

## REVIEW OF METHAM SODIUM, DAZOMET AND METHYLISOTHIOCYANATE (MITC)

Volume I

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### Preface

The NRA report on the Special Review of Metham Sodium, Dazomet and Methylsiothiocyanate (MITC) is published as a three volume set. The contents of each volume is as follows;

**Volume one** is a record of the special review, including a regulatory history of metham sodium and recommendations for use of metham sodium and dazomet containing products in Australia.

**Volume two** provides the summary reports of the assessment of toxicological data for metham, dazomet and MITC, including a summary of comparative toxicology of the three compounds. It also contains the occupational health and safety (OH&S) risk assessment of metham (soil fumigant use) dazomet and MITC and provides recommendations for use of dazomet and soil fumigant use of metham. This volume also includes an OH&S risk assessment of root inhibitor use of metham and recommendations for use of metham as a root inhibitor.

**Volume three** contains the full reports of the toxicological assessments for Metham-Sodium, Dazomet and MITC.

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#### Executive Summary

#### REVIEW OUTCOMES

The purpose of this document is to report on the National Registration Authority (NRA) special review of three chemicals: metham sodium, dazomet and methylisothiocyanate (MITC).

The NRA initiated a review of metham sodium, following reports of adverse experiences where occupational and public health and safety issues were raised in connection with the use of this chemical. In light of these reports the NRA was concerned that the use of products containing metham may pose an undue hazard to the safety of the people exposed to it during its handling or that it could have an effect that is harmful to human beings.

Following its reconsideration which included an assessment of the available data on metham and a concurrent evaluation of the available data for the related chemicals dazomet and methylisothiocyanate (MITC), the NRA has determined;

1. that the product labelling on the currently registered products does not adequately reflect the possible risks associated with the use of these chemicals and:
2. certain methods of application of metham, when not used in strict accordance with label directions may constitute an undue hazard to public and/or occupational safety.

Review recommendations governing the use of products containing metham and dazomet are provided below. These recommendations are aimed at providing the appropriate warning and precautionary statements on labels, raising the level of information and training available to the users and restricting the product to those uses which are deemed safe.

### **Recommendations**

1. The National Drugs and Poisons Schedule Committee (NDPSC) of the Australian Health Minister's Advisory Council (AHMAC) determined Schedule 6 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) as being appropriate for metham sodium, dazomet and MITC.
2. No amendments to the existing First Aid Instructions on metham sodium or dazomet product labels or to the existing approvals of technical grade active constituents (TGAC) for metham and dazomet are recommended.
3. Safety Directions and Personal Protective Equipment requirements specified on the current label have been revised substantially to make them commensurate with the risks associated with the use of these chemicals. (see Safety Directions, pp 14 & 16).
4. Re-entry, re-handling period and other precautionary statements on labels, (including requirements for a reference to the MSDS on all labels of products containing metham and dazomet) have been specified to reflect occupational health and safety risks associated with the use of these products.
5. Existing uses of metham sodium continue, subject to certain restrictions on hand-directed spraying, treatments of potting soil, irrigation applications (the application using linear (lateral move) or center pivot systems be discontinued and only trickle irrigation application be permitted), and tobacco plant bed applications. Labels are to carry statements specifically prohibiting the discontinued methods of application to ensure they are not allowed under any State control of use regimes.
6. Given the interest in the continued availability of center-pivot irrigation application of metham, the option of a permit for this method of application be pursued with States, chemical registrants and users, to enable the generation of data required for assessment.
7. Existing uses of dazomet are supported.
8. Requirements for specific training in the use of metham sodium and dazomet products have been established.
9. Fact Sheets designed to provide written technical reference material for trainers and users are required to be submitted for assessment as a condition of registration. Technical Fact Sheets and brochures already developed by some registrants could form the basis of these sheets. MSDS for all products are to be submitted for assessment. Time frames are proposed for compilation and assessment of information for end users.
10. An implementation and evaluation period will be set (from 1 January 1998 to 30 June 1998) to assess the operational effectiveness of revised conditions of registration, including the training requirements for the use of metham sodium and dazomet. Time frames are proposed. Following this evaluation, metham and dazomet may be declared restricted chemical products by regulation, if deemed necessary.
11. The supply and use of products containing metham sodium and dazomet under the existing labelling is only permitted until **30 June 1998**. Registrants are required to have all amendments resulting from the reconsideration of metham sodium and dazomet incorporated on labels of products containing these compounds, by that date.

### **BACKGROUND**

Metham sodium is a dithiocarbamate soil fumigant with fungicide, nematocide, herbicide and insecticide activity. Metham sodium is registered in Australia in several end use products (EUPs) for the control of weeds, nematodes, symphylids (except in Tasmania), fungi, soil insects and other soil-borne pests in ornamentals, food and fibre crops and tobacco. Metham sodium is also registered for use as an inhibitor of root growth in sewer lines.

Dazomet is registered to control germinating seeds of weeds, soil fungi, and nematodes.

Methylisothiocyanate (MITC), a soil fumigant no longer registered in Australia, is also considered in this review as it is the major degradation product that imparts soil fumigant activity to both metham and dazomet.

Metham sodium has been the subject of reports of adverse effects over a period of time, especially when used via certain types of irrigation equipment. These reports were initially addressed under the arrangements existing at the time by the Advisory Committee on Agricultural Chemicals (ACAC) by revising the directions of use to restrict the use of metham sodium via certain types of irrigation equipment.

