoxicity ‡ (Annex IIA, point 5.4)

Metam and MITC are unlikely to be genotoxic ¹⁾	
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¹⁾ Based on a negative Ames test, an equivocal HGPRT assay in CHO cells, one positive and one equivocal in vitro chromosomal aberration test in human lymphocytes, a negative UDS test in hepatocytes, a negative in vivo Micronucleus test in mice, and a negative in vivo chromosomal aberration test in Chinese hamsters.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5) metam sodium

Target/critical effect ‡	Nasal cavity (rat) urinary bladder (mice)	
Relevant NOAEL ‡	1.5 mg/kg bw/day; 2-year, rat 1.9 mg/kg bw/day; 24-month, mouse	
Carcinogenicity ‡	Angiosarcomas in mice	R40

Long term toxicity and carcinogenicity (Annex IIA, point 5.5) MITC

Target/critical effect ‡	Changes in some WBC parameters	
Relevant NOAEL ‡	0.44 mg/kg bw/day; 2-year, rat 3.3 mg/kg bw/day; 24-month, mouse	
Carcinogenicity ‡	MITC is unlikely to pose a risk to humans	

Reproductive toxicity (Annex IIA, point 5.6) metam sodium

Reproduction toxicity

Reproduction target / critical effect ‡	Decreased pup and litter weight at the parental toxic dose in the rat	
Relevant parental NOAEL ‡	0.03 mg/L (4 mg/kg bw/day)	
Relevant reproductive NOAEL ‡	>0.1 mg/L (12 mg/kg bw/day)	
Relevant offspring NOAEL ‡	0.03 mg/L (4 mg/kg bw/day)	

Developmental toxicity

Developmental target / critical effect ‡	Increased incidence of variations and retardations at maternally toxic dose in rats; decreased number live fetuses and increased incidence of dead implants at maternal toxic doses in rabbits	
Relevant maternal NOAEL ‡	Rat: 5 mg/kg bw/day Rabbit: 5 mg/kg bw/day	R63
Relevant developmental NOAEL ‡	Rat: 5 mg/kg bw/day Rabbit: 10 mg/kg bw/day	

Reproductive toxicity (Annex IIA, point 5.6) MITC

Reproduction toxicity

Reproduction target / critical effect ‡	Reproduction parameters not significantly	
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Relevant parental NOAEL ‡	altered	
Relevant reproductive NOAEL ‡	0.7 mg/kg bw/day	
Relevant offspring NOAEL ‡	>3.6 mg/kg bw/day	
	>3.6 mg/kg bw/day	
Developmental toxicity		
Developmental target / critical effect ‡	Decreased fetal weight at maternal toxic doses in rabbits	
Relevant maternal NOAEL ‡	Rat: 3 mg/kg bw/day Rabbit: 3 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 10 mg/kg bw/day Rabbit: 10 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7) metam sodium

Acute neurotoxicity ‡	NOAEL > 1500 mg/kg bw	
Repeated neurotoxicity ‡	NOAEL = 14.7 mg/kg bw/d	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No studies performed
Studies performed on metabolites or impurities ‡	No further studies performed

Medical data ‡ (Annex IIA, point 5.9) metam sodium

No medical surveillance data for manufacturing plant personnel was found for metam sodium.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡ metam sodium	0.001 mg/kg bw/day	dog, 1-year gavage study	100
ADI MITC	0.004 mg/kg bw/day	dog, 90-d drinking water study	100
AOEL ‡ metam sodium	0.001 mg/kg bw/day	dog, 1-year gavage	100
AOEL MITC	0.004 mg/kg bw/day	dog, 90-d drinking water study	100
ARfD ‡ metam sodium	0.1 mg/kg bw	rat, overall developmental toxicity	100
ARfD MITC	0.03 mg/kg bw	rat, developmental study	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Concentrate: 1%; 12%: for the dilution ‡ Rat in vivo and comparative in vitro (human/rat skin)
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‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles.

Local effects

Metam sodium produces local effects after single exposure (corrosive for skin). For the operator these local effects are covered in the risk assessment/management by means of assignment of R- and S-phrases. Furthermore, irritant dermatitis is reported among workers cleaning up a spill of metam sodium in California in 1991 and persistent respiratory health effects occurred after a metam sodium spill in California in 1994 (see DAR section 6.9.3). MITC also produces local effects (irritation of upper airways)

after single and repeated exposure. For bystanders/resident no personal protective equipment can be assigned to cover the local effects. This has therefore, been taken into account in the risk assessment.