In 1994, metham sodium was placed on the NRA's special review program following reports of adverse effects by an orchardist in Victoria who experienced eye irritation and nausea when using metham sodium to fumigate soil according to label directions. The available data on the related compounds dazomet and methylisothiocyanate (MITC), have also been evaluated concurrently as part of this review.

All registered end-use products containing metham sodium and dazomet, the associated label approvals and the approvals of the TGACs (and dazomet breakdown product, MITC) were subject to reconsideration. The review focussed on safety directions and methods of application specified on the existing product labels.

The registrants of metham and dazomet products and TGAC approval holders were notified of the proposed reconsideration in September 1995 under section 32(2) of the AgVet Code. They were required to provide any relevant data of which they were aware. Some of the data evaluated as part of the review have been designated as protected.

State regulatory authorities were notified of the review in August 1994 and their comments were obtained at various stages during the review. In providing their comments State authorities also obtained views from other relevant parties in their jurisdiction such as regional agricultural experts, providers of chemical user training, contract applicators and other users of these chemicals. These comments have been taken into account in the reconsideration.

The Commonwealth Department of Health and Family Services and Worksafe Australia evaluated the available data on toxicity and occupational health and safety respectively. The issue of poisons scheduling of metham was referred to the National Drugs and Poisons Schedule Committee (NDPSC).

## 1.1 INTRODUCTION

Metham belongs to the dithiocarbamate class of chemicals, with fungicide, nematocide, herbicide and insecticide activity. Metham (as the sodium salt, metham sodium) is registered in Australia in several end use products (EUPs) as non-residual pre planting treatments, for the control of weeds, nematodes, symphylids (except in Tasmania), fungi, soil insects and other soil-borne pests in ornamentals, food and fibre crops and tobacco. Metham sodium is also registered as an inhibitor of root growth in sewer lines. Root growth inhibitors are for use of plumbers, drainers and sanitary engineers for the control of roots in sewer lines.

A single product containing dazomet is registered for the control of nematodes, soil inhabiting insects, germinating seeds of weeds and fungi. Methylisothiocyanate (MITC), a soil fumigant no longer registered in Australia, is the major degradation product of metham and dazomet. MITC

is also considered in this review as it is the major degradation product that imparts soil fumigant activity to both metham and dazomet.

## 1.2 REASONS FOR REVIEW

The use of metham sodium has been the subject of reports of adverse experiences where occupational and public health and safety issues were raised over a period of time. Reports of adverse experiences were often associated with the use of metham sodium via certain types of irrigation equipment. These reports were initially addressed under the arrangements existing at the time by the Advisory Committee on Agricultural Chemicals (ACAC) by revising the directions of use to restrict the use of metham sodium via certain types of irrigation equipment.

In 1994 the NRA, the Commonwealth Department of Health and the Victorian State Authorities received correspondence from an orchardist in Shepparton, Victoria, of an adverse experience with the use of Vapam Liquid Soil Fumigant when applying the chemical using personal protective equipment according to the label directions. The Victorian Authorities and the Commonwealth Department of Health and Family Services advised the NRA that the directions of use and safety directions on the product labels should be reviewed and Victorian authorities further advised that consideration be given to reviewing the scheduling of metham sodium.

In light of this advice the NRA was of the view that the use of products containing metham may pose an undue hazard to the safety of people exposed to it during its handling or that it could have an effect that is harmful to human beings.

The NRA Board agreed to place metham sodium under the NRA Special Review program. The Inter-agency Coordinating Committee (ICC) considered that the apparent problems with metham sodium were due to methylisothiocyanate (MITC) liberated during use. On that basis Dazomet, another registered chemical that breaks down into MITC, and MITC itself should also be evaluated in the review.

The Department of Health and Human Services in conjunction with Worksafe Australia conducted the review of first aid and safety directions while the issue of poisons scheduling was referred to the National Drugs and Poisons Schedule Committee (NDPSC). Comments from States were also solicited regarding the appropriateness of the directions for use specified on the currently registered product labels.

## 1.3 SCOPE OF THE REVIEW

All registered end-use products containing metham sodium and dazomet, the associated label approvals and approvals of the active constituents metham sodium and dazomet were subject to review. The available data on MITC was also evaluated under this review. The review emphasis was on safety directions and methods of application specified on product labels with the aim of making recommendations for future safe use of these compounds in Australia.

## 1.4 NOTIFICATION OF REVIEW

The registrants of metham and dazomet products and TGAC approval holders were notified of the proposed reconsideration in September 1995 under section 32(2) of the AgVet Code. They were required to provide any relevant data of which they were aware. Some of the data evaluated as part of the review have been designated for proprietary protection. The Registration Liaison Committee (RLC) was notified of the review in August 1994. Comments from the State Coordinators were obtained on the directions for use for metham and dazomet at that time and later in January 1997 when the draft recommendations from the review were being compiled.

## 1.5 REGISTRATION STATUS

The following 10 product registrations and four TGAC approvals were included in the NRA's

review with the involvement of ten registrants and/or TGAC approval holders. All ten registrants/approval holders participated in the review by providing responses and/or data.