Data requirements active substance

No additional data requirements are identified.

1.1 Toxicity of the formulated product (IIIA 7.1)

Metam sodium is only available as an aqueous solution containing about 510 g/L a.i. and the product is equivalent to the technical active substance as manufactured. Therefore, all acute toxicity studies were conducted with aqueous metam sodium (or potassium) solutions as manufactured and are described in Annex II, point B.6.2 (DAR, section 6.14).

It was agreed that for operators applying metam sodium, the relevant assessment is for MITC (EFSA Scientific Report on Metam (2011); 9(9) 2334). Also for workers, bystanders and residents, the relevant assessment is considered to be for MITC.

Acute toxicity (Annex IIA, point 5.2) metam sodium

Rat LD ₅₀ oral ‡	896 mg/kg bw	R22
Rat LD ₅₀ dermal ‡	> 2000 mg/kg bw	-
Rat LC ₅₀ inhalation ‡	2.54 mg/L air /4h (whole body)	R20
Skin irritation ‡	Corrosive	R34
Eye irritation ‡	Non-irritant	-
Skin sensitisation ‡	Sensitising (M & K)	R43

Acute toxicity (Annex IIA, point 5.2) MITC

Rat LD ₅₀ oral ‡	147 mg/kg bw	R25
Rat LD ₅₀ dermal ‡	1290 mg/kg bw	R21
Rat LC ₅₀ inhalation ‡	0.54 mg/L air /4h (whole body)	R23 R37
Skin irritation ‡	Corrosive	R34
Eye irritation ‡	No study required	-
Skin sensitisation ‡	Sensitising (M & K)	R43

1.1.1 Data requirements formulated product

No additional data requirements are identified.

1.2 Dermal absorption (IIIA 7.3)

See List of Endpoints. The formulation Monam Cleanstart is identical to the tested formulation. For the risk assessment, dermal absorption values of 1% for the concentrate.

1.3 Available toxicological data relating to non-active substances (IIIA 7.4)

See 4.1. Metam sodium is only available as an aqueous solution containing about 510 g/L a.i. and the product is equivalent to the technical active substance as manufactured.

1.4 Exposure/risk assessments

Overview of the intended uses

Monam Cleanstart is a SC (suspension concentrate) formulation and contains 510 g/L metam sodium. Application of Metam sodium is carried out by a soil-injection technique using tractor-mounted equipment. The intended uses are listed under Appendix 1 (GAP).

1.4.1 Operator exposure/risk

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)

For metam sodium no TLV has been set. The AOEL will be used for the risk assessment. Since the formulation is applied up to two times during the period July - October, a semi-chronic exposure duration is applicable for the operator (including contract workers). A semi-chronic AOEL is therefore derived. The semi-chronic EU-AOEL of MITC is 0.004 mg/kg bw/day (= 0.28 mg/day for a 70 kg operator), based on

the NOAEL of 0.4 mg/kg bw/day in a 90-d drinking water study with dogs and a safety factor of 100 is used for the risk assessment (see List of Endpoints).

Because metam sodium is almost instantly hydrolysed to MITC, it was agreed in the PRAPeR meeting of experts 54 (subgroup1) held in Parma in July 2008 that the operator, worker and bystander risk assessment should be performed for MITC (EFSA Scientific Report on Metam (2011); 9(9): 2334).

Exposure measurements / estimations

No appropriate exposure models are available to calculate exposure during mixing, loading and application to the volatile MITC that is formed rapidly after application of Monam Cleanstart when metam sodium enters into contact with soil, as is also confirmed by the DAR (section B.6.15.1).

Mixing

Since the formulation Monam Cleanstart is used without dilution, exposure during mixing will not occur since no mixing is necessary.

Loading

In the Dutch operating instructions, the following directions for use are prescribed:

“Wear suitable dermal protective clothing, gloves with long shafts and rubber boots during all activities during which skin contact with the formulation may occur, including the soil disinfection and the first cultivation activities after application of the formulation. Take off all contaminated clothing. Immediately rinse off gloves and boots that may have been in contact with the formulation with plenty of water. Store gloves outside the cabin. Wear a full face mask with B2-P3 filter, ideally with proflow blower, during the preparation of the equipment, during trouble shooting and the internal cleaning of the equipment.”