**Table 1: Products and TGACs included in the review**

<b>Product Name</b>	<b>Registrant</b>
<b>Metham Sodium</b>	
Chemfarm Metham Soil Fumigant (40664)	Chemfarm Australia
Craig Mostyn Metham Soil Fumigant (41171)	Craig Mostyn & Co P/L
Agchem Vapam Liquid Soil Fumigant (45752)	CropCare Australasia P/L
Davison Metham Soil Fumigant (46437)	Davison Industries P/L
Farmoz Metham Soil Fumigant (46806)	Farmoz Chemicals P/L
Sanafoam Vaporooter Foaming Root Inhibitor (31299)	ICI Australia Operations P/L
National Metham Sodium Soil Fumigant (41507)	Nufarm Ltd
Nufarm Metham Soil Fumigant (34049)	Nufarm Ltd
SA Rural Agencies Metham Soil Fumigant (45355)	SA Rural Industries P/L
<b>Dazomet</b>	
Basf Basamid Granular Soil Fumigant (34036)	BASF Australia Ltd
<b>Active Constituents</b>	<b>Approval Holder</b>
<b>Metham Sodium</b>	
Metham Sodium TGAC (44238)	Nufarm Ltd
Metham Sodium (44239)	UCB Chemicals
Metham Sodium Manufacturing Concentrate (44240)	CropCare Australasia P/L
<b>Dazomet</b>	
Dazomet TGAC (44459)	BASF Australia Ltd

## 1.6 REGULATORY STATUS IN AUSTRALIA

The ACAC and Drugs and Poisons Schedule Standing Committee (DPSSC) considered information on adverse experiences associated with the use of metham provided by Victoria in August 1991. Following its consideration, the DPSSC determined at the time that the existing scheduling at Schedule 6 of the SUSDP was appropriate for metham. In October 1992, the ACAC in consultation with registrants, revised the directions of use to restrict the use of metham sodium via certain types of irrigation equipment. Use was only permitted through approved irrigation systems which included trickle irrigation (Queensland only), linear (lateral move) or centre pivot irrigation equipment specifically designed to apply agricultural chemicals and certified by the manufacturer.

## 1.7 REGULATORY STATUS OVERSEAS

The regulatory authorities in Germany and USA have reviewed or placed restrictions on the use of metham sodium. In 1986, German authorities prohibited the use of metham sodium in protected water catchment areas (with certain exceptions) and in natural parks and reserves.

In 1991, the US Environment Protection Agency (US EPA) instructed registrants of metham, through a data call-in notice, to complete a range of acute, subchronic and chronic mammalian tests, exposure data, chemical data and ecotoxicity data. The US EPA is awaiting/reviewing data on metham, dazomet and MITC (US EPA, 1994).

US metham labels require the following protective equipment to be worn by workers carrying out any operations that are likely to involve direct contact with the product, including

mixing/loading, equipment calibration or adjustment, clean up and repair of application equipment, sampling, clean up of spills, fumigant transfer and rinsate disposal. This equipment is also required for any operations occurring within 6 feet of unshielded, pressurised hoses containing metham products.

- A properly fitted half-facepiece respirator with organic vapour cartridge;
- Non-venting chemical goggles (or a full-facepiece respirator with organic vapour cartridge);
- A body covering with long sleeves and long pants;
- When a closed system is not used, mixer/loaders should wear chemical resistant aprons or cloth overalls; and
- Chemical resistant gloves and boots.

Workers operating or monitoring application equipment or entering treated areas within 48 hours of application should wear chemical resistant footwear and a body covering with long sleeves and long pants. In addition, the following protective equipment should be available to workers operating tractor drawn application equipment, monitoring application equipment or re-entering treated areas within 48 hours after application:

- A properly fitted half-facepiece respirator with organic vapour cartridge and non-venting chemical goggles (or a full-facepiece respirator with organic vapour cartridge) to be worn when odour is detected; and
- Chemical resistant gloves (to be worn if direct contact with the product is likely).

In July 1991, the California EPA issued a warning to pregnant women to avoid exposure to metham. Both metham and MITC were placed on California's list of most highly controlled chemicals. Use of these chemicals is only permitted when persons are adequately trained and hold a permit for their use (The Bureau of National Affairs Inc., 1994).

## 1.8 EXISTING METHODS OF APPLICATION FOR METHAM SODIUM

A close scrutiny of the existing methods of application formed a significant part of the review. The following methods of application were specified on the approved labels for metham sodium at the time of commencement of the review.

- sprinkler can method (for small areas up to 2 Square meters) - sprinkle solution from watering can and then water in;
- soil injection followed by rolling, or directly ahead of bed shaper;
- rotary tiller method, whereby solution is sprinkled or sprayed on the soil, cultivated in and then the soil is rolled;
- approved irrigation systems - trickle (Queensland only), linear or centre pivot systems;
- potting soil, the chemical was added to soil in a cement mixer or sprayed on to a soil stream as it is ejected from a shredder;
- spot spraying;
- application by plumbers, drainers and sanitary engineers to the sewer line.

These uses were specified following a revision of the label directions conducted under the purview of ACAC. Field experience with the use of metham sodium included several adverse incidents especially in Victoria and Western Australia that, while not directly attributable to the actual method of application, indicated a need for raising metham product labels to provide clearer warnings.

## 1.9 CONSULTATION WITH STATE AUTHORITIES

At various times during the review the States/Territories and other members of the RLC provided the input which is summarised below. Most comments from States where there is significant use of metham and/or dazomet containing products, pointed to the need for labels to be amended to enable safer use of these products.

## **Tasmania and Northern Territory**

Minimal use of metham takes place in these locations. The Northern Territory recommended that the compound should warrant restricted chemical classification.

## **Queensland**

Queensland authorities commented that questions raised in the submission detailing the adverse experience in 1994 had already been addressed by the label revisions adopted in October 1992. The response from Queensland also contained excerpts from the reports of Drugs and Poisons Schedule Standing Committee (DPSSC) 62/August 92 and ACAC 8/90. These attachments detailed the action taken in 1992 to revise the label directions for use for metham containing products.

## **Western Australia**

Western Australia pointed out the importance of Metham Sodium to horticulture in that State as it is the only broad-spectrum, soil 'sterilant' available once the use of Methyl Bromide is phased out under the Montreal protocol. WA response discussed suitable methods of application for metham sodium and commented that applying metham from a motorised hand-held boom would maximise the potential for occupational exposure. Comments were also provided on chemigation use and experiences with this type of application using overhead sprinklers in small and large properties in WA. WA supported a review of first aid and safety warning statements and Poison Scheduling and requested further opportunity to comment on the preferred application methods.

## **Victoria**

Victoria provided extensive comment on the directions and methods of use of metham sodium in several regions of that State. These included a published paper on controlling Nightshade with metham, containing data on the behaviour of the chemical in soil and detailed expert comments from officers of the Department of Agriculture.

Comment was also provided of the relative merits of and local experiences with individual methods of application. Several recommendations relating to the labelling, scheduling, allowable methods of application, packaging and use and requirements for training of users were made. Comments obtained from the Occupational Health and Safety Authority (OHSA) in Victoria were also included.

## **New South Wales (NSW)**

The response from NSW commented briefly on an investigation conducted by the experts in NSW Agriculture and alluding to the complexity of the issues raised by the reported adverse experience. The NSW response also pointed out the importance of metham to that State's agriculture, recommending that the labels be suitably amended to render the products safer to use.

## **Plant Health Committee (PHC)**

A response from a PHC member pointed out that the metham label does not warn that high pressure sprays should not be used to apply metham prior to rotary-hoeing. The reported incident of intoxication may have been due to the use of a motor driven hand boom. It was advised that the product label needs to be redrafted to provide clear use instructions.

## **Environment Australia**

Environment Protection Authority (EPA) commented in 1994 on the environmental concerns

arising over sprinkler application of metham sodium because of high toxicity to fish and aquatic invertebrates and high application rates. To avoid damage to aquatic ecosystems, the product should be applied by soil injection or some other technique which minimises the risk of transport off site in run-off, rather than through fixed sprinkler irrigation systems.

The effectiveness of metham sodium depends on its decomposition in soil to MITC. To be effective against soil dwelling pests, the volatile MITC must be retained in the soil. As well as favouring such retention, soil injection or some other application method which aims to avoid localised high surface concentrations, should eliminate the problem of irritation to nearby residents from fugitive MITC vapours.

### **1.10 PUBLIC CONSULTATION**

Several members of the public and Local Government Institutions provided correspondence and reports of their experiences and their concerns relating to exposure to metham. While no specific requests for public comment were made as part of the review of metham and dazomet, any submissions or representations from interested members of the public and other stakeholders were taken into consideration in the review.

In conducting special reviews, the NRA also obtains stakeholder comments through the State regulatory authorities. In the context of this review of metham sodium and dazomet, State authorities obtained views from a wide cross-section of stakeholders in their jurisdictions, such as regional agricultural experts, providers of chemical user training, contract applicators and other users of these chemicals. All these views and comments were taken into consideration during the review.

A further round of extensive consultation with the State regulatory authorities and product registrants/and approval holders preceded the formulation of recommendations of the review. Comments and views provided by these groups were again considered by the NRA and the agencies advising the NRA in this special review.

### **1.11 PUBLIC HEALTH STANDARDS**

As part of the review the Department of Health and Family Services conducted an extensive assessment of the toxicity of metham, dazomet and MITC, including evaluation of previously unevaluated data and consolidation of previous toxicology reports. The full reports of this assessment are included at Appendix 1, while summary reports of toxicity of the three chemicals, plus a comparative review of the toxicity of metham, dazomet and MITC are provided at Part 2.

Currently, metham, dazomet and MITC are in Schedule 6 of the SUSDP. No ADI has been set for MITC or metham, but an ADI of 0.005 mg/kg/d for dazomet has been established. The ADI was based on an NOEL of 0.5 mg/kg (established in a 1-year dietary dog study and a 2-year dietary rat reproductive study) and a safety factor of 100.

Recent data on dazomet has resulted in a proposed amendment for the ADI for dazomet to 0.0005 mg/kg/day based on the LOEL of 0.5 mg/kg/day in a chronic 2 year rat study and using a 1000 fold safety factor.

The scheduling of metham, dazomet and MITC in Schedule 6 of the SUSDP is considered appropriate on toxicological grounds.

### **1.12 SAFETY DIRECTIONS AND OCCUPATIONAL HEALTH AND SAFETY STANDARDS**

Worksafe Australia conducted the OH&S assessment of the available data on metham sodium dazomet and MITC. Resulting from this assessment, Worksafe Australia proposed a range of measures designed to minimise occupational and bystander exposure to these chemicals. The majority of these recommendations dealing as they are with product use restrictions (Metham),

safety directions precautions, re-entry and re-handling statements, reference to MSDS and other additional information (Metham and Dazomet), have direct implications for product labelling. Accordingly, these are presented under the heading "Product Label Amendments". Other recommendations from the OH&S assessment relate primarily to training and information provision and the setting of an exposure standard for MITC. The full report of the OH&S assessment is included at Part 3.

### **Training and information provision; restriction on availability - metham sodium and dazomet**

Training is essential to minimise on-site and off-site effects of volatile degradation products. Training must cover the general aspects of chemical handling plus the specific requirements of MITC-generating chemicals. Sources of information and relevant topics for educational material concerning these specific requirements are provided in the OHS assessment report for metham sodium and dazomet at Part 3.

Material safety data sheets that meet NOHSC requirements are required for all existing metham sodium and dazomet products.