Because of the loading procedure can be considered as ‘closed system’ and full personal protective equipment should be used, the exposure during loading is considered negligible.

Application

In the updated DAR Re-submission of May 2011, 4 exposure studies were included in which metam sodium was applied by soil injection (2 studies), soil fumigation (1 study) or drip-irrigation (1 study). The soil injection and fumigation applications were open field studies, while the drip-irrigation study was a greenhouse/tunnel study.

For Monam Cleanstart, the open field soil injection studies were the relevant studies. A brief summary of the studies is included:

Study 1: Mulder et al. 1994

Metam-sodium (510 g/L) was applied onto 15 different parcels at 12 different field locations in the Netherlands during soil decontamination of industrial potato land. Tractor-drawn equipment was used with 12 parcels treated with spade injector and 3 parcels treated with cultivator injection equipment, respectively. In order to avoid exposure during turning at the headlands all injection equipments used were fitted with an anti-drip systems, i.e. anti-drip caps or blow-through system. Irrespective of the injection equipment used all tractors were fitted with one to two flat driven rollers for sealing of the soil. Application rate of Monam was 300 L/ha.

The MITC exposure study performed after soil injection application of Metam-sodium under representative field conditions demonstrated that in some situations there was exceeding of the inhalation AOEL of MITC. Appropriate respiratory protection is recommended for the operator during the whole process.

Note Ctgb: *no bystander/resident exposure was measured.*

Study 2: De Rooij et al. 1993

Metam-sodium (BASF monam, Aamonam, Shell-NMC and Luxan monam (Metam-sodium 510 g/L) was applied for soil decontamination purposes onto 11 representative bulb parcels at an application rate ranging from 420 L/ha to 700 L/ha. All parcels were treated using specialized equipment, i.e. cultivator injectors that inject Metam-sodium into the soil at a depth of about 18 – 20 cm. Immediately after injection, one or two flat rollers one of which was a driven roller to ensure that the soil was well compressed and sealed compressed the soil. In all cases, the injection activities started on the downwind side of the parcel thereby reducing additional exposure because of emission of MITC from parcels that

were already treated. The MITC exposure studies demonstrated that after soil injection application of Metam-sodium on eleven representative fields under representative conditions the AOEL of MITC was exceeded in most of the field parcels treated when RPE was absent. Overall, it can be concluded that under these experimental conditions, operator exposure to MITC is below AOEL only with special protective equipment.

Note CTGB: No bystander/resident exposure was measured.

Study 3: Links et al. 2006

In this study, metam sodium was applied at 300L/ha with a tractor mounted Rumpstad shear injector to approximately 5 Ha (application rate according to label 300L/Ha). The machine featured a working width of 3 m. Metam sodium was loaded in the tank (capacity 500 L) that was located at the front of the tractor. Via a flexible pressure tubing metam sodium was transported under pressure to the spray valves below the plough. The Rumpstad injected metam sodium in the soil at a depth of 15-20 cm, and worked the soil with a roto-tiller. After injection the soil was flattened with a roller that was part of the application equipment. Besides operator exposure, the degradation products of metam sodium were determined after application in a field at different locations, from the edge of the field (location 1-8) to a maximum distance of 225 meters (location 9-16).

Findings: MIC, CS₂ and methylamine were not detected around the treated field; all values were below the limit of detection.

Potential exposure of the operator to MITC was 76.51 µg/m³ which represents 0.00956 mg/kg bw/d. The stationary air measurement inside the tractor during these tasks was 70.33 µg/m³ which is equivalent to 0.00879 mg/kg bw/d and outside the tractor the concentration MITC were 0.107 mg/m³ representing 0.0134 mg/kg bw/d.

Air concentrations of MITC around the field ranged from the limit of detection (0.042 µg/m³) to a maximum value of 35.97 µg/m³ with a geometric mean of 0.87 µg/m³ (GM calculated with 100% LOD for concentrations <LOD, n=96). The 95th percentile was 13.22 µg/m³ and the 75th percentile 6.41 µg/m³. No direct relation could be found between the time expired after application (with a maximum of 3 days) and the MITC air concentrations at the different locations, although the first measurements over 4 hours was at almost every location the highest. Wind direction, on the other hand, seems to be important with the highest concentrations occurring downwind.