The registrants are required to compile product Fact Sheets, concerning the safe use of these chemicals for users and bystanders. All Fact Sheets should be submitted to Worksafe Australia for assessment to ensure they are of consistent quality. Fact Sheets should be made available to users via the Farm Chemicals Users Course or specific module and the point of sale; they should be provided to equipment manufacturers/sellers and chemical retailers by the registrants. Technical fact sheets and brochures already developed by some registrants could form the basis of new sheets.

Requirements for user training and information provision including the submission of MSDS for assessment will be phased-in during the implementation stage that commences on 1 July 1997. Applicants/registrants will be advised by letter regarding specific timetables for these activities.

### **Product Label Amendments**

Several label amendments are required and should be incorporated on the product labels before 30 June 1998.

These label amendments are applicable to the directions for use, (Metham) Prohibitions (Metham), Safety Directions Precautions, Re-entry and Re-handling statements, Reference to MSDS and other additional information (Metham and Dazomet). For further details including the wording and positioning of the required amendments please refer to label text for Metham and Dazomet at pp 18-25.

### **Exposure standards**

Worksafe Australia proposed that the Exposure Standards Expert Working Group of the National Occupational Health and Safety Commission (NOHSC) considers setting an exposure standard for MITC.

## **1.13 REVIEW OUTCOMES AND RECOMMENDATIONS**

Following its reconsideration which included an assessment of the available data on metham and a concurrent evaluation of the available data for the related chemicals dazomet and MITC, the NRA has determined ;

1. that the product labelling on the currently registered products does not adequately reflect the possible risks associated with the use of these chemicals and;
2. certain methods of application of metham, when not used in strict accordance with label

directions may constitute an undue hazard to public and/or occupational safety.

Review recommendations governing the use of products containing metham and dazomet are provided below. These recommendations are aimed at providing the appropriate warning and precautionary statements on labels, raising the level of information and training available to the users and restricting the product to those uses which are deemed safe.

### ***Recommendations***

1. The National Drugs and Poisons Schedule Committee (NDPSC) of the Australian Health Minister's Advisory Council (AHMAC) determined Schedule 6 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) as being appropriate for metham sodium, dazomet and MITC.
2. No amendments to the existing First Aid Instructions on metham sodium or dazomet product labels or to the existing approvals of technical grade active constituents (TGAC) for metham and dazomet are recommended.
3. Safety Directions and Personal Protective Equipment requirements specified on the current label have been revised substantially to make them commensurate with the risks associated with the use of these chemicals. (see Safety Directions, pp 14 & 16).
4. Re-entry, re-handling period and other precautionary statements on labels, (including requirements for a reference to the MSDS on all labels of products containing metham and dazomet) have been specified to reflect occupational health and safety risks associated with the use of these products.
5. Existing uses of metham sodium continue, subject to certain restrictions on hand-directed spraying, treatments of potting soil, irrigation applications (the application using linear (lateral move) or center pivot systems be discontinued and only trickle irrigation application be permitted), and tobacco plant bed applications. Labels are to carry statements specifically prohibiting the discontinued methods of application to ensure they are not allowed under any State control of use regimes.
6. Given the interest in the continued availability of center-pivot irrigation application of metham, the option of a permit for this method of application be pursued with States, chemical registrants and users, to enable the generation of data required for assessment.
7. Existing uses of dazomet are supported.
8. Requirements for specific training in the use of metham sodium and dazomet products have been established.
9. Fact Sheets designed to provide written technical reference material for trainers and users are required to be submitted for assessment as a condition of registration. Technical Fact Sheets and brochures already developed by some registrants could form the basis of these sheets. MSDS for all products are to be submitted for assessment. Time frames are proposed for compilation and assessment of information for end users.
10. An implementation and evaluation period will be set (from 1 January 1998 to 30 June 1998) to assess the operational effectiveness of revised conditions of registration, including the training requirements for the use of metham sodium and dazomet. Time frames are proposed. Following this evaluation, metham and dazomet may be declared restricted chemical products by regulation, if deemed necessary.
11. The supply and use of products containing metham sodium and dazomet under the existing labelling is only permitted until **30 June 1998**. Registrants are required to have all amendments resulting from the reconsideration of metham sodium and dazomet incorporated on labels of products containing these compounds, by that date.

#### **1.14 PROTECTED INFORMATION STATUS OF SUBMITTED DATA**

Certain studies submitted by the registrants in response to the NRA's data call-in have been designated as protected information. Two occupational exposure studies on metham submitted by UCB Australia Ltd. and sixteen toxicity studies on dazomet submitted by Hoechst Schering AgrEvo Pty Ltd. are in this category. All studies designated for data protection are identified below.

Occupational Exposure studies on metham submitted by UCB Australia Ltd;

1. Rosenheck L (1993a) Worker Mixer/Loader and Applicator Exposure from Field Applications of Metham-Sodium, Pan-Ag Study No EF-91-360, August 1993, Sponsor Metham-Sodium Task Force c/o ICI Americas Inc.
2. Rosenheck L (1993b) Worker Loader and Applicator Exposure from Field Applications of Metham-Sodium, Pan-Ag Study No 92205, May 1993, Sponsor Metham-Sodium Task Force c/o ICI Americas Inc.

Toxicity studies on dazomet submitted by Hoechst Schering AgrEvo Pty Ltd;

1. Brusick, D. J. Stetka, D. (1979) Mutagenicity evaluation of N 521 in an *in vitro* cytogenetic assay measuring sister chromatid exchange and chromosome aberrations. Litton Bionetics, Inc., Maryland, USA. LBI Project No. 20990. Reg. Doc. #BASF 79/0167. March 1979.
2. Brusick, D. J. Weir, R. J. (1976) Mutagenicity evaluation of sample #100. Litton Bionetics, Inc., Maryland, USA. LBI Project No. 2683. Reg. Doc. #BASF 76/0107. 26 October 1976.
3. Cifone, M. A. (1986) Evaluation of dazomet techn. (99.3%) CH.03584, 84/198 in the *in vivo/in vitro* rat hepatocyte unscheduled DNA synthesis assay. Hazleton Biotechnologies Company, Maryland, USA. HBC Project No.: 20991. RZ-Report No.: 86/249. September 1986.
4. Cifone, M.A. Myhr, B.C. (1985) Evaluation of dazomet in the rat primary hepatocyte unscheduled DNA synthesis assay. Litton Bionetics, Inc., Maryland, USA. LBI Project No. 20991. RZ-Report No: 85/217. June 1985.
5. Gelbke, H.P. (1989) Report on *in vitro* cytogenetic investigations of dazomet in human lymphocytes. BASF Aktiengesellschaft, Department of Toxicology, Federal Republic of Germany. Project No. 30M0318/854174. Reg. Doc. #BASF: 89/0094. 4 April 1989.
6. Gelbke, H.-P. Engelhardt, G. (1985) Cytogenetic investigations in NMRI mice after a single oral administration of dazomet. BASF Aktiengesellschaft, Department of Toxicology, Federal Republic of Germany. Project No.: 26M0198/8421. RZ-Report No: 85/154. 24 May 1985.
7. Gelbke, H. P. Jackh, R. (1986) Report on a point mutation test carried out on CHO cells (HGPRT locus) with the test substance dazomet (substance No. 84/198). BASF Aktiengesellschaft, Department of Toxicology, Germany. RZ-Report No: 86/215. 18 August 1986.
8. Hofmann, H.T. (1975c) Acute oral toxicity of Basamid granular to the rat. BASF Medizinisch-Biologische Forschungslaboratorien Gewerbehygiene und Toxikologie. Reg. Doc. #BASF 75/0041. 27 August 1975.
9. Kieczka, H. Kirsch, P. (1986) Maximization test for the sensitizing potential of dazomet in guinea pigs. Report no. 85/399, project no. 30H318/85. 20 December, 1985 (Addendum 29 July, 1986). BASF Aktiengesellschaft, Department of Toxicology, Germany.
10. MacKenzie, K. (1987) 21-Day dermal toxicity study in rabbits. Hazleton Laboratories America, Inc., Wisconsin, USA. HLA 6220-100. Reg. Doc. #BASF 87/0408. 17 June 1987.
11. Majeska, J. B., Zamek, R., Cameron, N. Matheson, D.W. (1980a) N-521 mutagenicity evaluation in *Salmonella typhimurium*. The *In Vitro* Toxicology Section, Environmental Health Center, Stauffer Chemical Company, USA. Report No. T-10044. Reg. Doc. #BASF 80/0217. 9 June 1980.
12. Majeska, J. B., Matheson, B. W., Hertzler, K. O'Lone, S. (1980b) N-521, mutagenicity evaluation in mouse lymphoma multiple endpoint test. The *In Vitro* Toxicology Section, Environmental Health Center, Stauffer Chemical Company, USA. Report No. T-10136. Reg. Doc. #BASF 80/0218. 20 November 1980.
13. Matheson, D. W., Brusick, D. (1978) Mutagenicity evaluation of N-521 in the *in vitro* transformation of BALB/3T3 cells assay, T-6412. Litton Bionetics, Inc., Maryland, USA. LBI Project No. 20840. Reg. Doc. #BASF 78/0145. 2 June 1978.
14. Matheson, D.W. Majeska, J.B. (1980) N-521 Morphological transformation of BALB/3T3 cells. *In vitro* Toxicology Section, Environmental Health Center, Stauffer Chemical Company, USA. Report No. T-10137. Reg. Doc. #BASF 80/0219. 5 December 1980.
15. Miltenburger, H.G., Volkner, W. Bauer, A. (1985) A study of chromosome aberrations in Chinese hamster spermatogonia with dazomet. Laboratory for Mutagenicity Testing of

the Technical University Darmstadt, Federal Republic of Germany. RZ-Report No: 85/375. 14 November 1985.

16. Weil, C. S. Palm, P. E. (1960) Results of Two Years of inclusion of CRAG 974 in the diet of rats. Mellon Institute of Industrial Research, University of Pittsburgh, USA. Reg. Doc#BASF 60/0008. June 1960.

### 1.15 PRODUCT LABEL AMENDMENTS

#### LABEL TEXT

#### METHAM SODIUM - Labelling Requirements

**NOTE: The following label text is provided as a guide only and includes primarily those parts of the label that require amendment as a result of the NRA special review. The applicants/registrants must ensure that their respective product labels fully comply with current labelling requirements and guidelines.**

#### DIRECTIONS FOR USE:

**RESTRAINTS:** DO NOT apply to a dry soil.

DO NOT exceed rates specified.

DO NOT use in high winds.

DO NOT apply in low humidity or when temperature is above 32 °C.