Substance	Experimental conditions	MITC Concentration (µg/m ³)
Location 1: 10 samples	Field boundary, upwind, measure during whole study duration	<0.042
Location 2: 10 samples	Field boundary, upwind, measure during whole study duration	<0.042
Location 3: 10 samples	Field boundary, downwind	4.47 – 23.71
Location 4: 10 samples	Field boundary, downwind, measure during whole study duration	0.07-1.82
Location 5	Field boundary, downwind	Pump defect, no valid measurement.
Location 6: 10 samples	Field boundary, downwind, measure during whole study duration	4.77-24.35
Location 7: 10 samples	Field boundary, downwind, measure during whole study duration	4.21-13.31
Location 8: 10 samples	Field boundary, measure during whole study duration	0.042-6.85
Location 9: 2 samples	100 m of field, upwind	0.08
Location 10: 1 sample	100 m of field, upwind	0.09
Location 11: 1 sample	100 m of field, upwind	0.04

Substance	Experimental conditions	MITC Concentration ($\mu\text{g}/\text{m}^3$)
Location 12: 9 samples	100 m of field, downwind, measure during whole study duration	0.66-3.62
Location 13: 10 samples	100 m of field, downwind, measure during whole study duration	2.10-13.19
Location 14 : 10 samples	100 m of field, downwind, measure during whole study duration	0.042-35.96
Location 15: 1 sample	200 m of field, upwind	0.1
Location 16: 1 sample	200 m of field, upwind	0.09
Geometric mean		0.87
Minimum – maximum:		0.042 -35.97

De metingen t.b.v. de operator blootstelling vonden plaats op het raam en boven een wiel van een trekker; de hoogte waarop gemeten is voor de bystanders (langs het veld), is echter niet gespecificeerd in de samenvatting in de DAR. De meting duur om het veld is 4 dagen lang (voor operator 3 dagen). Er is veel variatie in wanneer er pieken van MITC gemeten worden. Toch wordt wel gemeld dat het meeste gemeten wordt de eerste 4 uur na toepassing.

Note CTGB: The dose used in the study 300 L/ha is below the intended use 750 L/ha.

No specific resident exposure is calculated in the DAR. Therefore, a resident exposure assessment is carried out using the “bystander” exposure values from the study in the DAR. These values are also representative for residents as they were taken either directly besides or further from the field.

Table 1: Resident exposure estimate to MITC after application of Monam Cleanstart based on the results from the study Link et al. 2006

	Exposure level	Peak value	GM	75th	95th
Adult					
Maximum value	air level ($\mu\text{g}/\text{m}^3$) ¹	35.97	0.87	6.41	13.22
	exposure ($\mu\text{g}/\text{kg bw}/\text{d}$) ²	8.27	0.2001	1.4743	3.0406
	% ³ AOEL	207	5.0	36.9	76.0
Child					
Maximum value	air level ($\mu\text{g}/\text{m}^3$) ¹	35.97	0.87	6.41	13.22
	exposure ($\mu\text{g}/\text{kg bw}/\text{d}$) ⁴	38.49	0.9309	6.8587	14.15
	% ³ AOEL	962	23.3	171	354

¹: maximum air concentration; ²: taking into account a respiration rate of 0.23 m³/day/kg, and a 24 h breathing period, default b.w.=60 kg, in the absence of RPE. ³: AOEL (MITC) =0.004 mg/kg b.w./d

⁴: taking into account a respiration rate of 1.07 m³/day/kg, and a 24 h breathing period, default b.w.=10 kg (default in EFSA OPEX calculator), in the absence of RPE.

Only with the use of the geometric mean does the resident exposure not exceed the AOEL. However, the acceptability of the GM can be questioned since this represent the mean of both the downwind and upwind situation. A 75th percentile is considered to be more appropriate. It is worth noting that the acute reference dose of 30 $\mu\text{g}/\text{kg bw}/\text{d}$ for MITC is exceeded for children when using the peak exposure value.

Based on the assessment, it can be concluded that adverse health effects cannot be excluded for residents living near fields treated with Monam Cleanstart.

In the study an application rate of 300 L/ha was used, while the current application rate for Monam cleanstart is 750 L/ha, a factor of 2.5 higher. It can therefore be expected that the actual exposure level are higher than those measured in this study.

Study 4: Saeed et al. 2000

This study was conducted in four fallow fields intended to be grown with potatoes. Methyl isothiocyanate air concentrations were measured above these fields following application of metam-sodium (345 g a.i/kg) either through injection using a ground rig (fields 1 and 2) or by chemigation using the center-pivot irrigation systems (fields 3 and 4). Both methods are used commercially in Wisconsin for the application

of the fumigant and are claimed to be equally effective. Solutions of metam-sodium (345g a.i. /kg) were injected in the soil at a rate of 480litre/ha (166 kg/ ha) in fields one and two using a ground applicator with knives or shanks spaced 15cm apart. The knives were pulled through the soil at a depth of 25cm and the fumigant was released from ports behind each shank at depths of 5, 15 and 25cm. A soil compactor was connected to each rig to compact the soil over the furrow made by the injection shanks. In fields three and four the fumigant solution at a rate of 480 liter/ha was mixed with 169m³/ha of irrigation water through a metering pump that was connected to the center-pivot irrigation system. Immediately following fumigant application to each of the four fields, equipment for measuring MITC air concentration, temperature and wind speed was installed and measurements were started. The focus of this study was to estimate the loss of MITC by volatilization when metam-sodium was applied through either chemigation or injection to arable fields. Methyl isothiocyanate is the principal product of the transformation and constitutes about 90% of the total amount of metam-sodium applied to soils.

On most sampling occasions, higher MITC emissions were observed in chemigated than in injected fields. The highest MITC concentrations were 11.2 and 7.4µg/m³ recorded 10cm above the ground 6-8h following application and the lowest concentrations were 0.7 and 0.2 µg/m³ observed at 200cm 30 and 35h after application above chemigated and fumigated fields, respectively. Volatilization losses measured by trapping vaporized MITC indicated that in all treated fields, regardless of application method, average MITC air concentrations were highest in the first 8h following application and decreased thereafter. It was found that use of a soil compactor following fumigant injection into the soil had a substantial effect in reducing MITC emissions (Saeed and Rouse, unpublished data). Thus, manipulation of soil surface to reduce MITC loss by volatilization could serve as an approach to environmentally acceptable disease control practices.

Field/time after application (h)	MITC air concentration (µg/m ³)		
	200 cm	100 cm	10cm
Injected field 1: 166 kg/ha (480L)			
5.3	1.1	1.2	1.3
11.4	1.3	1.4	1.6
29.4	0.9	1.0	1.1
78	0.7	0.8	0.9
Mean:	1.0	1.1	1.22
Injected field 2: 166 kg/ha (480L)			
4	0.4	0.9	7.0
6	0.9	1.3	7.4
11	0.4	0.5	5.9
27.5	0.3	1.0	1.0
29.5	0.5	1.6	1.6
34.5	0.2	0.4	0.4
Mean:	0.45	0.95	3.88
Chemigated field 3: 166 kg/ha (480L) diluted in 169m³ water/ha			
3	1.6	2.0	3.5
6	0.9	1.3	2.8
8.4	2.0	3.0	11.2
10	1.2	1.3	4.0
14	0.7	0.8	1.7
Mean:	1.28	1.7	4.64
Chemigated field 4: 166 kg/ha (480L) diluted in 169m³ water/ha			
6.3	4.6	5.9	7.1
10.3	1.2	2.1	3.2
14.3	2.9	2.9	4.8
18.3	4.6	6.4	6.5
22.3	2.0	2.3	2.8
26.3	1.4	1.7	1.8
30.3	0.7	0.8	1.3
Mean:	2.5	3.15	3.9

The mean exposure was the highest at 10 cm ranging between 1.22 to 4.64 µg/m³. The highest peak exposure was measured also measured at 10 cm above ground with 11.2 µg/m³.

Note CTGB: Residential exposure is calculated using the exposure levels shown in the table above. Separate exposure estimates are made for the injected fields and het chemigated field. To estimate the exposure for children the air concentration at both 10cm and 100 cm is used. For adults only the 100 cm air concentration is used.