Situation	Pest Controlled	State	Rate	Critical Comments
Sites for Seedbeds, Lawns & other limited areas	Germinating Weed Seeds including Winter Grass, Prince of Wales Feather, Fat Hen, Nematodes, Symphylids(Not Tas.) (GardenCentipede), Fungus Diseases	All States	25-50L per 50L water per 1000m <sup>2</sup>	SOIL INJECTIONS: Use the higher rate for heavier soils. Injection points or injection nozzles under a blade should be 12cm apart, 10-15cm deep in a well prepared moist soil. Immediately after injection, compact the soil by rolling. Water lightly to prevent escape of gas. Repeat irrigation after 2-3 days for light soils or soils which crack or dry out quickly. Prevent run off.
	including Rhizoctonia, Pythium, Fusarium, Phytophthora, Verticillium, Sclerotinia and Club Root of Crucifers		1.1 L per 12L water per 10m <sup>2</sup>	ROTARY TILLER: Spray or sprinkle diluted solution in front of tiller. Roll immediately to compact soil. Lightly water as above.
Field: Application to Total Area	Germinating Weed Seeds including Winter Grass, Prince of Wales Feather, Fat Hen, Nematodes, Symphylids(Not Tas.) (GardenCentipede),	N.S.W., Qld., S.A., Vic., W.A.	250-500L per 400-700L water per ha	SOIL INJECTION: Use the higher rate for heavier soils. Follow water method for injection described

	Fungus Diseases	only		under seedbeds.
	including Rhizoctonia, Pythium, Fusarium, Phytophthora, Verticillium, Sclerotinia and Club Root of Crucifers		600-800L per 900-1100L water per ha	APPROVED ONLY for Trickle irrigation systems designed to apply agricultural chemicals as certified by the manufacturer and under plastic sheeting. Use the higher rate for heavier soils. Use system to give large droplet size. For shallow pests in the top 30cm or less of soil - run system for 5-10 minutes. For next 10-20 minutes inject solution into irrigation system and continue watering until soil is wet as deep as control is needed. Keep moist for 2-3 days for light soils or soils which crack or dry out quickly. For control deeper than 45cm divide recommended dose into three equal parts and apply at intervals during irrigation period.
			250-500L per 400-700L water per ha	ROTARY TILLER: Spray or sprinkle diluted solution in front of tiller. Roll immediately to compact soil. Irrigate at once with enough water to seal the soil surface. Repeat irrigation after 2-3 days for light soils or soils that crack or dry out quickly.
Field: Application to Beds or Rows	Germinating Weed Seeds including Winter Grass, Prince of Wales Feather, Fat Hen, Nematodes, Symphylids (Not Tas.)	All States	250-500L per 400-700L water per ha	SOIL INJECTION: Use the higher rate for heavier soils. Solution may be injected into preformed beds or as a band treatment. Follow the instructions for injection above. For a wider treated band space two or more injection points at intervals of 12cm apart. All methods should be at a depth of 10-15cm.
	(Garden Centipede), Fungus Diseases including Rhizoctonia, Pythium,		400-800L per 700-1000L	BEDS - SOIL COVERING METHOD: Use the higher rate for heavier soils.

	Fusarium, Phytophthora,		water per ha	Inject or drip into moist soil directly ahead of the bed shaper. Use sufficient water to ensure uniform application. Cover with 7-15mm of moist soil. Roll to compact immediately.
	Verticillium, Sclerotinia and Club Root of Crucifers		250-500L per 400-700L water per ha	ROTARY TILLER: Spray or sprinkle diluted solution in front of tiller. Roll immediately to compact soil. Irrigate at once with enough water to seal the soil surface. Repeat irrigation after 2-3 days for light soils that crack or dry out quickly
		Qld. only	250-800L per treated ha	TRICKLE IRRIGATION: Use the higher rate for heavier soils. 5-8 weeks prior to planting soil must be bed-formed with trickle tape and plastic mulch. Thoroughly wet soil to allow weed(-seed to germinate. Apply Metham to moist soil by injecting into mainline using a suitable pump sufficient to wet entire root zone. Use a longer injection period for heavier soils. Flush all lines and equipment with clean water after use. Puncture plastic 2 weeks after treatment to allow dissipation of Metham. Heavy nematode infestation may require further treatment prior to second crop. ENSURE INJECTION CAPACITY CAN HANDLE LARGE RATES OR USE SPLIT APPLICATIONS.
Potting Soil	Germinating Weed Seeds including Winter Grass, Prince of Wales Feather, Fat Hen,	All States	600mL per m <sup>2</sup> soil mixture	CEMENT MIXER: Mix moist soil thoroughly, adding Metham to lidded mixer in a well ventilated area. Empty soil into a pile and cover with plastic sheeting to keep in gas.

	Nematodes, Symphylids (NotTas.) (GardenCentipede), Fungus Diseases including Rhizoctonia,		1.1 L per 12L water per 10m <sup>2</sup>	ROTARY TILLER METHOD: Spread soil smoothly to a depth of 20cm. Apply Metham over entire surface and till to maximum adjustable depth of tiller. Treat further layers as necessary and seal top layer with water.
Tobacco Plant Bed	Pythium, Fusarium, Phytophthora, Verticillium, Sclerotinia and Club Root of Crucifers	N.S.W., Qld. only	9.75L per 700-900L water per 100m <sup>2</sup>	TOBACCO SEED BED: Use the higher rate for heavier soils. Apply in Autumn through an approved irrigation system, sprayers or any suitable approved equipment. Follow instructions for seedbeds or plant beds. DO NOT treat tobacco plant beds by hand directed methods.
	Onion Weed	W.A. only	1.1 L per 50L water per 5m <sup>2</sup>	SPOT TREATMENT: Spray entire surface area using drenching nozzles.

**NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.**

#### PROHIBITIONS:

**DO NOT USE BY HAND DIRECTED SPRAYING INCLUDING SPRINKLER CAN**

**DO NOT TREAT POTTING SOIL BY LOOSE MIXED METHOD OR VIA SHREDDER**

**DO NOT USE BY FLOOD IRRIGATION OR OVERHEAD SPRINKLER SYSTEMS**

[Insert General Instructions, Cultivation and Planting Intervals etc., here. The text of these should be as per the current labelling guidelines.]

#### Precautions

Workers previously experiencing skin or respiratory tract irritation from metham-sodium or dazomet exposure should not work with metham-sodium products.

After mixing with water do not allow mixture to stand as poisonous fumes are released on standing.

Workers manually sealing should wear the personal protective clothing specified for applicators.

#### Re-entry period

**Field uses:** Do not allow entry into treated areas for 48 hours. When prior entry is necessary,

wear personal protective equipment specified for applicators. Clothing must be laundered after each day's use.

**Greenhouse application, including under plastic:** Do not allow entry into treated areas for 7 days. When prior entry is necessary, wear personal protective equipment specified for applicators. Clothing must be laundered after each day's use. Thoroughly ventilate greenhouses for 24 hours after removing plastic.

### Re-handling period

**Potting soil:** Treated soil is to remain covered by plastic sheeting or similar material impermeable to MITC, for 7 days after treatment. When prior handling is necessary, wear personal protective equipment specified for applicators. Clothing must be laundered after each day's use.

### Protection of Crops, Native & other Non-Target Plants

DO NOT spray desirable plants and lawns and avoid spray drift. DO NOT apply within 1 metre of drip line of plants. DO NOT use in greenhouses where plants are present. DO NOT apply under weather conditions or from spraying equipment, that may cause spray to drift onto nearby susceptible plants/crops, cropping lands and pastures.

### Protection of Wildlife, Fish, Crustaceans & Environment

DO NOT contaminate streams, rivers or waterways with the chemical or used containers.

**Storage and disposal:** as per current labelling requirements.

**SAFETY DIRECTIONS:** Harmful if absorbed by skin contact or swallowed. Poisonous if inhaled. Will damage the eyes, nose and throat and skin. Repeated exposure may cause allergic disorders. Interacts with alcohol. Do not inhale vapour or spray mist. The fumes first cause smarting, then watering of eyes. This should be taken as a warning sign. The liquid can cause burns. Use and store in well ventilated areas. When opening the container and preparing product for use, wear cotton overalls buttoned to the neck and wrist, a washable hat, apron (chemical resistant), elbow-length (nitrile, neoprene) gloves, chemical resistant footwear, a full facepiece respirator with organic vapour/gas cartridge or canister [or goggles and half facepiece respirator with organic vapour cartridge or canister].

When using the prepared (spray) (foam), wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length (nitrile, neoprene) gloves, chemical resistant footwear, a full facepiece respirator with organic vapour/gas cartridge or canister [or goggles and half facepiece respirator with organic vapour cartridge or canister].

If clothing becomes contaminated with product or wet with spray, remove clothing immediately. If product or vapour on skin, immediately wash area with soap and water. If product or vapour in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles, respirator and if rubber wash with detergent and warm water and contaminated clothing. Do not re-use footwear until thoroughly aired.

**FIRST AID:** as per current labelling (TGA) requirements.

### Additional Information

For additional information refer to the Material Safety Data Sheet and Fact Sheets available from the registrant (*insert name of registrant*) and point of sale.

## DAZOMET - Labelling Requirements

**NOTE:** The following label text is provided as a guide only and includes primarily those parts of the label that require amendment as a result of the NRA special review. The applicants/registrants must ensure that their respective product labels fully comply with current labelling requirements and guidelines.

### Precautions

Workers previously experiencing skin or respiratory tract irritation from dazomet or metham-sodium exposure should not work with dazomet products.

Workers performing manual water-sealing and plastic sealing should wear the personal protective clothing specified for applicators plus a respirator with organic vapour/gas cartridge and goggles.

### Re-entry period

**Field uses:** Do not allow entry into treated areas for 48 hours. When prior entry is necessary, wear personal protective equipment specified for applicators. Clothing must be laundered after each day's use.

**Greenhouse application, including under plastic:** Do not allow entry into treated areas for 7 days. When prior entry is necessary, wear personal protective equipment specified for applicators with goggles and a half face respirator with organic vapour/gas cartridge. Clothing must be laundered after each day's use. Thoroughly ventilate greenhouses for 24 hours after removing plastic.

### Re-handling period

**Potting soil:** Treated soil is to remain covered by plastic sheeting or similar material impermeable to MITC, for 7 days after treatment. When prior handling is necessary, wear personal protective equipment specified for applicators with goggles and a half face respirator with organic vapour/gas cartridge. Clothing must be laundered after each day's use.

### Protection of Crops, Native & other Non-Target Plants

as per current labelling requirements.

### Protection of Wildlife, Fish, Crustaceans & Environment

as per current labelling requirements.

### Storage and disposal

as per current labelling requirements.

## SAFETY DIRECTIONS

Product is poisonous if swallowed. Will irritate the eyes, nose and throat and skin. Avoid contact with eyes and skin. Do not inhale dust. The fumes first cause smarting, then watering of eyes. This should be taken as a warning sign. When the opening container and using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) elbow-length (nitrile, neoprene) gloves and chemical resistant footwear. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and contaminated clothing. Do not re-use footwear until thoroughly aired.

**FIRST AID:** as per current labelling (TGA) requirements.

**Additional Information**

For additional information refer to the Material Safety Data Sheet and Fact Sheets available from the registrant (*insert name of registrant*) and/or chemical reseller/point of sale.