Table 2: Resident exposure estimate to MITC after application of Monam Cleanstart based on the results from the study Saeed et al. 2000

	Exposure level	Peak value	Mean	Peak value	Mean
		Injected field		Chemigated field	
Adult (100 cm air concentration)					
Maximum value	air level ($\mu\text{g}/\text{m}^3$) ¹	1.6	1.1	6.4	3.15
	exposure ($\mu\text{g}/\text{kg bw}/\text{d}$) ²	0.368	0.253	1.472	0.7245
	% ³ AOEL	9.2	6.325	36.8	18.1
Child (100 cm air concentration)					
Maximum value	air level ($\mu\text{g}/\text{m}^3$) ¹	1.6	1.1	6.4	3.15
	exposure ($\mu\text{g}/\text{kg bw}/\text{d}$) ⁴	1.712	1.177	6.848	3.3705
	% ³ AOEL	42.8	29.4	171	84.3
Child (10 cm air concentration)					
Maximum value	air level ($\mu\text{g}/\text{m}^3$) ¹	7.4	3.88	11.2	4.64
	exposure ($\mu\text{g}/\text{kg bw}/\text{d}$) ⁴	7.918	4.1516	11.984	4.9648
	% ³ AOEL	198	104	300	124

¹: maximum air concentration;

²: taking into account a respiration rate of 0.23 m³/day/kg, and a 24 h breathing period, default b.w.=60 kg, in the absence of RPE.

³: AOEL (MITC) =0.004 mg/kg b.w./d

⁴: taking into account a respiration rate of 1.07 m³/day/kg, and a 24 h breathing period, default b.w.=10 kg (default in EFSA OPEX calculator), in the absence of RPE.

The estimated resident exposure is exceeded for children for both application methods. Therefore, adverse health effects cannot be excluded for residents living near fields treated with Monam Cleanstart.

It is noted that the application rate used in the study (480 L/ha) is below the current application rate of Monam Cleanstart (700 L/ha) so actual exposure level are expected to be even higher.

Study 5: Van den Berg, F. 1993

Behaviour of Metam sodium and MITC in soil as well as the emission of MITC in the air was described by a computer simulation model and results compared with measured figures after soil injection application of Metam sodium into the soil of two selected fields in the Netherlands (field A near Valtermond and field B near Eeserveen).

For both fields, Metam sodium was applied at an application rate of 300 L/ha (510 g Metam sodium/L) and injected at a depth of approx. 18 cm using a horizontal blade injector with spray nozzles below the blades and subsequent compression of the soil with a roller. The treated area comprised 5.9 ha for both fields.

Both the computed as well as the measured MITC concentrations in the air demonstrated that a bystander walking at the downwind side of a fumigated field (distance 0 – 214 m) approx. 1 to 9 days after treatment is exposed to MITC concentrations amounts to 14 $\mu\text{g}/\text{m}^3$. The measurements were taken at 1.5 meters above ground. The study lasted 7-9 days, with a total of 4 – 5 measurements.

Note CTGB: Based on the maximum computed MITC level of 14 $\mu\text{g}/\text{m}^3$ an internal exposure value of 3.22 $\mu\text{g}/\text{kg bw}$ is calculated for adults (80.5% of the AOEL) and 14.98 $\mu\text{g}/\text{kg bw}$ for children (374.5% of the AOEL). Based on the maximum measured exposure concentration of 3.1 $\mu\text{g}/\text{kg bw}$ an estimated internal exposure is calculated of 0.713 $\mu\text{g}/\text{kg bw}$ (17.8% of the AOEL) and 3.317 $\mu\text{g}/\text{kg bw}$ (83% of the AOEL) for adults and children, respectively. It should be noted the application rate used in the study (300 L/ha) was below the current application rate of Monam Cleanstart (700 L/ha). Therefore, it can be expected that the actual exposure level will be higher.

Study 6: Schepel en Dijksterhuis 2003

Bystanders might also be present during breaking of the seal after soil fumigation with Metam-sodium or when the plastic film is opened to prepare the soil for planting. In such a case, bystanders might be exposed to remainders of the volatile compound MITC, which is released from the soil due to the breaking of the seal or opening of plastic film coverage. The MITC concentrations in air after breaking of seal or opening/removing of a plastic film coverage before planting can be estimated from the measurements at the edge of the field during and after breaking the seal (experimental protocol detailed under point B.6.15.4.2.1). The maximum air concentration of $8.8834 \mu\text{g}/\text{m}^3$ was found 50 m downwind in the time period 0-2 h after breaking the seal 14 days after fumigation with Metam sodium at an application rate of 300 L/ha.

Note CTGB: *Based on the maximum computed MITC level of $8.8 \mu\text{g}/\text{m}^3$ an internal exposure value of $2.02 \mu\text{g}/\text{kg bw}$ is calculated for adults (50.6% of the AOEL) and $9.42 \mu\text{g}/\text{kg bw}$ for children (235% of the AOEL). Based on the assessment, it can be concluded that adverse health effects cannot be excluded for residents near field treated with Monam Cleanstart.*

It should be noted the application rate used in the study (300 L/ha) was below the current application rate of Monam Cleanstart (700 L/ha). Therefore, it can be expected that the actual exposure level will be even higher.

Local effects:

The highest air concentration surrounding the field in all studies was $35.97 \mu\text{g}/\text{m}^3$. MITC can induce local effects, such as eye irritation, skin irritation and respiratory irritation. However, these effects were observed in rats at higher concentrations than the levels found in the exposure studies.

Overall summary of the resident exposure assessment

Six field exposure studies are available. Of these six, four included measurements of air concentrations that could be used for bystander/resident exposure assessment. Overall, based on the risk assessment using these exposure studies it is concluded that **adverse health effects cannot be excluded** for children living near fields treated with Monam Cleanstart.

Reactie onderbouwing etiketwijziging Monam

Voorgestelde risk mitigation measurements:

Op perceelszijden grenzend aan percelen met een woon- of verblijfsbestemming, een bufferzone van 7,5 meter aanhouden (gemeten vanaf de kadastrale grens).

Reactie Ctgb: De aanvrager stelt een bufferzone van 7.5 m voor. Hiervoor verwijzen ze naar het nog in te dienen dossier voor de herregistratie van Monam en deze bufferzone zou berekend zijn met een bufferzone calculator. In de onderbouwing wordt kort aangegeven dat deze bufferzone calculator gebaseerd is op diverse studies waarbij de concentratie in de lucht in de omgeving is gemeten. Het is echter niet duidelijk onder welke condities deze studies zijn uitgevoerd (middel, werkzame stof, vluchtigheid, application rate, toepassingsmethode, locaties waar gemeten is, etc.). Het is daarom onduidelijk in hoeverre deze gegevens geschikt zijn voor het gebruik van metam-natrium in de Nederlandse situatie. Aangezien we hier te weinig informatie over hebben zullen we uitgaan van de informatie van de blootstellingstudies in de DAR van metam.

In de DAR is er 1 studie waarbij op verschillende afstanden van het veld gemeten is (0, 100 en 200 m) in Nederland. In deze studie werd de hoogste concentratie MITC gemeten op 100 meter afstand van het veld (zie onderstaande tabel). Over het geheel gezien lijkt er weinig verschil te zijn in de concentratie MITC aan de rand van het veld (downwind) en op 100 m afstand (downwind). Op basis van deze experimentele gegevens blijkt dat een bufferzone van 7.5 m dus geen verlaging van de blootstelling zal veroorzaken.

Substance	Experimental conditions	MITC Concentration ($\mu\text{g}/\text{m}^3$)
Location 1: 10 samples	Field boundary, upwind, measure during whole study duration	<0.042
Location 2: 10 samples	Field boundary, upwind, measure during whole study duration	<0.042
Location 3: 10 samples	Field boundary, downwind	4.47 – 23.71
Location 4: 10 samples	Field boundary, downwind, measure during whole study duration	0.07-1.82
Location 5	Field boundary, downwind	Pump defect, no valid measurement.
Location 6: 10 samples	Field boundary, downwind, measure during whole study duration	4.77-24.35
Location 7: 10 samples	Field boundary, downwind, measure during whole study duration	4.21-13.31
Location 8: 10 samples	Field boundary, measure during whole study duration	0.042-6.85
Location 9: 2 samples	100 m of field, upwind	0.08
Location 10: 1 sample	100 m of field, upwind	0.09
Location 11: 1 sample	100 m of field, upwind	0.04
Location 12: 9 samples	100 m of field, downwind, measure during whole study duration	0.66-3.62
Location 13: 10 samples	100 m of field, downwind, measure during whole study duration	2.10-13.19
Location 14 : 10 samples	100 m of field, downwind, measure during whole study duration	0.042- 35.96
Location 15: 1 sample	200 m of field, upwind	0.1
Location 16: 1 sample	200 m of field, upwind	0.09

Substance	Experimental conditions	MITC Concentration ($\mu\text{g}/\text{m}^3$)
Geometric mean		0.87
Minimum – maximum:		0.042 -35.97

Van de 200 m afstand zijn alleen upwind metingen aanwezig. Er kan dus geen indicatie gegeven worden welke afstand nodig is voor een geschikte bufferzone.

De toepassing uitstellen indien de volgende weersomstandigheden, binnen 48 uur na toepassing, voorspeld worden:

- mist;
- temperatuursinversie;
- windstil weer.

Reactie Ctgb: Dit advies is in de praktijk moeilijk uitvoerbaar en te handhaven. Kan er 48 uur van te voren voorspeld worden dat de weeromstandigheden zo blijven?

Voorkom stuiven door op stuifgevoelige gronden aanvullende maatregelen te nemen zoals b.v. toepassen van papiercellulose.

Reactie Ctgb: Op basis van de omschrijving in de DAR lijkt dat in de meeste veldstudies de grond niet afgedekt is met folie maar alleen met “roller” gesloten is. Afdekking met bijv. papiercellulose zou de blootstelling mogelijk kunnen verlagen, maar hier zijn geen gegevens over.

Overige punten:

Moet schaarinjectie verplicht worden gesteld?

Reactie Ctgb: Hier valt weinig over zeggen. In de DAR staat 1 studie waar 2 verschillende toepassingsmethodes met elkaar vergeleken worden (injectie in veld 1 en 2 en irrigatie systeem in veld 3 en 4). Gemiddeld lijkt de injectietoepassing tot iets lagere blootstelling te leiden. Echter, op 10 cm hoogte is er eigenlijk geen verschil tussen veld 2 en veld 4 (zie tabel hieronder). Schaarinjectie zou een mogelijke verlaging kunnen geven van de blootstelling, maar op basis van de weinige gegevens die er zijn kan dit niet geconcludeerd worden.

Field/time after application (h)	MITC air concentration ($\mu\text{g}/\text{m}^3$)		
	200 cm	100 cm	10 cm
Injected field 1: 166 kg/ha (480L)			
5.3	1.1	1.2	1.3
11.4	1.3	1.4	1.6
29.4	0.9	1.0	1.1
78	0.7	0.8	0.9
Mean:	1.0	1.1	1.22
Injected field 2: 166 kg/ha (480L)			
4	0.4	0.9	7.0
6	0.9	1.3	7.4
11	0.4	0.5	5.9
27.5	0.3	1.0	1.0
29.5	0.5	1.6	1.6
34.5	0.2	0.4	0.4
Mean:	0.45	0.95	3.88
Chemigated field 3: 166 kg/ha (480 L) diluted in 169m³ water/ha			
3	1.6	2.0	3.5
6	0.9	1.3	2.8
8.4	2.0	3.0	11.2
10	1.2	1.3	4.0
14	0.7	0.8	1.7
Mean:	1.28	1.7	4.64

Field/time after application (h)	MITC air concentration ($\mu\text{g}/\text{m}^3$)		
	200 cm	100 cm	10 cm
Chemigated field 4: 166 kg/ha (480 L) diluted in 169m ³ water/ha			
6.3	4.6	5.9	7.1
10.3	1.2	2.1	3.2
14.3	2.9	2.9	4.8
18.3	4.6	6.4	6.5
22.3	2.0	2.3	2.8
26.3	1.4	1.7	1.8
30.3	0.7	0.8	1.3
Mean:	2.5	3.15	3.9

Moet een maximale dosering van 300 L/ha verplicht worden gesteld?

Reactie Ctgb: In de DAR zijn verschillende doseringen gebruikt in de blootstellingstudies (300 – 700 L/ha). In de studie die voor omwonenden de meest relevante informatie levert is 300 L/ha gebruikt. Daarom lijkt een maximale toepassing van 300 L/ha geschikt.

Verder moet echter ook gespecificeerd worden hoe diep het middel geïnjecteerd moet worden. In de studies in de DAR is het middel 15-25 cm diep ingebracht. Op het huidige gebruiksvoorschrift staat 10 cm.